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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2020
OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____
Commission File Number: 001-38311

Denali Therapeutics Inc.
(Exact name of registrant as specified in its charter)

Delaware	**46-3872213**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

161 Oyster Point Blvd.
South San Francisco, CA, 94080
(Address of principal executive offices and zip code)

(650) 866-8548
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.01 per share	DNLI	NASDAQ Global Select Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The number of outstanding shares of the registrant's common stock as of October 28, 2020 was 119,918,496.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Denali Therapeutics Inc.

Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands, except share amounts)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 351,047	$ 79,449
Short-term marketable securities	610,154	335,907
Prepaid expenses and other current assets	9,665	14,675
Total current assets	970,866	430,031
Long-term marketable securities	20,341	39,886
Property and equipment, net	42,265	46,732
Operating lease right-of-use asset	32,976	33,923
Other non-current assets	3,858	2,659
Total assets	$ 1,070,306	$ 553,231
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,806	$ 2,590
Accrued compensation	9,010	8,739
Accrued clinical costs	4,689	5,042
Other accruals and other current liabilities	11,531	6,569
Operating lease liability, current	4,508	3,665
Related party contract liability	44,854	—
Other contract liabilities	28,015	18,739
Total current liabilities	105,413	45,344
Contract liabilities, less current portion	16,557	43,753
Operating lease liability, less current portion	65,407	68,865
Other non-current liabilities	379	379
Total liabilities	187,756	158,341
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Convertible preferred stock, $0.01 par value; 40,000,000 shares authorized as of September 30, 2020 and December 31, 2019; 0 shares issued and outstanding as of September 30, 2020 and December 31, 2019	—	—
Common stock, $0.01 par value; 400,000,000 shares authorized as of September 30, 2020 and December 31, 2019; 119,795,216 shares and 96,189,935 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	1,524	1,288
Additional paid-in capital	1,480,315	818,803
Accumulated other comprehensive income	11	350
Accumulated deficit	(599,300)	(425,551)
Total stockholders' equity	882,550	394,890
Total liabilities and stockholders' equity	$ 1,070,306	$ 553,231

See accompanying notes to unaudited condensed consolidated financial statements.

Denali Therapeutics Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Collaboration revenue:				
Collaboration revenue from customers	$ 9,388	$ 13,508	$ 18,751	$ 21,717
Other collaboration revenue	5	96	93	289
Total collaboration revenue	9,393	13,604	18,844	22,006
Operating expenses:				
Research and development	53,704	52,544	157,872	141,831
General and administrative	15,805	11,215	42,332	35,601
Total operating expenses	69,509	63,759	200,204	177,432
Loss from operations	(60,116)	(50,155)	(181,360)	(155,426)
Interest and other income, net	1,944	3,782	7,611	11,411
Loss before income taxes	(58,172)	(46,373)	(173,749)	(144,015)
Income tax benefit (provision)	(56)	113	—	426
Net loss	(58,228)	(46,260)	(173,749)	(143,589)
Other comprehensive income (loss):				
Net unrealized gain (loss) on marketable securities, net of tax	(540)	(317)	(339)	1,211
Comprehensive loss	$ (58,768)	$ (46,577)	$ (174,088)	$ (142,378)
Net loss per share, basic and diluted	$ (0.54)	$ (0.48)	$ (1.65)	$ (1.50)
Weighted average number of shares outstanding, basic and diluted	107,490,702	95,859,048	105,217,770	95,449,570

See accompanying notes to unaudited condensed consolidated financial statements.

Denali Therapeutics Inc.

Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)
(In thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2019	96,189,935	$ 1,288	$ 818,803	$ 350	$ (425,551)	$ 394,890
Issuance of common stock in follow-on offering, net of issuance costs of $632	9,000,000	90	193,858	—	—	193,948
Issuance of common stock in connection with the Biogen Stock Purchase Agreement	13,310,243	133	420,013	—	—	420,146
Issuances under equity incentive plans	1,001,905	10	11,123	—	—	11,133
Vesting of restricted stock units	293,133	3	(3)	—	—	—
Stock-based compensation	—	—	36,521	—	—	36,521
Net loss	—	—	—	—	(173,749)	(173,749)
Other comprehensive loss	—	—	—	(339)	—	(339)
Balance at September 30, 2020	119,795,216	$ 1,524	$ 1,480,315	$ 11	$ (599,300)	$ 882,550
Balance at June 30, 2020	105,897,872	$ 1,385	$ 1,041,303	$ 551	$ (541,072)	$ 502,167
Issuance of common stock in connection with the Biogen Stock Purchase Agreement	13,310,243	133	420,013	—	—	420,146
Issuances under equity incentive plans	412,389	4	5,749	—	—	5,753
Vesting of restricted stock units	174,712	2	(2)	—	—	—
Stock-based compensation	—	—	13,252	—	—	13,252
Net loss	—	—	—	—	(58,228)	(58,228)
Other comprehensive loss	—	—	—	(540)	—	(540)
Balance at September 30, 2020	119,795,216	$ 1,524	$ 1,480,315	$ 11	$ (599,300)	$ 882,550
Balance at December 31, 2018	94,662,435	$ 1,273	$ 774,158	$ (649)	$ (227,937)	$ 546,845
Issuances under equity incentive plans	781,107	7	4,149	—	—	4,156
Vesting of early exercised common stock	125,001	2	83	—	—	85
Vesting of restricted stock awards and units	419,064	4	(4)	—	—	—
Stock-based compensation	—	—	29,489	—	—	29,489
Net loss	—	—	—	—	(143,589)	(143,589)
Other comprehensive income	—	—	—	1,211	—	1,211
Balance at September 30, 2019	95,987,607	$ 1,286	$ 807,875	$ 562	$ (371,526)	$ 438,197
Balance at June 30, 2019	95,656,896	$ 1,283	$ 798,277	$ 879	$ (325,266)	$ 475,173
Issuances under equity incentive plans	233,983	2	677	—	—	679
Vesting of early exercised common stock	31,249	—	21	—	—	21
Vesting of restricted stock awards and units	65,479	1	(1)	—	—	—
Stock-based compensation	—	—	8,901	—	—	8,901
Net loss	—	—	—	—	(46,260)	(46,260)
Other comprehensive loss	—	—	—	(317)	—	(317)
Balance at September 30, 2019	95,987,607	$ 1,286	$ 807,875	$ 562	$ (371,526)	$ 438,197

See accompanying notes to unaudited condensed consolidated financial statements.

Denali Therapeutics Inc.

Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2020	**2019**
Operating activities		
Net loss	$ (173,749)	$ (143,589)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	6,410	5,936
Stock–based compensation expense	36,521	29,489
Net amortization of discounts on marketable securities	(1,074)	(4,032)
Non-cash adjustment to operating lease expense	(1,669)	2,333
Other non-cash items	18	(427)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	3,819	5,812
Accounts payable	147	466
Accruals and other current liabilities	4,880	2,876
Contract liabilities	(17,920)	(2,797)
Related party contract liability	44,854	—
Net cash used in operating activities	(97,763)	(103,933)
Investing activities		
Purchases of marketable securities	(687,523)	(219,139)
Purchases of property and equipment	(1,900)	(15,146)
Maturities and sales of marketable securities	433,557	339,612
Net cash provided by (used in) investing activities	(255,866)	105,327
Financing activities		
Proceeds from issuance of common stock in connection with the Biogen Stock Purchase Agreement	420,146	—
Proceeds from public offering of common stock, net of issuance costs	193,948	—
Proceeds from exercise of awards under equity incentive plans	11,133	4,156
Net cash provided by financing activities	625,227	4,156
Net increase in cash, cash equivalents and restricted cash	271,598	5,550
Cash, cash equivalents and restricted cash at beginning of period	80,949	78,623
Cash, cash equivalents and restricted cash at end of period	$ 352,547	$ 84,173
Supplemental disclosures of cash flow information		
Tenant improvements provided by the landlord	$ —	$ 11,343
Property and equipment purchases accrued but not yet paid	$ 32	$ 1,500

See accompanying notes to unaudited condensed consolidated financial statements.

Denali Therapeutics Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Significant Accounting Policies

Organization and Description of Business

Denali Therapeutics Inc. ("Denali" or the “Company”) is a biopharmaceutical company, incorporated in Delaware, that discovers and develops therapeutics to defeat neurodegenerative diseases. The Company is headquartered in South San Francisco, California.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) for interim financial information and the instructions to Form 10-Q and Article 10 of SEC Regulation S-X for interim financial information.

These unaudited condensed consolidated financial statements and notes should be read in conjunction with the audited consolidated financial statements and notes thereto contained in the Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the Securities and Exchange Commission on February 27, 2020 (the "2019 Annual Report on Form 10-K"). The Condensed Consolidated Balance Sheet as of December 31, 2019 was derived from the audited annual consolidated financial statements as of the period then ended. Certain information and footnote disclosures typically included in the Company's annual consolidated financial statements have been condensed or omitted. The accompanying unaudited condensed consolidated financial statements reflect all adjustments that, in the opinion of management, are necessary for a fair statement of the results of the interim periods presented. All such adjustments are of a normal recurring nature except for the impacts of adopting new accounting standards discussed below. These interim financial results are not necessarily indicative of results expected for the full fiscal year or for any subsequent interim period.

During the nine months ended September 30, 2020, except as discussed below in the sections titled "Marketable Securities" and "Recently Adopted Accounting Pronouncement," there were no material changes to the Company's significant accounting and financial reporting policies from those reflected in the 2019 Annual Report on Form 10-K. For further information with regard to the Company’s Significant Accounting Policies, please refer to Note 1, "Significant Accounting Policies," to the Company’s Consolidated Financial Statements included in the 2019 Annual Report on Form 10-K.

Principles of Consolidation

These unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation. For the Company and its subsidiary, the functional currency has been determined to be U.S. dollars. Monetary assets and liabilities denominated in foreign currency are remeasured at period-end exchange rates. Non-monetary assets and liabilities denominated in foreign currencies are remeasured at historical rates. Foreign currency transaction gains and losses resulting from remeasurement are recognized in interest and other income, net in the Condensed Consolidated Statements of Operations and Comprehensive Loss.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the Company to make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at the date of the condensed consolidated financial statements, as well as the reported amounts of expenses during the reporting period. Actual results could differ from those estimates, and such differences could be material to the Condensed Consolidated Balance Sheets and Statements of Operations and Comprehensive Loss.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents, marketable securities and forward foreign currency exchange contracts. Substantially all of the Company's cash and cash equivalents are deposited in accounts with financial institutions that management believes are of high credit quality. Such deposits have and will continue to exceed federally insured limits. The Company maintains its cash with accredited financial institutions and accordingly, such funds are subject to minimal credit risk.

The Company's investment policy limits investments to certain types of securities issued by the U.S. government, its agencies and institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash, cash equivalents and marketable securities and issuers of marketable securities to the extent recorded on the Condensed Consolidated Balance Sheets. As of September 30, 2020 and December 31, 2019, the Company has no off balance sheet concentrations of credit risk.

The Company is exposed to counterparty credit risk on all of its derivative financial instruments. The Company has established and maintains strict counterparty credit guidelines and enters into hedges only with financial institutions that are investment grade or better to minimize the Company's exposure to potential defaults. The Company does not require collateral to be pledged under these agreements.

The Company is subject to a number of risks similar to other early-stage biopharmaceutical companies, including, but not limited to, the need to obtain adequate additional funding, possible failure of current or future preclinical testing or clinical trials, its reliance on third parties to conduct its clinical trials, the need to obtain regulatory and marketing approvals for its product candidates, competitors developing new technological innovations, the need to successfully commercialize and gain market acceptance of the Company's product candidates, its right to develop and commercialize its product candidates pursuant to the terms and conditions of the licenses granted to the Company, protection of proprietary technology, the ability to make milestone, royalty or other payments due under any license or collaboration agreements, and the need to secure and maintain adequate manufacturing arrangements with third parties. If the Company does not successfully commercialize or partner any of its product candidates, it will be unable to generate product revenue or achieve profitability.

The COVID-19 pandemic has caused increased risk and uncertainty for the Company. Credit risk associated with investments in securities may increase if any institution with which the Company has an investment is significantly impacted by the COVID-19 pandemic. As of September 30, 2020, the Company has not realized any losses on its cash deposits or investments. Further, COVID-19 may impact the timelines and progress of the Company's preclinical activities and clinical trials, and may impact its ability to raise capital in the near term.

Segments

The Company has one operating segment. The Company's chief operating decision maker, its Chief Executive Officer, manages the Company's operations on a consolidated basis for the purposes of allocating resources.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments with original maturities of 90 days or less at the date of purchase to be cash and cash equivalents. Cash equivalents are reported at fair value.

The Company's restricted cash consists of the letter of credit for the Company's headquarters building lease, and is included within other non-current assets on the accompanying Condensed Consolidated Balance Sheets.

Marketable Securities

The Company generally invests its excess cash in money market funds and investment grade short to intermediate-term fixed income securities. Such investments are included in cash and cash equivalents, short-term marketable securities, or long-term marketable securities on the Condensed Consolidated Balance Sheets, are considered available-for-sale, and reported at fair value with net unrealized gains and losses included as a component of stockholders' equity.

The Company classifies investments in securities with remaining maturities of less than one year, or where its intent is to use the investments to fund current operations or to make them available for current operations, as short-term investments. The Company classifies investments in securities with remaining maturities of over one year as long-term investments. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest and other income, net in the Condensed Consolidated Statements of Operations and Comprehensive Loss. Realized gains and losses and declines in value determined to be due to credit losses on marketable securities, if any, are included in interest and other income, net.

The Company periodically evaluates the need for an allowance for credit losses. This evaluation includes consideration of several qualitative and quantitative factors, including whether it has plans to sell the security, whether it is more likely than not it will be required to sell any marketable securities before recovery of its amortized cost basis, and if the entity has the ability and intent to hold the security to maturity, and the portion of any unrealized loss that is the result of a credit loss. Factors considered in making these evaluations include quoted market prices, recent financial results and operating trends, implied values from any recent transactions or offers of investee securities, credit quality of debt instrument issuers, expected cash flows from securities, other publicly available information that may affect the value of the marketable security, duration and severity of the decline in value, and the Company's strategy and intentions for holding the marketable security.

Accounts Receivable

Accounts receivable are included within prepaid expenses and other current assets on the Condensed Consolidated Balance Sheets. The accounts receivable balance represents amounts receivable from the Company's collaboration partners, net of an allowance for credit losses, if required.

Derivatives and Hedging Activities

The Company measures its derivative instruments at fair value, and accounts for them as either assets or liabilities included within prepaid assets and other current assets and other accruals and current liabilities, respectively, on the Condensed Consolidated Balance Sheets. Derivatives are adjusted to fair value through interest and other income, net in the Condensed Consolidated Statements of Operations and Comprehensive Loss.

Leases

The Company adopted Accounting Standards Update ("ASU") No. 2016-02, *Leases* as of January 1, 2019. A determination is made as to whether an arrangement is a lease at inception. A right-of-use ("ROU") asset and operating lease liability is recognized for identified operating leases in the Condensed Consolidated Balance Sheets. The changes in operating lease ROU assets and operating lease liabilities are presented net within non-cash adjustment to operating lease expense in the Condensed Consolidated Statements of Cash Flows.

ROU assets represent the Company's right to use the underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments due over the lease term, with the ROU assets adjusted for lease incentives received. When determining the present value of lease payments, the Company uses its incremental borrowing rate on the date of lease commencement, or the rate implicit in the lease, if known. The Company does not assume renewals in its determination of the lease term unless the renewals are deemed by management to be reasonably certain at lease inception.

Leases with an initial term of 12 months or less are not recorded on the balance sheet, unless they include an option to purchase the underlying asset that the Company is reasonably certain to exercise. The Company recognizes lease expenses on a straight-line basis over the lease term. The Company has leases with lease and non-lease components, which the Company has elected to account for as a single lease component.

Revenue Recognition

License and Collaboration Revenue

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, Collaborative Arrangements ("ASC 808") to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 808 and those that are more reflective of a vendor-customer relationship and, therefore, within the scope of Topic 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to Topic 606. The accounting treatment pursuant to Topic 606 is outlined below.

The terms of licensing and collaboration agreements entered into typically include payment of one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; payments for manufacturing supply and research and development services and royalties on net sales of licensed products. Each of these payments results in license, collaboration and other revenue, except for revenues from royalties on net sales of licensed products, which are classified as royalty revenue. The core principle of Topic 606 is to recognize revenue when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received in exchange for those goods or services.

In determining the appropriate amount of revenue to be recognized as the Company fulfills its obligations under each of its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

Amounts received prior to satisfying the revenue recognition criteria are recorded as contract liabilities in the Company's Condensed Consolidated Balance Sheets. If the related performance obligation is expected to be satisfied within the next twelve months this will be classified in current liabilities. Amounts recognized as revenue prior to the Company having an unconditional right (other than a right that is conditioned only on the passage of time) to receipt are recorded as contract assets in the Company's Condensed Consolidated Balance Sheets. If the Company expects to have an unconditional right to receive the consideration in the next twelve months, this will be classified in current assets. A net contract asset or liability is presented for each contract with a customer.

At contract inception, the Company assesses the goods or services promised in a contract with a customer and identifies those distinct goods and services that represent a performance obligation. A promised good or service may not be identified as a performance obligation if it is immaterial in the context of the contract with the customer, if it is not separately identifiable from other promises in the contract (either because it is not capable of being separated or because it is not separable in the context of the contract), or if the performance obligation does not provide the customer with a material right.

The Company considers the terms of the contract to determine the transaction price. The transaction price is the amount of consideration to which the Company expects to be entitled in exchange for transferring promised goods or services to a customer. The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both. Variable consideration will only be included in the transaction price when it is not considered constrained, which is when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur.

If it is determined that multiple performance obligations exist, the transaction price is allocated at the inception of the agreement to all identified performance obligations based on the relative standalone selling prices ("SSP"). The relative SSP for each deliverable is estimated using external sourced evidence if it is available. If external sourced evidence is not available, the Company uses its best estimate of the SSP for the deliverable.

Revenue is recognized when, or as, the Company satisfies a performance obligation by transferring a promised good or service to a customer. An asset is transferred when, or as, the customer obtains control of that asset, which for a service is considered to be as the services are received and used. The Company recognizes revenue over time by measuring the progress toward complete satisfaction of the relevant performance obligation using an appropriate input or output method based on the nature of the service promised to the customer.

After contract inception, the transaction price is reassessed at every period end and updated for changes such as resolution of uncertain events. Any change in the transaction price is allocated to the performance obligations on the same basis as at contract inception, or to a single performance obligation as applicable.

Management may be required to exercise considerable judgment in estimating revenue to be recognized. Judgment is required in identifying performance obligations, estimating the transaction price, estimating the SSP of identified performance obligations, which may include forecasted revenue, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success, and estimating the progress towards satisfaction of performance obligations.

Comprehensive Income (Loss)

Comprehensive income (loss) is composed of net loss and certain changes in stockholders' equity that are excluded from net loss, primarily unrealized gains or losses on the Company's marketable securities.

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is the same as basic net loss per share, since the effects of potentially dilutive securities are antidilutive given the net loss for each period presented.

Recently Issued Accounting Pronouncement

In December 2019, the Financial Accounting Standards Board ("FASB") issued ASU No. 2019-12*, Income Taxes (Topic 740) Simplifying the Accounting for Income Taxes.* ASU No. 2019-12 modifies ASC 740 to simplify several aspects of accounting for income taxes, including eliminating certain exceptions to the guidance in ASC 740 related to the approach for intraperiod tax allocation. The guidance is effective for fiscal years beginning after December 15, 2020 and interim periods within those fiscal years, with early adoption permitted, and is required to be adopted prospectively, with the exception of certain specific amendments. The Company is currently finalizing its assessment of the impact of this ASU, and does not expect it to have a material impact on its Condensed Consolidated Financial Statements.

Recently Adopted Accounting Pronouncement

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments*. ASU 2016-13 requires measurement and recognition of expected credit losses for financial assets. In April 2019, the FASB issued clarification to ASU 2016-13 within ASU 2019-04, *Codification Improvements to Topic 326, Financial Instruments-Credit Losses, Topic 815, Derivatives and Hedging*, *and Topic 825, Financial Instruments*. The Company adopted this standard as of January 1, 2020 using a modified retrospective approach. Adoption of the standard did not have a material impact on the Condensed Consolidated Financial Statements.

2. Fair Value Measurements

Assets and liabilities measured at fair value at each balance sheet date are as follows (in thousands):

	September 30, 2020			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 326,640	$ —	$ —	$ 326,640
Short-term marketable securities:				
U.S. government treasuries	542,637	—	—	542,637
U.S. government agency securities	—	10,111	—	10,111
Corporate debt securities	—	43,919	—	43,919
Commercial paper	—	13,487	—	13,487
Long-term marketable securities:				
U.S. government treasuries	5,153	—	—	5,153
U.S. government agency securities	—	15,188	—	15,188
Foreign currency derivative contracts	—	109	—	109
Total	$ 874,430	$ 82,814	$ —	$ 957,244
Liabilities:				
Foreign currency derivative contracts	$ —	$ 173	$ —	$ 173
Total	$ —	$ 173	$ —	$ 173

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 54,163	$ —	$ —	$ 54,163
U.S. government treasuries	15,989	—	—	15,989
Short-term marketable securities:				
U.S. government treasuries	250,070	—	—	250,070
U.S. government agency securities	—	2,000	—	2,000
Corporate debt securities	—	53,479	—	53,479
Commercial paper	—	30,358	—	30,358
Long-term marketable securities:				
U.S. government treasuries	13,869	—	—	13,869
Corporate debt securities	—	26,017	—	26,017
Foreign currency derivative contracts	—	85	—	85
Total	$ 334,091	$ 111,939	$ —	$ 446,030
Liabilities:				
Foreign currency derivative contracts	$ —	$ 8	$ —	$ 8
Total	$ —	$ 8	$ —	$ 8

The carrying amounts of prepaid expenses and other current assets, accounts payable and accrued liabilities approximate their fair values due to their short-term maturities.

The Company's Level 2 securities are valued using third-party pricing sources. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly.

There were no transfers of assets or liabilities between the fair value measurement levels during the three and nine months ended September 30, 2020 or 2019.

3. Cash and Marketable Securities

Cash, cash equivalents and restricted cash

A reconciliation of cash, cash equivalents, and restricted cash reported within the Condensed Consolidated Balance Sheets to the amount reported within the Condensed Consolidated Statements of Cash Flows is shown in the table below (in thousands):

	September 30, 2020	December 31, 2019	September 30, 2019	December 31, 2018
Cash and cash equivalents	$ 351,047	$ 79,449	$ 82,673	$ 77,123
Restricted cash included within other non-current assets	1,500	1,500	1,500	1,500
Total cash, cash equivalents, and restricted cash	$ 352,547	$ 80,949	$ 84,173	$ 78,623

Marketable securities

All marketable securities were considered available-for-sale at September 30, 2020 and December 31, 2019. On a recurring basis, the Company records its marketable securities at fair value using Level 1 or Level 2 inputs as discussed in Note 2, "Fair Value Measurements". The amortized cost, gross unrealized holding gains or losses, and fair value of the Company's marketable securities by major security type at each balance sheet date are summarized in the tables below (in thousands):

	September 30, 2020			
	Amortized Cost	Unrealized Holding Gains	Unrealized Holding Losses	Aggregate Fair Value
Short-term marketable securities:				
U.S. government treasuries[1]	$ 542,479	$ 161	$ (3)	$ 542,637
U.S. government agency securities[2]	10,122	—	(11)	10,111
Corporate debt securities	43,703	216	—	43,919
Commercial paper	13,487	—	—	13,487
Total short-term marketable securities	609,791	377	(14)	610,154
Long-term marketable securities:				
U.S. government treasuries	5,153	—	—	5,153
U.S. government agency securities[3]	15,189	—	(1)	15,188
Total long-term marketable securities	20,342	—	(1)	20,341
Total	$ 630,133	$ 377	$ (15)	$ 630,495

(1) Unrealized holding losses on 8 securities with an aggregate fair value of $73.3 million.
(2) Unrealized holding losses on 2 securities with an aggregate fair value of $10.1 million.
(3) Unrealized holding losses on 1 securities with an aggregate fair value of $15.2 million.

	December 31, 2019			
	Amortized Cost	Unrealized Holding Gains	Unrealized Holding Losses	Aggregate Fair Value
Short-term marketable securities:				
U.S. government treasuries[1]	$ 249,478	$ 594	$ (2)	$ 250,070
U.S. government agency securities	1,999	1	—	2,000
Corporate debt securities[2]	53,396	94	(11)	53,479
Commercial paper	30,358	—	—	30,358
Total short-term marketable securities	335,231	689	(13)	335,907
Long-term marketable securities:				
U.S. government treasuries[3]	13,865	6	(2)	13,869
Corporate debt securities[4]	25,998	34	(15)	26,017
Total long-term marketable securities	39,863	40	(17)	39,886
Total	$ 375,094	$ 729	$ (30)	$ 375,793

(1) Unrealized holding losses on 2 securities with an aggregate fair value of $9.3 million.
(2) Unrealized holding losses on 4 securities with an aggregate fair value of $25.9 million.
(3) Unrealized holding losses on 1 security with an aggregate fair value of $10.1 million.
(4) Unrealized holding losses on 3 securities with an aggregate fair value of $17.2 million.

As of December 31, 2019, some of the Company's marketable securities were in an unrealized loss position, and unrealized losses were immaterial as of September 30, 2020. The Company has not recognized an allowance for credit losses as of September 30, 2020 and there was no other-than-temporary impairment as of December 31, 2019. The Company determined that it had the ability and intent to hold all marketable securities that have been in a continuous loss position until maturity or recovery. Further, these marketable securities were initially, and continue to be, held with investment grade, high credit quality institutions. All marketable securities with unrealized losses as of each balance sheet date have been in a loss position for less than twelve months or the loss is not material.

The Company recorded unrealized gains on marketable securities in other comprehensive income for the three and nine months ended September 30, 2019. The Company recorded a tax benefit of $0.1 million and $0.4 million for the three and nine months ended September 30, 2019 on the Condensed Consolidated Statements of Operations and Comprehensive Loss and a corresponding tax charge in other comprehensive income. There was no unrealized gain on marketable securities in other comprehensive income for the three and nine months ended September 30, 2020.

All of the Company's marketable securities have an effective maturity of less than two years.

4. Derivative Financial Instruments

Foreign Currency Exchange Rate Exposure

The Company uses forward foreign currency exchange contracts to hedge certain operational exposures resulting from potential changes in foreign currency exchange rates. Such exposures result from portions of the Company's forecasted cash flows being denominated in currencies other than the U.S. dollar, primarily the Euro and British Pound. The derivative instruments the Company uses to hedge this exposure are not designated as cash flow hedges, and as a result, changes in their fair value are recorded in interest and other income, net, on the Company's Condensed Consolidated Statements of Operations and Comprehensive Loss.

The fair values of forward foreign currency exchange contracts are estimated using current exchange rates and interest rates and take into consideration the current creditworthiness of the counterparties. Information regarding the specific instruments used by the Company to hedge its exposure to foreign currency exchange rate fluctuations is provided below.

The following table summarizes the Company's forward foreign currency exchange contracts outstanding as of September 30, 2020 and December 31, 2019, respectively (notional amounts in thousands):

Foreign Exchange Contracts	Number of Contracts	Aggregate Notional[(1)] Amount in Foreign Currency	Maturity
Euros	24	3,630	Oct 2020 - Aug 2021
British Pounds	26	3,736	Oct 2020 - Aug 2021
Total at September 30, 2020	50		
Euros	23	1,500	Jan 2020 - Nov 2020
British Pounds	15	2,285	Jan 2020 - Jun 2020
Swiss Francs	10	129	Jan 2020 - Aug 2020
Total at December 31, 2019	48		

(1) The notional amount represents the net amount of foreign currency that will be received upon maturity of the forward contracts.

5. Acquisition

In August 2016, the Company entered into a License and Collaboration Agreement ("F-star Collaboration Agreement") with F-star Gamma Limited ("F-star Gamma"), F-star Biotechnologische Forschungs-Und Entwicklungsges M.B.H ("F-star GmbH") and F-star Biotechnology Limited ("F-star Ltd") (collectively, "F-star") to leverage F-star's modular antibody technology and the Company's expertise in the development of therapies for neurodegenerative diseases. Under the F-star Collaboration Agreement, the Company made payments to F-star totaling $11.5 million. In connection with the entry into the F-star Collaboration Agreement, the Company also purchased an option for an upfront option fee of $0.5 million (the "buy-out-option"), to acquire all of the outstanding shares of F-star Gamma pursuant to a pre-negotiated buy-out option agreement (the "Option Agreement").

In May 2018, the Company exercised the Option Agreement and entered into a Share Purchase Agreement (the "Purchase Agreement") with the shareholders of F-star Gamma and Shareholder Representative Services LLC, pursuant to which the Company acquired all of the outstanding shares of F-star Gamma (the "Acquisition").

As a result of the Acquisition, F-star Gamma became a wholly-owned subsidiary of the Company and the Company changed the entity's name to Denali BBB Holding Limited. In addition, the Company became a direct licensee of certain intellectual property of F-star Ltd by way of the Company's assumption of F-star Gamma's license agreement with F-star Ltd, dated August 24, 2016, (the "F-star Gamma License"). The Company made initial exercise payments under the Purchase Agreement and the F-star Gamma License, in the aggregate, of $17.8 million. In addition, the Company is required to make future contingent payments, to F-star Ltd and the former shareholders of F-star Gamma, up to a maximum amount of $447.0 million in the aggregate upon the achievement of certain defined preclinical, clinical, regulatory and commercial milestones. These include up to $27.0 million in preclinical contingent payments, $50.0 million in clinical contingent payments, $120.0 million in regulatory contingent payments and $250.0 million in commercial contingent payments. The amount of the contingent payments will vary based on whether F-star delivers an Fcab (constant Fc-domains with antigen-binding activity) that meets pre-defined criteria and whether the Fcab has been identified solely by the Company or solely by F-star or jointly by the Company and F-star. In June 30, 2019, the Company made a payment of $1.5 million to F-star Ltd upon the achievement of a specified preclinical milestone in the Company's ETV:IDS program.

The Company concluded that the assets acquired and liabilities assumed upon the exercise of the Option Agreement did not meet the accounting definition of a business, and as such, the acquisition was accounted for as an asset purchase. As the transaction was accounted for as an asset purchase rather than a business combination, the Company did not recognize any contingent consideration on the acquisition date. To date, the Company has paid consideration of $19.8 million in the aggregate, consisting of up-front and contingent consideration, all of which was recorded as research and development expense as incurred. The Company recognized $1.5 million of contingent consideration as research and development expense for the three and nine months ended September 30, 2019. There has been no contingent consideration recognized for the three and nine months ended September 30, 2020. Any future contingent consideration is expected to be recognized as incurred in research and development expense on the Condensed Consolidated Statements of Operations and Comprehensive Loss.

Under the F-star Collaboration Agreement, the Company is responsible for certain research costs incurred by F-star Ltd in conducting activities under an agreed development plan for each Fcab, for up to 24 months after the target Fcab is accepted. The Company's responsibility for research costs under the first development plan related to an Fcab that targets the transferrin receptor was completed during the year ended December 31, 2018. The responsibility for costs under the second development plan related to an undisclosed Fcab target commenced in February 2019. The Company recognized $0.3 million and $0.9 million in research and development expense related to the funding of F-star Ltd activities under this development plan during the three and nine months ended September 30, 2020, respectively, and $0.3 million and $0.8 million for the three and nine months ended September 30, 2019, respectively.

6. Collaboration Agreements

Biogen

Provisional Biogen Collaboration Agreement and Common Stock Purchase Agreement

On August 5, 2020, the Company entered into a binding Provisional Collaboration and License Agreement (“Provisional Biogen Collaboration Agreement”) with Biogen Inc.’s subsidiaries, Biogen MA Inc. (“BIMA”) and Biogen International GmbH (“BIG”) (BIMA and BIG, collectively, “Biogen”) pursuant to which the Company granted Biogen a license to co-develop and co-commercialize Denali’s small molecule LRRK2 inhibitor program (the “LRRK2 Program”), an option in respect of each of (i) the Company’s amyloid beta program utilizing the Company's Transport Vehicle ("TV") technology platform to cross the blood-brain barrier and (ii) one other unnamed program also utilizing the Company's TV technology platform (the “Option Programs”), and a right of first negotiation with respect to two additional unnamed programs for indications within Alzheimer’s disease, Parkinson’s disease, amyotrophic lateral sclerosis ("ALS") and multiple sclerosis utilizing the Company's TV technology platform (the “ROFN Programs”) should the Company decide to seek a collaboration with a third party for such programs. The Provisional Biogen Collaboration Agreement is a binding agreement, which became effective on the closing of the Common Stock Purchase Agreement ("SPA"), as described further below. The Provisional Biogen Collaboration Agreement expired in October 2020 upon the execution of a Definitive LRRK2 Collaboration and License Agreement (“LRRK2 Agreement”) with Biogen on October 4, 2020 and a Right of First Negotiation, Option and License Agreement (the “ROFN and Option Agreement”) on October 6, 2020 (collectively, the "Definitive Biogen Collaboration Agreement").

Under the terms of the Provisional Biogen Collaboration Agreement, Biogen was obligated to pay the Company a $560.0 million upfront payment, payable upon execution of the Definitive Biogen Collaboration Agreement, which occurred in October 2020. With respect to the LRRK2 Program, Biogen will make milestone payments up to approximately $1.1 billion upon achievement of certain development and commercial events. Such milestone payments include $375.0 million in development, $375.0 million upon first commercial sale, and $375.0 million in net sales-based milestones. The Company will share 50% of the profits and losses with Biogen for LRRK2 Products in the United States, and 40% of such profits and losses in China. The Company will be entitled to receive royalties in the high teens to low twenties percentages on net sales for LRRK2 Products outside of the United States and China.

Under the terms of the Provisional Biogen Collaboration Agreement, through the effective date of the Definitive Biogen Collaboration Agreement, the Company conducted and controlled LRRK2 clinical development. Subsequently, the Company and Biogen will jointly develop LRRK2 Products pursuant to a clinical development plan set forth within the LRRK2 Agreement. The parties will share responsibility and costs for global development of LRRK2 Products pursuant to a mutually agreed development plan and budget, with Biogen funding 60% and the Company funding 40% of such costs. The Company has the ability to opt out of the development cost sharing arrangement, as further described below.

The Company may opt out of development cost sharing worldwide and upon such election, from any further profit sharing from the LRRK2 Program. The Company also has the right to opt-out of the profit sharing arrangement for the LRRK2 Program or for only those LRRK2 Products that do not penetrate the blood-brain barrier (“Peripheral LRRK2 Products”), in each of the United States and China. After such an opt out, the Company will no longer be obligated to share in the development and commercialization costs for, or be entitled to share in the applicable revenues from, such LRRK2 Program (or from the LRRK2 Peripheral Products). Additionally, following a change of control of the Company, Biogen may, within a specified period of time, elect to terminate the Company’s right to share commercialization costs and revenues from the LRRK2 Program in China. If the Company chooses to exercise its opt out rights, the Company will be entitled to receive tiered royalties on net sales of the applicable LRRK2 Program in the relevant country (or countries). The royalty rates for the applicable LRRK2 Program will be a percentage in the high teens to low twenties, but may increase to the mid-twenties if the Company has met certain co-funding thresholds or there has been a first commercial sale at the time of the Company's election.

In addition to the LRRK2 Program, Biogen received an exclusive option to license two preclinical programs enabled by the Company's TV technology platform, which platform aims to improve brain uptake of biotherapeutics, including its Antibody Transport Vehicle ("ATV"): Abeta program ("ATV enabled anti-amyloid beta program") and a second program utilizing the Company's TV technology for an unnamed target ("TV program"), excluding small molecules, Adeno-associated viruses ("AAV") and oligonucleotides. Biogen’s option may be exercised up to initiation of investigational new drug ("IND")-enabling studies for each program and continues for each program until a specified period of time after delivery of an option data package, or thirty business days after the 5th anniversary of the effective date of the Provisional Biogen Collaboration Agreement, whichever is earlier.

Further, Biogen will have the right of first negotiation ("ROFN") on two additional TV-enabled therapeutics within Alzheimer’s disease, Parkinson’s disease, ALS and multiple sclerosis should the Company decide to seek a collaboration with a third party for such programs, but this does not include any of the Company’s small molecule, AAV and oligonucleotide programs. The ROFN period continues until seven years after the effective date of the Provisional Biogen Collaboration Agreement or the date on which the Company has offered Biogen two ROFN Programs, whichever is earlier. However, if the Company does not execute an agreement with a third party with respect to a particular ROFN Program offered to Biogen within a specified amount of time, Biogen will have one additional right to exercise the ROFN again with respect to such ROFN Program.

In connection with the Provisional Biogen Collaboration Agreement, the Company entered into a common stock purchase agreement (the "Stock Purchase Agreement") with BIMA on August 5, 2020, pursuant to which the Company agreed to issue and sell, and BIMA agreed to purchase, 13,310,243 shares of the Company’s common stock (the “Shares”) for an aggregate purchase price of $465.0 million pursuant to the terms and conditions thereof. Since the shares of common stock owned by Biogen as of September 30, 2020 represent more than 10% of the voting interest of the Company, Biogen is considered a related party as defined in ASC 850. Management determined that it is appropriate to account for the Provisional Biogen Collaboration Agreement and the SPA as one arrangement because they were entered into at the same time with interrelated financial terms.

On September 22, 2020, the Company closed the sale of the Shares to BIMA pursuant to the Stock Purchase Agreement. The estimated fair market value of the Shares issued to Biogen was $420.1 million, based on the closing stock price of $35.87 on the date of issuance adjusted by a discount for lack of marketability due to certain holding period restrictions, which was valued using an option pricing model. This stock issuance resulted in a $44.9 million premium paid to the Company above the estimated fair value of the Company's common stock (the "Stock Premium"), which was recorded as a related party contract liability in the Condensed Consolidated Balance Sheets. The Stock Premium was the only consideration allocated to the Provisional Biogen Collaboration Agreement as of September 30, 2020

Upon inception, the Company identified the LRRK2 license as the only distinct performance obligation under ASC 606 associated with the Provisional Biogen Collaboration Agreement. No performance obligations were identified related to the Option or ROFN Programs since the relevant financial and operational terms were not considered to be sufficiently defined in the Provisional Biogen Collaboration Agreement to allow the Company to determine its obligations. Further, the Company was required to perform interim LRRK2 development activities subject to cost sharing in the period prior to finalization of the clinical development plan set forth within the LRRK2 Agreement.

The Company believes that the Provisional Biogen Collaboration Agreement is a collaboration arrangement as defined in ASC 808, Collaborative Agreements. The Company also believes that Biogen meets the definition of a customer as defined in ASC 606, Revenue From Contracts With Customers, for the LRRK2 license, but does not meet the definition of a customer for the interim LRRK2 development activities for which the Company will fund 40% of total costs. Since ASC 808 does not address recognition and measurement, the Company looked to other accounting literature for guidance where the unit of account does not fall under ASC 606, and determined that for the interim LRRK2 development activities subject to cost sharing provisions, the guidance in ASC 730, Research and Development should be applied.

At inception, there was no transaction price for the Provisional Biogen Collaboration Agreement. On September 22, 2020, as noted above, the $44.9 million Stock Premium was included in the transaction price. All other potential future payments were considered constrained at inception and through September 30, 2020 since they were all contingent on the execution of the Definitive Biogen Collaboration Agreement. For this reason, and due to the uncertainty surrounding the execution of the Definitive Biogen Collaboration Agreement as of September 30, 2020, the Company did not conclude it was probable that a significant reversal in the amount recognized would not occur.

As of September 30, 2020, management determined that no performance obligation had been satisfied or delivered to Biogen. License delivery is contingent on transfer of control to Biogen, which had not occurred as of September 30, 2020. Since no performance obligation had been satisfied as of September 30, 2020, no related party revenue was recognized under ASC 606 in the three and nine months ended September 30, 2020. The entire transaction price was recorded within related party contract liability on the Condensed Consolidated Balance Sheet as of September 30, 2020. Further, since cost sharing reimbursement related to the interim LRRK2 development activities performed prior to September 30, 2020 was contingent upon execution of the Definitive Biogen Collaboration Agreement, no offset to research and development expense from a related party was included in the Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2020, and no related party receivable was recorded on the Condensed Consolidated Balance Sheet as of September 30, 2020.

In assessing the Provisional Biogen Collaboration Agreement, management exercised considerable judgment in estimating revenue to be recognized, specifically related to determining the separate performance obligations under the Agreement and estimating the timing of delivery of those performance obligations.

As of September 30, 2020, the Company had not achieved any milestones or recorded any product sales under the Provisional Biogen Collaboration Agreement.

Definitive Biogen Collaboration Agreement

The Company entered into the LRRK2 Agreement with Biogen on October 4, 2020 and the ROFN and Option Agreement on October 6, 2020. Collectively these are known as the Definitive Biogen Collaboration Agreement, the material terms of which are consistent with, and supersede, the Provisional Biogen Collaboration Agreement discussed above.

Under the ROFN and Option Agreement, with respect to the options granted by the Company to Biogen, Biogen is obligated to pay to the Company an aggregate of up to $270.0 million in option exercise and development milestone payments, up to $325.0 million upon first commercial sale, and up to $290.0 million of net sales-based milestone payments, following the achievement of certain prespecified milestone events and if Biogen exercises both of its options. Furthermore, Biogen is obligated to pay to the Company royalties in the mid-single digit to mid-teens percentages, depending on the program for which Biogen exercises its option and upon the achievement of certain sales thresholds.

In October 2020, the Company received upfront payments totaling $560.0 million pursuant to the Definitive Biogen Collaboration Agreement. Management is in the process of assessing the accounting impact of the execution of the Definitive Biogen Collaboration Agreement.

Sanofi

In October 2018, the Company entered into a Collaboration and License Agreement ("Sanofi Collaboration Agreement") with Genzyme Corporation, a wholly owned subsidiary of Sanofi S.A. ("Sanofi") pursuant to which certain small molecule CNS and peripheral receptor interacting serine/threonine protein kinase 1 ("RIPK1") inhibitors contributed by Sanofi and by the Company will be developed and commercialized. The Sanofi Collaboration Agreement became effective in November 2018 when the Hart-Scott-Rodino ("HSR") requirements were satisfied at which time Sanofi paid the Company an upfront payment of $125.0 million. Under the Sanofi Collaboration Agreement, the Company is eligible to receive milestone payments from Sanofi up to approximately $1.1 billion upon achievement of certain clinical, regulatory and sales milestone events. Such milestone payments include $215.0 million in clinical milestone payments and $385.0 million in regulatory milestone payments for CNS Products, as defined, that are developed and approved in the United States, by the European Medicines Agency ("EMA") and in Japan for three indications, including Alzheimer's disease. These milestones also include $120.0 million in clinical milestone payments, $175.0 million in regulatory milestone payments and $200.0 million in commercial milestone payments for Peripheral Products, as defined, that are developed and approved in the United States, by the EMA and Japan for three indications.

The Company will share profits and losses equally with Sanofi for CNS Products sold in the United States and China, and receive variable royalties on net sales for CNS Products sold outside of the United States and China and for Peripheral Products sold worldwide.

The Company and Sanofi will jointly develop CNS Products pursuant to a global development plan. The Company will be responsible, at its own cost, for conducting Phase 1 and Phase 2 trials for CNS Products in Alzheimer’s disease and any activities required to support such clinical trials and specific for Alzheimer’s disease. The Company conducted, at Sanofi’s cost, a Phase 1b trial for the initial lead CNS penetrant RIPK1 inhibitor, DNL747 (SAR443060), in ALS. In June 2020, the Company announced that clinical activities on DNL747 would be paused and efforts focused on the development of the backup preclinical candidate, DNL788. Sanofi is responsible, at its cost, for all other Phase 1 and Phase 2 trials for CNS Products, including for multiple sclerosis. Sanofi will lead the conduct of all Phase 3 and later stage development trials for CNS Products, with Sanofi and the Company funding 70% and 30% of such costs, respectively. Sanofi will also lead the commercialization activities globally for CNS Products, subject to certain options that the Company has to conduct co-commercialization activities with respect to each CNS Product in the United States and China.

Sanofi will be responsible, at its cost, for conducting activities relating to the development and commercialization of all Peripheral Products. Denali will be entitled to receive tiered royalties in the low- to mid- teen percentages on net sales of Peripheral Products.

The Company identified the following distinct performance obligations associated with the Sanofi Collaboration Agreement upon inception: the CNS program license, the Peripheral program license, the Phase 1 and Phase 2 trials for CNS Products for Alzheimer's disease ("Alzheimer's Disease Services"), and the Phase 1b trial for DNL747 for ALS and associated activities ("Retained Activities").

The Company believes that the Sanofi Collaboration Agreement is a collaboration arrangement as defined in ASC 808. The Company also believes that Sanofi meets the definition of a customer as defined in ASC 606, Revenue From Contracts With Customers for three of the performance obligations identified at inception, but does not meet the definition of a customer for the Alzheimer's Disease Services. Further, Sanofi does not meet the definition of a customer for all Phase 3 and later stage development trials for CNS Products led by Sanofi for which the Company will fund 30% of total costs. Since ASC 808 does not address recognition and measurement, the Company looked to other accounting literature for guidance where the performance obligation does not fall under ASC 606, and determined that for the Alzheimer's Disease Services, the guidance in ASC 606 should be analogized for the recognition, measurement and reporting of this performance obligation, and for the cost sharing provisions, the Company determined that the guidance in ASC 730, Research and Development should be applied.

The transaction price at inception included upfront fixed consideration of $125.0 million. All potential future milestones and other payments were considered constrained at the inception of the Sanofi Collaboration Agreement since the Company could not conclude it was probable that a significant reversal in the amount recognized would not occur. From inception through September 30, 2020, the transaction price increased by $21.3 million, consisting of $11.3 million related to costs incurred for Retained Activities that were no longer constrained, and $10.0 million related to a milestone triggered in July 2019. The transaction price increased by $0.1 million and $0.9 million for the three and nine months ended September 30, 2020, respectively, related entirely to costs incurred for Retained Activities that were determined to no longer be constrained during these periods. The transaction price increased by $12.4 million and $19.2 million for the three and nine months ended September 30, 2019, respectively, related to the $10.0 million milestone triggered in July 2019, as well as $2.4 million and $9.2 million, respectively, for Retained Activities that were determined to no longer be constrained during these periods.

The respective standalone value for each of the performance obligations was determined by applying the SSP method and the transaction price allocated based on the relative SSP method with revenue recognition timing to be determined either by delivery or the provision of services.

The Company used an adjusted market assessment approach to estimate the selling price for the program licenses, and an expected cost plus margin approach for estimating the Alzheimer's Disease Services and the Retained Activities. The program licenses and existing know-how were delivered on the effective date of the Sanofi Collaboration Agreement. The Alzheimer's Disease Services and the Retained Activities are expected to be delivered over time as the services are performed. For the Alzheimer's Disease Services, revenue will be recognized over time using the input method, based on costs incurred to perform the services, since the level of costs incurred over time is thought to best reflect the transfer of services to Sanofi. For the Retained Activities, revenue will be recognized over time using the output method, based on amounts invoiced to Sanofi, since this is believed to directly correlate to the value of the services performed.

A contract liability of $3.4 million and $3.5 million was recorded on the Condensed Consolidated Balance Sheets as of September 30, 2020 and December 31, 2019, respectively. This contract liability relates to the portion of the Alzheimer's Disease Services performance obligation yet to be satisfied, with such amounts to be recognized over the estimated period of the services, which is expected to be several years. The Company recorded a receivable associated with the Sanofi Collaboration Agreement on the Condensed Consolidated Balance Sheets as of September 30, 2020 and December 31, 2019 of $0.1 million and $1.2 million, respectively.

In assessing the Sanofi Collaboration Agreement, management is required to exercise considerable judgment in estimating revenue to be recognized. Management applies judgment in determining the separate performance obligations, in estimating the selling price, in determining when control was transferred to Sanofi for the licenses, and in estimating total future costs when using the input method.

Through September 30, 2020, the Company has received milestone payments of $10.0 million and has not recorded any product sales recorded under the Sanofi Collaboration Agreement.

Takeda

In January 2018, the Company entered into a Collaboration and Option Agreement ("Takeda Collaboration Agreement") with Takeda Pharmaceutical Company Limited ("Takeda"), pursuant to which the Company granted Takeda an option to develop and commercialize, jointly with the Company, certain biologic products that are enabled by the Company's blood-brain barrier ("BBB") delivery technology and intended for the treatment of neurodegenerative disorders. The programs were the Company's ATV:BACE1/Tau and ATV:TREM2 and PTV:PGRN programs. The Takeda Collaboration Agreement became effective in February 2018, at which time Takeda paid the Company an upfront payment of $40.0 million. Takeda may pay up to an aggregate of $25.0 million with respect to each of the three programs directed to a target and based upon the achievement of certain preclinical milestone events, up to $75.0 million in total, $5.0 million of which was paid upon the Takeda Collaboration Agreement becoming effective. In February 2019, the agreement was amended to replace the ATV:BACE1/Tau program with the ATV:Tau program. The amendment did not have a material impact to the condensed consolidated financial statements.

Under the Takeda Collaboration Agreement and unless otherwise agreed jointly between both parties, the Company will be responsible, at its cost, for conducting activities relating to pre-Investigational New Drug ("IND") development of biologic products directed to the three identified targets and enabled by its BBB delivery technology targeting TfR during the applicable research period. The period through which the option can be exercised continues for each target until the first biologic product directed to the relevant target is IND-ready or approximately five years after selection of the target, whichever is earlier.

If Takeda exercises its option with respect to a particular target, then Takeda will have the right to develop and commercialize, jointly with the Company, a specified number of biologic products enabled by its BBB delivery technology that were developed during the research period and which are directed to the relevant target. The Company will grant to Takeda a co-exclusive license under the intellectual property the Company controls related to those biologic products.

Takeda is obligated to pay the Company a $5.0 million option fee for each target for which Takeda exercises its option, up to $15.0 million in total.

In addition, if Takeda exercises its option for all three collaboration programs, Takeda may be obligated to pay the Company up to an aggregate of $407.5 million upon achievement of certain clinical milestone events and up to an aggregate of $300.0 million in regulatory milestone events relating to receipt of regulatory approval in the United States, certain European countries and Japan. Takeda may also be obligated to pay the Company up to $75.0 million per biologic product upon achievement of a certain sales-based milestone, or an aggregate of $225.0 million if one biologic product from each program achieves this milestone.

If Takeda exercises its option for a particular target, the Company and Takeda will share equally in the development and commercialization costs, and, if applicable, the profits, for each collaboration program.

Pursuant to the terms of the Takeda Collaboration Agreement, the Company entered into a common stock purchase agreement (the "Stock Purchase Agreement") with Takeda on January 3, 2018, pursuant to which Takeda purchased 4,214,559 shares of the Company's common stock (the "Shares") for an aggregate purchase price of $110.0 million. The sale of the Shares closed on February 23, 2018. The fair market value of the common stock sold to Takeda was $94.4 million, based on the closing stock price of $22.40 on the date of issuance, resulting in a $15.6 million premium paid to the Company above the fair value of the Company's common stock which was credited to contract liability in the Company's Condensed Consolidated Balance Sheets.

The Company believes that the Takeda Collaboration Agreement is a collaboration arrangement as defined in ASC 808. Further, during the research period, the Company believes that the arrangement is a contract with a customer as defined in ASC 606, Revenue From Contracts With Customers. The Takeda Collaboration Agreement and the Stock Purchase Agreement are being accounted for as one arrangement because they were entered into at the same time with interrelated financial terms.

The Company identified performance obligations during the research period consisting of the license, the development options, and joint steering committee ("JSC") participation together with the research services for each collaboration program. The license rights, JSC involvement, option and research services are considered to be a single performance obligation for each program since the research services are highly interrelated with the option and JSC involvement and will significantly modify the license. The performance obligations under each of the three programs are separate since the activities and risks under the programs are distinct.

The Company determined that all other goods or services which are contingent upon Takeda exercising its option for each program were not considered performance obligations at the inception of the Takeda Collaboration Agreement.

The transaction price at inception included fixed consideration consisting of the upfront fee of $40.0 million, the $15.6 million premium on the sale of common stock, and the first preclinical milestone payment of $5.0 million. It also included variable consideration of $26.0 million relating to future milestones that were not constrained. The amount of variable consideration was estimated using the most likely amount method.

The remaining $44.0 million of preclinical milestones were considered constrained at the inception of the Takeda Collaboration Agreement since the Company could not conclude it is probable that a significant reversal in the amount recognized will not occur. Additionally, cost and profit sharing income, and the development and commercial milestones as outlined above, have not been considered given Takeda has not exercised its options for the development and commercial phases for any program. No change in the transaction price has been recorded since inception. This will be reassessed at each reporting period.

The transaction price has been ascribed in its entirety to the three performance obligations identified in the research term of the Takeda Collaboration Agreement.

Revenue is recognized when, or as, the Company satisfies its performance obligations by transferring the promised services to Takeda. Revenue is being recognized over time using the input method, based on costs incurred to perform the research services, since the level of costs incurred over time is thought to best reflect the transfer of services to Takeda. There were no material changes in estimates during the three and nine months ended September 30, 2020 or September 30, 2019.

A contract liability of $41.1 million and $59.0 million was recorded on the Condensed Consolidated Balance Sheets as of September 30, 2020 and December 31, 2019, respectively. This contract liability relates to the three performance obligations identified, with such amounts to be recognized over the estimated period of the pre-IND research services, which is expected to be several years. There was no receivable related to the Takeda Collaboration Agreement as of September 30, 2020 or December 31, 2019, respectively.

Revenue recognized relating to future milestone payments of $7.5 million and $2.4 million, which the Company concluded is probable that a significant reversal in the amount recognized will not occur, is presented net in the contract liability on the Condensed Consolidated Balance Sheets as of September 30, 2020 and December 31, 2019, respectively.

In assessing the Takeda Collaboration Agreement, management is required to exercise considerable judgment in estimating revenue to be recognized. Management applies judgment in determining the separate performance obligations in the research period, estimating variable consideration, and estimating total future costs when using the input method. There is some increase in the judgment required in estimating the timing of future costs due to the COVID-19 pandemic. This is because it is challenging to predict the duration and extent of the impact of the COVID-19 pandemic on the third-party service providers assisting with the Company's ATV:Tau, ATV:TREM2 and PTV:PGRN programs. This may impact the split between current and non-current contract liability on the Condensed Consolidated Balance Sheet in the future.

Through September 30, 2020, the Company had received $15.0 million in preclinical milestone payments from Takeda and had not recorded any product sales under the Takeda Collaboration Agreement.

Collaboration Revenue

Revenue disaggregated by collaboration agreement and performance obligation is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Takeda Collaboration Agreement[1]	$ 9,271	$ 1,085	$ 17,826	$ 2,507
Sanofi Collaboration Agreement				
Peripheral Program License	—	10,000	—	10,000
Retained Activities	117	2,423	925	9,210
Alzheimer's Disease Services[1]	5	96	93	289
Total Sanofi Collaboration Revenue	122	12,519	1,018	19,499
Total Collaboration Revenue	$ 9,393	$ 13,604	$ 18,844	$ 22,006

(1) Amounts represent revenue recognized during the period that was included in the contract liability balance at the beginning of the period.

7. License Agreements

Genentech

In June 2016, the Company entered into an Exclusive License Agreement with Genentech, Inc. (“Genentech”). The agreement gives the Company access to Genentech’s LRRK2 inhibitor small molecule program for Parkinson’s disease. Under the agreement, Genentech granted the Company (i) an exclusive, worldwide, sublicensable license under Genentech’s rights to certain patents and patent applications directed to small molecule compounds which bind to and inhibit LRRK2 and (ii) a non-exclusive, worldwide, sublicensable license to certain related know-how, in each case, to develop and commercialize certain compounds and licensed products incorporating any such compound.

The Company may owe Genentech milestone payments upon the achievement of certain development, regulatory, and commercial milestones, up to a maximum of $315.0 million in the aggregate. These milestones include up to $37.5 million in clinical milestone payments, $102.5 million in regulatory milestone payments and $175.0 million in commercial milestone payments. In addition, the Company may owe royalties on net sales of licensed products ranging from low to high single-digit percentages. Effective October 4, 2020, Biogen is responsible for 50% of any payment obligation to Genentech under this agreement.

To date, the Company has paid Genentech $12.5 million in the aggregate, including an upfront fee, a technology transfer fee and a clinical milestone payment, all of which was recorded as research and development expense as incurred. No expenses were recorded in the three and nine months ended September 30, 2020 or 2019.

8. Commitments and Contingencies

Lease Obligations

In May 2018, the Company entered into an amendment to its operating lease for its former corporate headquarters in South San Francisco (the "Headquarters Lease Amendment") to relocate and expand its headquarters to 148,020 rentable square feet in a building in South San Francisco, California (the "New Premises"). The Headquarters Lease Amendment has a contractual term of ten years from the legal commencement date, which was April 1, 2019, when the building was ready for occupancy. For accounting purposes, the lease commencement date was determined to be August 1, 2018, which was the date at which the Company was deemed to have obtained control over the property. The Company has an option to extend the lease term for a period of ten years by giving the landlord written notice of the election to exercise the option at least nine months, but not more than twelve months, prior to the expiration of the Headquarters Lease Amendment lease term. The Company determined that this renewal was not reasonably certain at lease inception.

The Headquarters Lease Amendment provides for monthly base rent amounts escalating over the term of the lease. In addition, the Headquarters Lease Amendment provided a tenant improvement allowance ("TIA") of up to $25.9 million, which was fully utilized, of which $4.4 million will be repaid to the landlord in the form of additional monthly rent. This is recorded as leasehold improvement assets and an offset to the lease ROU asset on the Condensed Consolidated Balance Sheets as of September 30, 2020 and December 31, 2019. The Company is also required to pay the operating expenses for the New Premises, such as taxes and insurance, which are treated as variable lease payments.

Management exercised judgment in applying the requirements of ASC 842, including the determination as to whether certain contracts contain a lease and for the Headquarters Lease Amendment, the discount rate used to determine the measurement of the lease liability. As the implicit rate of the Headquarters Lease Amendment was not known, the Company estimated a 9.0% discount rate, which was management's estimate of the Company's incremental borrowing rate. To estimate the incremental borrowing rate, management considered observable debt yields of comparable market instruments, as well as benchmarks within the Headquarters Lease Amendment that may be indicative of the rate implicit in the lease.

Total operating lease costs, including variable and short-term lease costs, were $2.8 million and $8.3 million for the three and nine months ended September 30, 2020, respectively, and $2.6 million and $7.4 million for the three and nine months ended September 30, 2019, respectively.

Operating lease liabilities are calculated as the net present value of the remaining lease payments over the remaining lease term. In determining the present value of lease payments, the Company uses its incremental borrowing rate based on the information available at the lease commencement date. As of September 30, 2020, the weighted average remaining lease term was 8.6 years and the weighted average discount rate used to determine the operating lease liability was 9.0%. Cash paid for amounts included in the measurement of lease liabilities for the nine months ended September 30, 2020 and September 30, 2019 of $7.2 million and $3.4 million, respectively, was included in net cash used in operating activities in the Company's Condensed Consolidated Statements of Cash Flows.

The following table reconciles the undiscounted cash flows for the next five years and total of the remaining years to the operating lease liabilities recorded in the Condensed Consolidated Balance Sheet as of September 30, 2020 (in thousands):

Year Ended December 31:		
2020 (three months)	$	2,536
2021		10,391
2022		10,731
2023		11,083
2024		11,447
Thereafter		54,074
Total undiscounted lease payments		100,262
Present value adjustment		(30,347)
Net operating lease liabilities	$	69,915

In October 2018, the Company entered into a sublease agreement ("Sublease Agreement") to sublease approximately 36,835 rentable square feet of space in its New Premises. The Sublease Agreement has a term of five years from the commencement date of April 12, 2019 and provides for the Company to receive monthly base rent amounts escalating over the term of the lease. The Company also passes through a portion of the operating expenses, such as taxes and insurance for the New Premises to the sublessee, which are treated as variable sublease income. Total sublease income, including rent and variable sublease cost reimbursements, was $0.9 million and $2.8 million for the three and nine months ended September 30, 2020, respectively, and $0.9 million and $1.7 million for the three and nine months ended September 30, 2019, respectively.

The following table details the future undiscounted cash inflows relating to the Sublease Agreement as of September 30, 2020 (in thousands):

Year Ended December 31:		
2020 (three months)	$	715
2021		2,925
2022		3,009
2023		3,096
2024		876
Thereafter		—
Total undiscounted sublease receipts	$	10,621

Indemnification

In the ordinary course of business, the Company may provide indemnifications of varying scope and terms to vendors, lessors, business partners, board members, officers, and other parties with respect to certain matters, including, but not limited to, losses arising out of breach of such agreements, services to be provided by the Company, negligence or willful misconduct of the Company, violations of law by the Company, or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with directors and certain officers and employees that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors, officers or employees. No demands have been made upon the Company to provide indemnification under such agreements, and thus, there are no claims that the Company is aware of that could have a material effect on the Company's Condensed Consolidated Balance Sheets, Condensed Consolidated Statements of Operations and Comprehensive Loss, or Condensed Consolidated Statements of Cash Flows.

Commitments

Effective September 2017, the Company entered into a Development and Manufacturing Services Agreement as amended ("DMSA") with Lonza Sales AG ("Lonza") for the development and manufacture of biologic products. Under the DMSA, the Company will execute purchase orders based on project plans authorizing Lonza to provide development and manufacturing services with respect to certain of the Company's antibody and enzyme products, and will pay for the services provided and batches delivered in accordance with the DMSA and project plan. Unless earlier terminated, the DMSA will expire on September 6, 2022.

As of September 30, 2020 and December 31, 2019, the Company had open non-cancellable purchase orders for biological product development and manufacturing costs totaling $17.6 million and $21.2 million, respectively. The activities under these purchase orders are expected to be completed by May 2027. As of September 30, 2020 and December 31, 2019, the Company had total non-cancellable purchase commitments under the DMSA of $12.0 million and $11.2 million, respectively.

During the three months ended September 30, 2020 and 2019, the Company incurred costs of $1.4 million and $3.0 million, respectively, and made payments of $0.8 million and $2.5 million, respectively, for the development and manufacturing services rendered under the DMSA. During the nine months ended September 30, 2020 and 2019, the Company incurred costs of $6.2 million and $9.7 million, respectively, and made payments of $6.0 million and $9.0 million, respectively, for the development and manufacturing services rendered under the DMSA.

Contingencies

From time to time, the Company may be involved in lawsuits, arbitration, claims, investigations and proceedings consisting of intellectual property, employment and other matters which arise in the ordinary course of business. The Company records accruals for loss contingencies to the extent that the Company concludes that it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated.

On September 10, 2020, the Company and all Directors were named in a shareholder derivative action filed in the Delaware Court of Chancery challenging the compensation paid to the Company's Directors since the IPO in December 2017.

This derivative complaint is in the early stages and therefore the Company cannot reasonably estimate a potential future loss or a range of potential future losses. However, the Company does not believe that an unfavorable resolution would have a material adverse effect on the Company's business, financial condition, and results of operations or prospects. No liability has been recorded relating to this matter in the Condensed Consolidated Balance Sheet at September 30, 2020.

9. Stock-Based Awards

The Company has issued stock-based awards from various equity incentive and stock purchase plans, as more fully described in Note 11, "Stock-Based Awards" to the consolidated financial statements in the Company's 2019 Annual Report on Form 10-K.

Stock Option Activity

The following table summarizes option award activity under the Company's 2017 Equity Incentive Plan and the 2015 Stock Incentive Plan:

	Number of Options		Weighted-Average Exercise Price
Balance at December 31, 2019	11,640,734	$	12.96
Granted	3,371,048		25.00
Exercised	(874,357)		10.63
Forfeited	(617,360)		20.60
Balance at September 30, 2020	13,520,065	$	15.77
Vested and expected to vest at September 30, 2020	11,775,333	$	18.00
Exercisable at September 30, 2020	5,437,269	$	13.80

The estimated fair value of stock options granted to employees were calculated using the Black-Scholes option-pricing model using the following assumptions:

	Nine Months Ended September 30,	
	2020	2019
Expected term (in years)	5.50 - 6.08	5.50 - 6.08
Volatility	65.2% - 67.1%	65.5% - 77.8%
Risk-free interest rate	0.3% - 1.7%	1.6% - 2.6%
Dividend yield	—	—

Restricted Stock Activity

Aggregated information regarding restricted stock for the nine months ended September 30, 2020 is summarized below:

	Share Awards & Units	Weighted-Average Fair Value at Date of Grant per Share
Unvested at December 31, 2019	882,636	$ 18.67
Granted	1,819,624	27.98
Vested and released	(293,133)	19.45
Forfeited	(139,230)	26.54
Unvested at September 30, 2020	2,269,897	$ 25.82
Expected to vest at September 30, 2020	2,269,897	$ 25.82

Stock-Based Compensation Expense

The Company's results of operations include expenses relating to stock-based compensation as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development	$ 7,781	$ 4,923	$ 20,981	$ 14,200
General and administrative	5,471	3,978	15,540	15,289
Total	$ 13,252	$ 8,901	$ 36,521	$ 29,489

10. Net Loss Per Share

Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share for all periods as the inclusion of all potential shares of common stock outstanding would have been anti-dilutive.

Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	Three and Nine Months Ended September 30,	
	2020	2019
Options issued and outstanding and ESPP shares issuable	13,680,889	11,981,119
Restricted shares subject to future vesting	2,269,897	826,511
Early exercised common stock subject to future vesting	—	10,423
Total	15,950,786	12,818,053

11. Related Party Transactions

On September 22, 2020, upon becoming an owner of record of more than 10% of the voting interest in the Company, Biogen became a related party under ASC 850. Refer to Note 6, "Collaboration Agreements" for further information.

12. Subsequent Events

On October 4, 2020, the Company entered into the LRRK2 Agreement, and on October 6, 2020, the Company entered into the ROFN and Option Agreement, both with Biogen. Refer to Note 6 and Note 7, "Collaboration Agreements" for further information.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with our condensed consolidated financial statements and the related notes to those statements included elsewhere in this Quarterly Report on Form 10-Q. This discussion and analysis and other parts of this report contain forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives, expectations, forecasts and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under the section titled "Risk Factors" included in this Quarterly Report on Form 10-Q.

Forward-looking statements include, but are not limited to, statements about:

- *the success, cost and timing of our development activities, preclinical studies and clinical trials, including the enrollment in such trials, and in particular the development of our blood-brain barrier ("BBB") platform technology, programs and biomarkers;*
- *the extent to which any dosing limitations that we have been subject to, and/or may be subject to in the future, may affect the success of our product candidates;*
- *the impact of preclinical findings on our ability to achieve exposures of our product candidates that allow us to explore a robust pharmacodynamic range of these candidates in humans;*
- *expectations regarding the transaction with Biogen, including all financial aspects of the collaboration and equity investment, the potential benefits and results of the transaction;*
- *the expected potential benefits and potential revenue resulting from strategic collaborations with third parties and our ability to attract collaborators with development, regulatory and commercialization expertise;*
- *the timing or likelihood of regulatory filings and approvals;*
- *our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations and/or warnings in the label of any approved product candidate;*
- *the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;*
- *the terms and conditions of licenses granted to us and our ability to license and/or acquire additional intellectual property relating to our product candidates and BBB platform technology;*
- *our ability to obtain funding for our operations, including funding necessary to develop and commercialize our current and potential future product candidates;*
- *our plans and ability to establish sales, marketing and distribution infrastructure to commercialize any product candidates for which we obtain approval;*
- *future agreements with third parties in connection with the commercialization of our product candidates;*
- *the size and growth potential of the markets for our product candidates, if approved for commercial use, and our ability to serve those markets;*
- *the rate and degree of market acceptance of our product candidates;*

- *existing regulations and regulatory developments in the United States and foreign countries;*
- *potential claims relating to our intellectual property and third-party intellectual property;*
- *our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;*
- *our potential plans and ability to develop our own manufacturing facilities;*
- *the pricing and reimbursement of our product candidates, if approved and commercialized;*
- *the success of competing products or platform technologies that are or may become available;*
- *our ability to attract and retain key managerial, scientific and medical personnel;*
- *the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;*
- *our ability to enhance operational, financial and information management systems;*
- *our financial performance; and*
- *our expectations regarding the impact of the COVID -19 pandemic on our business.*

These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described in "Risk Factors". In some cases, you can identify these statements by terms such as "anticipate," "believe," "could," "estimate," "expects," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes. These forward-looking statements reflect our beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this Quarterly Report on Form 10-Q and are subject to risks and uncertainties. We discuss many of these risks in greater detail in the section entitled "Risk Factors" included in Part II, Item 1A and elsewhere in this report. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We qualify all of the forward-looking statements in this Quarterly Report on Form 10-Q by these cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.

Overview

Our goal is to discover and develop therapeutics to defeat degeneration.

Our strategy is guided by three overarching principles that we believe will significantly increase the probability of success and will accelerate the timing to bring effective therapeutics to patients with neurodegenerative diseases:

- **Genetic Pathway Potential**: We select our therapeutic targets and disease pathways based on genes that, when mutated, cause, or are major risk factors for, neurodegenerative diseases. We refer to these genes as degenogenes;
- **Engineering Brain Delivery**: We engineer our product candidates to cross the BBB and act directly in the brain; and
- **Biomarker-Driven Development**: We discover, develop and utilize biomarkers to select the right patient population and demonstrate target engagement, pathway engagement and impact on disease progression of our product candidates.

We are developing a broad portfolio of targeted therapeutic candidates for neurodegenerative diseases. Our programs are at different stages of clinical and preclinical development, including four programs in clinical studies.

We have also developed a proprietary BBB platform technology, our transport vehicle ("TV"), which enables multiple modality-based platforms to deliver a wide range of large-molecule therapeutics across the BBB, including enzymes, antibodies, proteins and oligonucleotides. This technology is designed to engage specific BBB transport receptors, which are ubiquitously expressed in brain capillaries and facilitate transport of proteins into the brain. We are currently optimizing and broadening this platform technology.

Our four clinical-stage programs are:

- our leucine-rich repeat kinase 2 ("LRRK2") inhibitor program, partnered with Biogen, to address Parkinson’s disease;
- our eukaryotic translation initiation factor 2B ("EIF2B") activator program to address diseases such as ALS and frontotemporal dementia ("FTD");
- our ETV:IDS program, our most advanced program enabled by our enzyme transport vehicle ("ETV") technology, which is designed to restore iduronate 2-sulfatase ("IDS"), and reduce glycosaminoglycans, both peripherally and in the brain, in patients with mucopolysaccharidosis II ("MPS II", or "Hunter syndrome"); and
- our receptor interacting serine/threonine protein kinase 1 ("RIPK1") inhibitor program, partnered with Sanofi, to address peripheral inflammatory diseases such as cutaneous lupus and COVID-19.

Program	Product Candidate(s)	Clinical Phase	Indication(s)	Operational Control
LRRK2	DNL151	Ph 1 and Ph 1b	Parkinson's disease	Joint with Biogen
EIF2B	DNL343	Ph 1	ALS and FTD	Denali
ETV:IDS	DNL310	Ph 1/2	Hunter syndrome (MPS II)	Denali
RIPK1 (Peripheral)	DNL758	Ph 1b	Systemic inflammatory diseases	Sanofi

To complement our internal capabilities, we have entered into arrangements with biopharmaceutical companies, patient-focused data companies, numerous leading academic institutions and foundations to gain access to new product candidates, enable and accelerate the development of our existing programs and deepen our scientific understanding of certain areas of biology. We rely on third-party contract manufacturers to manufacture and supply our preclinical and clinical materials to be used during the development of our product candidates. We currently do not need commercial manufacturing capacity.

Since we commenced operations, we have devoted substantially all of our resources to discovering, acquiring and developing product candidates, building our BBB platform technology and assembling our core capabilities in understanding key neurodegenerative disease pathways.

Key operational and financing milestones in 2020 to date include:

- In January 2020, we announced positive results from our LRRK2 program. Phase 1b results with DNL201 in patients with Parkinson’s disease demonstrated high levels of target and pathway engagement and improvement of lysosomal biomarkers. Interim Phase 1 results with DNL151 in more than 150 healthy volunteers also met all safety and biomarker goals. Both clinical trials showed dose-dependent target engagement, improvement in biomarkers of lysosomal function and demonstrated safety profiles supporting progression to further development;
- In January 2020, we sold 9.0 million shares of common stock (inclusive of shares sold pursuant to an overallotment option granted to the underwriters in connection with the offering) through an underwritten public offering at a price of $23.00 per share for aggregate net proceeds of $193.9 million;
- In February 2020, we initiated a Phase 1 clinical trial for DNL343 (EIF2B) in healthy volunteers;
- In June 2020, we announced the results from Phase 1b clinical studies with small molecule RIPK1 inhibitor DNL747 in Alzheimer’s disease and ALS, and provided a broad RIPK1 program update including CNS compound DNL788 and peripherally-restricted compound DNL758. Safety endpoints were met in the Phase 1b patient studies with DNL747 in ALS and Alzheimer’s disease, however further dose escalation to achieve higher levels of target inhibition may be limited by preclinical chronic safety data. As such, we announced, together with our collaboration partner Sanofi, that we have decided to pause clinical studies with DNL747 and focus our efforts on accelerating development of DNL788, which we believe has superior drug properties and a more rapid path toward proof-of-concept clinical studies in patients in multiple neurological indications;

- In July 2020, we announced that our collaboration partner Sanofi has commenced dosing of DNL758, a peripherally-restricted small molecule inhibitor of RIPK1, in a Phase 1b clinical study in hospitalized adult patients with severe COVID-19 lung disease. In October, we provided an update that enrollment in the Phase 1b COVID-19 study is complete. Separately, Sanofi plans to initiate a Phase 2 clinical study of DNL758 in cutaneous lupus first half of 2021;

- In August 2020, we commenced dosing in a Phase 1/2 clinical study of DNL310 in Hunter syndrome patients. We plan to announce early biomarker data from the study by year end 2020;

- In August 2020, we entered into a binding Provisional Collaboration and License Agreement with Biogen to co-develop and co-commercialize our small molecule inhibitors of LRRK2 for Parkinson's disease. Under the Provisional Collaboration and License Agreement, Biogen also received rights to opt into two programs and a right of first negotiation for two additional programs, in each case for neurodegenerative diseases leveraging our TV technology platform to cross the BBB. In October 2020, the Provisional Collaboration and License Agreement expired upon the execution of the Definitive LRRK2 Collaboration and License Agreement and Right of First Negotiation, Option and License Agreement with Biogen (collectively the "The Biogen Collaboration Agreement"). In connection with the Biogen Collaboration Agreement, we received an equity investment of $465.0 million in September 2020 and an aggregate of $560.0 million in upfront payments in October 2020. We may be eligible to receive up to $1.1 billion in potential milestone payments plus profit sharing and royalties for the LRRK2 program;

- In August 2020, we announced the selection of DNL151 to progress into late stage clinical studies in Parkinson's disease patients with a kinase-activating mutation in LRRK2 and in sporadic Parkinson's disease patients. Patient enrollment is planned to commence in 2021 in collaboration with Biogen;

- In October 2020, our collaboration partner Sanofi submitted an IND application for DNL788 (SAR443820), a potent, selective brain-penetrant small molecule inhibitor of RIPK1. First-in-human dosing is planned to begin in late 2020 or early 2021; and

- To address risks posed by the COVID-19 pandemic, we have implemented policies that enable some of our employees to work remotely. For all on-site personnel, we have implemented several safety protocols, including regular, mandatory COVID-19 testing procedures and compliance measures for social distancing and use of personal protective equipment. After initial COVID-19 pandemic shutdown restrictions were put into place in March 2020, we experienced a pause in patient recruitment in several clinical trials. Recruitment has since resumed for all affected clinical trials.

We do not have any products approved for sale and have not generated any product revenue since our inception. We have funded our operations primarily from the issuance and sale of convertible preferred stock, and the proceeds from our initial public offering ("IPO"), follow-on offering, and payments received from our collaboration agreements with Takeda, Sanofi and Biogen.

We have incurred significant operating losses to date and expect to continue to incur operating losses for the foreseeable future. Our ability to generate product revenue will depend on the successful development and eventual commercialization of one or more of our product candidates. Our net losses were $58.2 million and $173.7 million for the three and nine months ended September 30, 2020, respectively, and $46.3 million and $143.6 million for the three and nine months ended September 30, 2019, respectively. As of September 30, 2020, we had an accumulated deficit of $599.3 million. We expect to continue to incur significant expenses and operating losses as we advance our current clinical stage programs through healthy volunteer and patient trials; broaden and improve our BBB platform technology; acquire, discover, validate and develop additional product candidates; obtain, maintain, protect and enforce our intellectual property portfolio; and hire additional personnel.

Components of Operating Results

Collaboration Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from product sales for the foreseeable future. All revenue recognized to date has been collaboration revenue from our collaboration agreements with Takeda and Sanofi.

In the future, we will continue to recognize revenue from the Takeda Collaboration Agreement and Sanofi Collaboration Agreement, and commence revenue recognition from the Biogen Collaboration Agreement, and may generate revenue from product sales or milestones, royalties and cost reimbursement from other collaboration agreements, strategic alliances and licensing arrangements. We expect that our revenue will fluctuate from quarter-to-quarter and year-to-year as a result of the timing and amount of license fees, milestones, reimbursement of costs incurred and other payments and product sales, to the extent any are successfully commercialized. If we fail to complete the development of our product candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

Operating Expenses

Research and Development

Research and development activities account for a significant portion of our operating expenses. We record research and development expenses as incurred. Research and development expenses incurred by us for the discovery and development of our product candidates and BBB platform technology include:

- external research and development expenses, including:
  - expenses incurred under arrangements with third parties, such as contract research organizations ("CROs"), preclinical testing organizations, contract development and manufacturing organizations ("CDMOs"), academic and non-profit institutions and consultants;
  - expenses to acquire technologies to be used in research and development that have not reached technological feasibility and have no alternative future use;
  - fees related to our license and collaboration agreements;
- personnel related expenses, including salaries, benefits and stock-based compensation expense; and
- other expenses, which include direct and allocated expenses for laboratory, facilities and other costs.

A portion of our research and development expenses are direct external expenses, which we track on a program-specific basis once a program has commenced late-stage IND-enabling studies.

Program expenses include expenses associated with our most advanced product candidates and the discovery and development of backup or next-generation molecules. We also track external expenses associated with our TV platform. These expenses include those incurred by us relating to our Takeda Collaboration Agreement, Sanofi Collaboration Agreement and Biogen Collaboration Agreement. All external costs associated with earlier stage programs, or that benefit the entire portfolio, are tracked as a group. We do not track personnel or other operating expenses incurred for our research and development programs on a program-specific basis. These expenses primarily relate to salaries and benefits, stock-based compensation, facility expenses including rent and depreciation, and lab consumables.

It is challenging to predict the nature, timing and estimated long-range costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, any of our product candidates. This is made more challenging by events outside of our control, such as the recent COVID-19 pandemic. We are also unable to predict when, if ever, material net cash inflows will commence from sales or licensing of our product candidates. This is due to the numerous risks and uncertainties associated with drug development, including the uncertainty of:

- our ability to add and retain key research and development personnel;
- our ability to establish an appropriate safety profile with IND-enabling toxicology studies;
- our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize, our product candidates;
- our successful enrollment in and completion of clinical trials;
- the costs associated with the development of any additional product candidates we identify in-house or acquire through collaborations;
- our ability to discover, develop and utilize biomarkers to demonstrate target engagement, pathway engagement and the impact on disease progression of our molecules;
- our ability to establish agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our product candidates are approved;
- the terms and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder;
- our ability to obtain and maintain patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates if and when approved;
- our receipt of marketing approvals from applicable regulatory authorities;
- our ability to commercialize products, if and when approved, whether alone or in collaboration with others; and
- the continued acceptable safety profiles of the product candidates following approval.

A change in any of these variables with respect to the development of any of our product candidates would significantly change the costs, timing and viability associated with the development of that product candidate. We expect our research and development expenses to increase at least over the next several years as we continue to implement our business strategy, advance our current programs, expand our research and development efforts, seek regulatory approvals for any product candidates that successfully complete clinical trials, access and develop additional product candidates and incur expenses associated with hiring additional personnel to support our research and development efforts. In addition, product candidates in later stages of clinical development generally incur higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials.

General and Administrative

General and administrative expenses include personnel-related expenses, such as salaries, benefits, travel and stock-based compensation expense, expenses for outside professional services and allocated expenses. Outside professional services consist of legal, accounting and audit services and other consulting fees. Allocated expenses consist of rent, depreciation and other expenses related to our office and research and development facility not otherwise included in research and development expenses.

We expect to continue to incur certain expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC and those of any national securities exchange on which our securities are traded, insurance expenses, investor relations activities and other administrative and professional services. We also expect to increase our administrative headcount as we advance our product candidates through clinical development, which will also increase our general and administrative expenses.

Interest and Other Income, Net

Interest and other income, net, consists primarily of interest income and investment income earned on our cash, cash equivalents, and marketable securities, gains and losses on foreign currency hedges, and sublease income.

Results of Operations

Comparison of the three and nine months ended September 30, 2020 and 2019

The following table sets forth the significant components of our results of operations (in thousands):

	Three Months Ended September 30,		Change	
	2020	2019	$	%
Collaboration revenue:				
Collaboration revenue from customers	$ 9,388	$ 13,508	$ (4,120)	(31) %
Other collaboration revenue	5	96	(91)	(95)
Total collaboration revenue	9,393	13,604	(4,211)	(31)
Operating expenses:				
Research and development	53,704	52,544	1,160	2
General and administrative	15,805	11,215	4,590	41
Total operating expenses	69,509	63,759	5,750	9
Loss from operations	(60,116)	(50,155)	(9,961)	20
Interest and other income, net	1,944	3,782	(1,838)	(49)
Loss before income taxes	(58,172)	(46,373)	(11,799)	25
Income tax benefit (provision)	(56)	113	(169)	(150)
Net loss	$ (58,228)	$ (46,260)	$ (11,968)	26 %

	Nine Months Ended September 30,		Change	
	2020	2019	$	%
Collaboration revenue:				
Collaboration revenue from customers	$ 18,751	$ 21,717	$ (2,966)	(14) %
Other collaboration revenue	93	289	(196)	(68)
Total collaboration revenue	18,844	22,006	(3,162)	(14)
Operating expenses:				
Research and development	157,872	141,831	16,041	11
General and administrative	42,332	35,601	6,731	19
Total operating expenses	200,204	177,432	22,772	13
Loss from operations	(181,360)	(155,426)	(25,934)	17
Interest and other income, net	7,611	11,411	(3,800)	(33)
Loss before income taxes	(173,749)	(144,015)	(29,734)	21
Income tax benefit	—	426	(426)	(100)
Net loss	$ (173,749)	$ (143,589)	$ (30,160)	21 %

Collaboration revenue

Collaboration revenue was $9.4 million and $18.8 million for the three and nine months ended September 30, 2020, respectively, and $13.6 million and $22.0 million for the three and nine months ended September 30, 2019, respectively. The decreases in collaboration revenue of $4.2 million and $3.2 million for the three and nine months ended September 30, 2020, respectively, compared to the comparative period in the prior year were due to a decrease in revenue from our collaboration with Sanofi driven by a $10.0 million milestone recognized in the three and nine months ended September 30, 2019 related to the Peripheral program, and the winding down of revenue for retained activities as activities are transferred to Sanofi. These decreases are partially offset by an increase in revenue from our collaboration with Takeda, driven by increased costs incurred in the programs partnered with Takeda.

Research and development expenses

Research and development expenses were $53.7 million and $157.9 million for the three and nine months ended September 30, 2020, compared to $52.5 million and $141.8 million for the three and nine months ended September 30, 2019.

The following table summarizes our research and development expenses by program and category (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
LRRK2 program external expenses	$ 6,497	$ 8,920	$ 22,263	$ 21,536
EIF2B program external expenses	3,433	1,538	6,739	3,739
ETV:IDS program external expenses	2,786	4,045	11,136	12,058
TV platform and other program external expenses	5,902	3,911	12,088	11,180
Other external research and development expenses	5,638	8,868	20,812	23,476
Personnel-related expenses [1]	21,176	16,423	60,298	45,413
Other unallocated research and development expenses	8,272	8,839	24,536	24,429
Total research and development expenses	$ 53,704	$ 52,544	$ 157,872	$ 141,831

[1] Personnel-related expenses include stock-based compensation expense of $7.8 million and $21.0 million for the three and nine months ended September 30, 2020, respectively, and $4.9 million and $14.2 million for the three and nine months ended September 30, 2019, respectively, reflecting an increase of $2.9 million and $6.8 million, respectively.

There was an increase in total research and development expenses of $1.2 million for the three months ended September 30, 2020 compared to the three months ended September 30, 2019. This increase was a result of a $4.8 million increase in personnel-related expenses, consisting of a $1.9 million increase in salaries and related expenses attributable to an increase in our research and development headcount, and a $2.9 million increase in stock-based compensation expense primarily attributable to new equity award grants. Additionally, there were increases in external expenses related to progression of our portfolio, including an increase of $1.9 million in EIF2B program external expenses reflecting the cost of the Phase 1 clinical trial, and an increase of $2.0 million in TV platform and other program external expenses. These increases were partially offset by a $3.2 million decrease in other external research and development expenses, primarily attributable to a decrease in DNL747 costs after completion of the Phase 1b trials, a $2.4 million decrease in LRRK2 program expenses, reflecting completion of DNL201 clinical activities, a $1.3 million decrease in ETV:IDS program external expenses primarily due to significant CMC activity in 2019, and a decrease in other unallocated research and development expenses of $0.6 million primarily attributable to decreased lab consumables costs and reductions in associated expenses related to COVID-19.

There was an increase in total research and development expenses of $16.0 million for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019. This increase was a result of a $14.9 million increase in personnel-related expenses, consisting of a $8.1 million increase in salaries and related expenses attributable to an increase in our research and development headcount, and a $6.8 million increase in stock-based compensation expense primarily attributable to new equity award grants. Additionally, there were increases in external expenses related to progression of our portfolio, including an increase of $3.0 million in EIF2B program external expenses reflecting the cost of the Phase 1 clinical trial, an increase of $0.9 million in TV platform and other program external expenses, an increase of $0.7 million in LRRK2 program external expenses driven by DNL151 progress in the clinic, and an increase in other unallocated research and development expenses of $0.1 million. These increases were partially offset by a decrease of $0.9 million in ETV:IDS program external expenses due to the $1.5 million contingent consideration payment to F-star and significant CMC activity, both in 2019, and a $2.7 million decrease in other external research and development expenses, primarily attributable to a decrease in DNL747 costs after completion of the Phase 1b trials.

General and administrative expenses

General and administrative expenses were $15.8 million for the three months ended September 30, 2020 compared to $11.2 million for the three months ended September 30, 2019. The increase of approximately $4.6 million was primarily attributable to a $2.0 million increase in personnel-related expenses, primarily driven by higher stock-based compensation expense in the three months ended September 30, 2019 primarily attributable to new equity award grants. Additionally, there was an increase of $2.0 million in professional services costs, primarily due to costs associated with the execution of the Biogen Collaboration Agreement, an increase of $0.5 million in other general and administrative costs related to other miscellaneous costs such as insurance and taxes, and a $0.1 million increase in facilities-related expenses.

General and administrative expenses were $42.3 million for the nine months ended September 30, 2020 compared to $35.6 million for the nine months ended September 30, 2019. The increase of approximately $6.7 million was primarily attributable to increases of $3.0 million in personnel-related expenses primarily driven by higher headcount, $2.8 million in professional services costs, primarily due to costs associated with the execution of the Biogen Collaboration Agreement, $0.6 million in other general and administrative costs related to other miscellaneous costs such as insurance and taxes, and $0.3 million in facilities-related expenses.

Interest and other income, net

Interest and other income, net was $1.9 million for the three months ended September 30, 2020 compared to $3.8 million for the three months ended September 30, 2019. The decrease of $1.9 million was primarily due to decreased interest income earned on our investments due to declining interest rates.

Interest and other income, net was $7.6 million for the nine months ended September 30, 2020 compared to $11.4 million for the nine months ended September 30, 2019. The decrease of $3.8 million was primarily due to a $5.0 million decrease in interest income earned on our investments due to declining interest rates, partially offset by an increase of $1.2 million in sublease income and reimbursements received in the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019.

Income tax benefit (provision)

Income tax provision associated with a decrease in unrealized gains on marketable securities in other comprehensive income was $0.1 million for the three months ended September 30, 2020 compared to an income tax benefit of $0.1 million for the three months ended September 30, 2019 associated with unrealized gains on marketable securities in other comprehensive income.

There was no income tax benefit associated with an unrealized gain on marketable securities in other comprehensive income for the nine months ended September 30, 2020 compared to $0.4 million for the nine months ended September 30, 2019.

Comparison of the three and nine months ended September 30, 2019 and 2018

Refer to “Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations” in our Form 10-Q for the three and nine months ended September 30, 2019 for a discussion of the results of operations for the three and nine months ended September 30, 2019 compared to the three and nine months ended September 30, 2018.

Liquidity and Capital Resources

Sources of Liquidity

We fund our operations primarily with the proceeds from our IPO, our follow-on offering, and payments received from our collaboration agreements with Takeda, Sanofi, and Biogen. We received net proceeds of $264.3 million from our IPO in December 2017. In January 2020, we sold 9.0 million shares of common stock (inclusive of shares sold pursuant to an overallotment option granted to the underwriters in connection with the offering) through an underwritten public offering at a price of $23.00 per share for aggregate net proceeds of $193.9 million.

Pursuant to the Takeda Collaboration Agreement, we have received $55.0 million related to upfront and milestone payments through September 30, 2020. Further, under the associated Stock Purchase Agreement we received $110.0 million in February 2018 for the sale and issuance of 4,214,559 shares of our common stock.

Pursuant to the Sanofi Collaboration Agreement, we have received $135.0 million related to upfront and milestone payments, and further payments of $11.2 million for performance of Retained Activities through September 30, 2020.

Pursuant to the common stock purchase agreement between Denali and Biogen (the "Biogen Stock Purchase Agreement"), we received $465.0 million in September 2020 for the sale and issuance of 13,310,243 shares of our common stock. In October 2020, we received $560.0 million from Biogen in upfront payments associated with the Biogen Collaboration Agreement.

As of September 30, 2020, we had cash, cash equivalents and marketable securities in the amount of $981.5 million.

Future Funding Requirements

To date, we have not generated any product revenue. We do not expect to generate any product revenue unless and until we obtain regulatory approval of and commercialize any of our product candidates, and we do not know when, or if, either will occur.

We expect to continue to incur significant losses for the foreseeable future, and we expect the losses to increase as we expand our research and development activities and continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. Further, we expect general and administrative expenses to increase as we continue to incur additional costs associated with supporting our growing operations. We are subject to all of the risks typically related to the development of new product candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Until we can generate a sufficient amount of revenue from the commercialization of our product candidates or from our existing collaboration agreements, or future agreements with other third parties, if ever, we expect to finance our future cash needs through public or private equity or debt financings. Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders, increased fixed payment obligations and the existence of securities with rights that may be senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Additionally, any future collaborations we enter into with third parties may provide capital in the near term but limit our potential cash flow and revenue in the future. Any of the foregoing could significantly harm our business, financial condition and prospects.

Since our inception, we have incurred significant losses and negative cash flows from operations. We have an accumulated deficit of $599.3 million through September 30, 2020. We expect to incur substantial additional losses in the future as we conduct and expand our research and development activities. We believe that our existing cash, cash equivalents and marketable securities will be sufficient to enable us to fund our projected operations through at least 12 months from the filling date of this Form 10-Q. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the progress of the development efforts of third parties with whom we have entered into license and collaboration agreements;
- our ability to maintain our current research and development programs and to establish new research and development, license or collaboration arrangements;
- our ability and success in securing manufacturing relationships with third parties or, in the future, in establishing and operating a manufacturing facility;
- the costs involved in prosecuting, defending and enforcing patent claims and other intellectual property claims;
- the cost and timing of regulatory approvals;
- our efforts to enhance operational, financial and information management systems and hire additional personnel, including personnel to support development of our product candidates; and
- the costs and ongoing investments to in-license and/or acquire additional technologies.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

Cash Flows

The following table sets forth a summary of the primary sources and uses of cash for each of the periods presented below (in thousands):

	Nine Months Ended September 30,	
	2020	**2019**
Net cash used in operating activities	$ (97,763)	$ (103,933)
Net cash provided by (used in) investing activities	(255,866)	105,327
Net cash provided by financing activities	625,227	4,156
Net increase in cash, cash equivalents and restricted cash	$ 271,598	$ 5,550

Net Cash Used In Operating Activities

During the nine months ended September 30, 2020, cash used in operating activities was $97.8 million, which consisted of a net loss of $173.7 million, adjusted by non-cash items primarily related to stock-based compensation and depreciation, partially offset by net amortization of discounts on marketable securities and non-cash rent expenses. Cash used in operating activities was also driven by changes in our operating assets and liabilities, including an increase in related party contract liability associated with the Biogen Collaboration Agreement.

Net Cash Provided By (Used In) Investing Activities

During the nine months ended September 30, 2020, cash used in investing activities was $255.9 million, which consisted of $687.5 million of purchases of marketable securities and $1.9 million of capital expenditures to purchase property and equipment, partially offset by $433.6 million in proceeds from the maturity of marketable securities.

Net Cash Provided By Financing Activities

During the nine months ended September 30, 2020, cash provided by financing activities was $625.2 million, which consisted of $420.1 million associated with the issuance of 13,310,243 shares of our common stock to Biogen in September 2020 under the Biogen Stock Purchase Agreement, $193.9 million in net cash proceeds from our follow-on offering completed in January 2020, and $11.1 million in proceeds from the exercise of options to purchase common stock and issuance of ESPP shares.

Discussion of the nine months ended September 30, 2019

Refer to “Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources” in our Form 10-Q for the nine months ended September 30, 2019 for a discussion of the cash flows for that period.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements.

Contractual Obligations and Commitments

In May 2018, we entered into an amendment to our operating lease for our former corporate headquarters in South San Francisco (the "Headquarters Lease Amendment") to relocate and expand our headquarters to 148,020 rentable square feet in a building in South San Francisco, California (the "New Premises"). The Headquarters Lease Amendment has a contractual term of ten years from the legal commencement date, which was April 1, 2019 when the building was ready for occupancy. For accounting purposes, the lease commencement date was determined to be August 1, 2018, which was the date at which we were deemed to have obtained control over the property. We have an option to extend the lease term for a period of ten years by giving the landlord written notice of the election to exercise the option at least nine months, but not more than twelve months, prior to the expiration of the Headquarters Lease Amendment lease term. We determined that this renewal was not reasonably certain at lease inception.

The Headquarters Lease Amendment provides for monthly base rent amounts escalating over the term of the lease. In addition, the Headquarters Lease Amendment provided a tenant improvement allowance ("TIA") of up to $25.9 million, which was fully utilized, of which $4.4 million will be repaid to the landlord in the form of additional monthly rent. This is recorded as leasehold improvement assets and an offset to the lease ROU asset on the Consolidated Balance Sheets as of September 30, 2020 and December 31, 2019. We are also required to pay the operating expenses for the New Premises, such as taxes and insurance, which are treated as variable lease payments.

Effective September 2017, we entered into a Development and Manufacturing Services Agreement, as amended ("DMSA") with Lonza Sales AG ("Lonza") for the development and manufacture of biologic products. Under the DMSA, we will execute purchase orders based on project plans authorizing Lonza to provide development and manufacturing services with respect to certain of our antibody and enzyme products, and will pay for the services provided and batches delivered in accordance with the DMSA and project plan. Unless earlier terminated, the DMSA will expire on September 6, 2022.

As of September 30, 2020 and December 31, 2019, we had open non-cancellable purchase orders for biological product development and manufacturing costs totaling $17.6 million and $21.2 million, respectively. The activities under these purchase orders are expected to be completed by May 2027. As of September 30, 2020 and December 31, 2019, we had total non-cancellable purchase commitments, under the DMSA of $12.0 million and $11.2 million, respectively.

During the three months ended September 30, 2020 and 2019, we incurred costs of $1.4 million and $3.0 million, respectively, and made payments of $0.8 million and $2.5 million, respectively, for the development and manufacturing services rendered under the DMSA. During the nine months ended September 30, 2020 and 2019, we incurred costs of $6.2 million and $9.7 million, respectively, and made payments of $6.0 million and $9.0 million, respectively, for the development and manufacturing services rendered under the DMSA.

Other than those detailed above, there have been no other material changes from the contractual obligations and commitments previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the SEC on February 27, 2020.

Critical Accounting Policies and Significant Judgments and Estimates

This discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, as well as the reported revenues recognized and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to our critical accounting policies and estimates during the nine months ended September 30, 2020 from those described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the SEC on February 27, 2020.

Recent Accounting Pronouncements

Except as described in Note 1 to the condensed consolidated financial statements under the headings "Recently Issued Accounting Pronouncement" and "Recently Adopted Accounting Pronouncement," there have been no new accounting pronouncements or changes to accounting pronouncements during the nine months ended September 30, 2020, as compared to the recent accounting pronouncements described in our Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the SEC on February 27, 2020, that are of significance or potential significance to us.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks in the ordinary course of our business, primarily related to interest rate and foreign currency sensitivities.

Interest Rate Sensitivity

We are exposed to market risk related to changes in interest rates. We had cash, cash equivalents and marketable securities of $981.5 million as of September 30, 2020, which consisted primarily of money market funds and marketable securities, largely composed of investment grade, short to intermediate term fixed income securities.

The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of investments in a variety of securities of high credit quality and short-term duration, according to our board-approved investment policy. Our investments are subject to interest rate risk and could fall in value if market interest rates increase. A hypothetical 10% relative change in interest rates during any of the periods presented would not have had a material impact on our condensed consolidated financial statements.

Foreign Currency Sensitivity

The majority of our transactions occur in U.S. dollars. However, we do have certain transactions that are denominated in currencies other than the U.S. dollar, primarily the Euro and British Pound, and we therefore are subject to foreign exchange risk. The fluctuation in the value of the U.S. dollar against other currencies affects the reported amounts of expenses, assets and liabilities primarily associated with a limited number of preclinical, clinical and manufacturing activities.

We seek to mitigate the impact of changes in currency exchange rates on cash flows from certain foreign currency denominated operating expenses by entering into forward foreign currency exchange contracts. Generally, the market risks of these contracts are offset by the corresponding gains and losses on the transactions being hedged.

We do not use derivative financial instruments for speculative trading purposes, nor do we hedge foreign currency exchange rate exposure in a manner that entirely offsets the effects of changes in foreign currency exchange rates. The counterparties to these forward foreign currency exchange contracts are creditworthy multinational commercial banks, which minimizes the risk of counterparty nonperformance. We regularly review our hedging program and may, as part of this review, make changes to the program.

As of September 30, 2020, we had open forward foreign currency exchange contracts with notional amounts of $9.1 million. A hypothetical 10% strengthening in foreign currency compared with the U.S. dollar at September 30, 2020 would have resulted in an increase in the value received over the remaining life of these contracts of approximately $0.9 million and, if realized, would positively affect earnings during the remaining life of the contracts. This analysis does not consider the impact of the hypothetical changes in foreign currency rates would have on the forecasted transactions that these foreign currency sensitive instruments were designated to offset.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of September 30, 2020, management, with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2020, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended September 30, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Reference is hereby made to our disclosures in “Legal Matters” under Note 8 to our Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q and the information under the heading “Contingencies” is incorporated by reference herein.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, including our financial statements and the related notes and the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations and the market price of our common stock. The risk factors set forth below are substantially the same as the risk factors included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 27, 2020.

Risks Related to Our Business, Financial Condition and Capital Requirements

We are in the early stages of clinical drug development and have a very limited operating history and no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability.

We are an early clinical-stage biopharmaceutical company with a very limited operating history, focused on developing therapeutics for neurodegenerative diseases, including Alzheimer’s disease, Parkinson’s disease and ALS. We commenced operations in May 2015, have no products approved for commercial sale and have not generated any revenue from product sales. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We are in Phase 1 or 1b clinical trials for our LRRK2, EIF2B, ETV:IDS and RIPK1 programs and have not initiated clinical trials for any of our other current product candidates. To date, we have not initiated or completed a pivotal clinical trial, obtained marketing approval for any product candidates, manufactured a commercial scale product, or arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Our short operating history as a company makes any assessment of our future success and viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to successfully overcome such risks and difficulties. If we do not address these risks and difficulties successfully, our business will suffer.

We have incurred significant net losses since our inception and anticipate that we will continue to incur net losses for the foreseeable future.

We have incurred significant net losses since our inception, including net losses of $58.2 million and $173.7 million for the three and nine months ended September 30, 2020, respectively, and $46.3 million and $143.6 million for the three and nine months ended September 30, 2019, respectively. As of September 30, 2020, we had an accumulated deficit of $599.3 million.

We have invested significant financial resources in research and development activities, including for our preclinical and clinical product candidates and our TV platform. We do not expect to generate revenue from product sales for several years, if at all. The amount of our future net losses will depend, in part, on the level of our future expenditures and revenue. Moreover, our net losses may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

We expect to continue to incur significant expenses and increasingly higher operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- continue our research and discovery activities;
- progress our current and any future product candidates through preclinical and clinical development;
- initiate and conduct additional preclinical, clinical or other studies for our product candidates;
- work with our contract manufacturers to scale up the manufacturing processes for our product candidates or, in the future, establish and operate a manufacturing facility;
- change or add additional contract manufacturers or suppliers;
- seek regulatory approvals and marketing authorizations for our product candidates;
- establish sales, marketing and distribution infrastructure to commercialize any products for which we obtain approval;
- acquire or in-license product candidates, intellectual property and technologies;
- make milestone, royalty or other payments due under any license or collaboration agreements;
- obtain, maintain, protect and enforce our intellectual property portfolio, including intellectual property obtained through license agreements;
- attract, hire and retain qualified personnel;
- provide additional internal infrastructure to support our continued research and development operations and any planned commercialization efforts in the future;
- experience any delays or encounter other issues related to our operations;
- meet the requirements and demands of being a public company; and
- defend against any product liability claims or other lawsuits related to our products.

Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

A pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, or the perception of its effects, may materially and adversely affect our business, operations and financial condition.

Public health outbreaks, such as epidemics or pandemics involving infectious or contagious diseases, such as COVID-19, may significantly disrupt our business. Such outbreaks pose the risk that we or our employees, contractors, suppliers, and other partners may be prevented from conducting business activities for an indefinite period of time due to the spread of the disease, due to shutdowns that may be requested or mandated by federal, state and local governmental authorities or certain employers, or due to the economic consequences associated with the pandemic. Business disruptions could include disruptions or restrictions on our ability to travel, as well as temporary closures of our facilities and the facilities of our partners, clinical trial sites, service providers, suppliers or contract manufacturers. While it is not possible at this time to estimate the overall impact that the COVID-19 pandemic could have on our business, the continued rapid spread of COVID-19, both across the United States and throughout much of the world, and the measures taken by the governments of countries and local authorities affected has disrupted and could delay the initiation of new clinical trials, the progress of our ongoing clinical trials, and could disrupt and delay our preclinical activities, and potentially the manufacture or shipment of both drug substance and finished drug product of our product candidates for preclinical testing and clinical trials and adversely impact our business, financial condition or operating results.

For example, as a result of the COVID-19 pandemic the state of California, where our corporate offices are located, has issued orders limiting activities to varying levels, including at the most restrictive level, an order for all residents to remain at home, except for the performance of essential activities, which include biomedical research. We have implemented policies that enable some of our employees to work remotely, and such policies may continue for an indefinite period. We have also implemented various safety protocols for all on-site personnel, including regular, mandatory COVID-19 testing procedures and compliance measures for social distancing and use of personal protective equipment. Our priority is to protect the health and safety of our employees, community, partners and clinical trial participants, while working to ensure the sustainability of our business operations as this unprecedented situation continues to evolve. We continue to evaluate the impact COVID-19 may have on our ability to effectively conduct our business operations as planned, and work with healthcare providers supporting our clinical studies to mitigate risk to patients while taking into account regulatory, institutional, and government guidance and policies, but there can be no assurance that we will be able to avoid part or all of any impact from the spread of COVID-19 or its consequences.

As the COVID-19 pandemic continues to spread around the globe, we have experienced and may continue to experience disruptions that could severely impact our business, preclinical programs and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials, particularly elderly subjects, who are at a higher risk of severe illness or death from COVID-19, which can be further complicated by the presence of comorbidities that are often present in subjects with neurodegenerative diseases;

- difficulties interpreting data from our clinical trials due to the possible effects of COVID-19 on subjects enrolled in our clinical trials that contract COVID-19;

- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;

- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of clinical trials;

- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others; limitations in resources that would otherwise be focused on the conduct of our business or our clinical trials, including because of sickness or the desire to avoid contact with large groups of people or as a result of government-imposed “shelter in place” or similar working restrictions;

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;

- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems, as well as delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;

- delays or difficulties in furthering our preclinical and clinical programs, due to interruptions or limitations in our third party service providers' business operations;

- interruption in global shipping that may affect the transport of clinical trial materials, such as investigational drug product used in our clinical trials;

- changes in clinical trial site procedures and requirements as well as regulatory requirements for conducting clinical trials during the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, implement additional procedures and policies, or to discontinue the clinical trials altogether, or which may result in unexpected costs and delays;

- delays or interruptions in the operations of or necessary interactions with the U.S. Food and Drug Administration ("FDA") or other regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel, which may impact review and approval timelines and result in unexpected costs and delays;

- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States;

- limitations on employee resources that would otherwise be focused on the conduct of our nonclinical studies and clinical trials, either because of sickness of employees and their families or the desire of employees to avoid contact with large groups of people; and

- negative impact on our ability to raise capital.

We have clinical trial sites for our clinical studies in the United States and Europe, certain of which have been affected by the COVID-19 pandemic due to prioritization of hospital resources toward the COVID-19 outbreak, travel or quarantine restrictions imposed by federal, state or local governments, and the inability to access sites for initiation and patient monitoring and enrollment. Healthcare facilities and offices may be required to focus limited resources on non-clinical trial matters, including treatment of COVID-19 patients, and may not be available, in whole or in part, for clinical trial services related to our clinical trials. As a result, patient screening, new patient enrollment, monitoring and data collection may be affected. We experienced a pause in enrollment in our DNL151 Phase 1 and Phase 1b trials, our DNL343 Phase 1 trial, and our ETV:IDS program observational biomarker study. In all cases, recruitment has resumed. However, further pauses or delays could occur depending on the progression of the pandemic. The completion of such trials could be delayed as a result.

We may be required to develop and implement additional clinical trial policies and procedures designed to help protect subjects from the COVID-19 virus. For example, in March 2020, the FDA issued a guidance, which the FDA subsequently updated, on conducting clinical trials during the pandemic, which describes a number of considerations for sponsors of clinical trials impacted by the pandemic, including the requirement to include in the clinical trial report contingency measures implemented to manage the clinical trial, and any disruption of the clinical trial as a result of the COVID-19 pandemic; a list of all subjects affected by the COVID-19-pandemic related study disruption by unique subject identifier and by investigational site and a description of how the individual's participation was altered; and analyses and corresponding discussions that address the impact of implemented contingency measures (e.g., participant discontinuation from investigational product and/or study, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the clinical trial. In June 2020, FDA also issued a guidance on good manufacturing practice considerations for responding to COVID-19 infection in employees in drug and biologic products manufacturing, including recommendations for manufacturing controls to prevent contamination of the products.

Some third-party manufacturers that supply us materials for product candidates or other materials necessary to manufacture product to conduct preclinical tests and clinical trials are located in countries affected by COVID-19, and we may experience delays in advancing these tests and trials, if our third-party manufacturers experience disruptions such as temporary closures or suspension of services. The spread of an infectious disease, including COVID-19, may also result in the inability of our suppliers to deliver components or raw materials on a timely basis or at all. Currently, we do not expect delays to our clinical trials due to manufacturing or supply-chain issues, and we believe we have sufficient drug supplies to complete ongoing trials as well as additional drug substance supplies expected to be sufficient to support planned clinical trials well into 2021. Furthermore, the spread of the virus may affect the operations of key governmental agencies, such as the FDA, which may delay the development of our product candidates. Such events may result in a period of business disruption, and in reduced operations, or doctors and medical providers may be unwilling to participate in our clinical trials, any of which could materially affect our business, operations and financial condition.

The COVID-19 pandemic continues to rapidly evolve. The extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease and to address its impact, including on financial markets or otherwise. While the extent of the impact of the COVID-19 pandemic on our business and financial results is uncertain, a continued and prolonged public health crisis could have a material negative impact on our business, operations and financial condition.

To the extent the COVID-19 pandemic adversely affects our business, operations and financial condition, it may also have the effect of heightening many of the risks described in this "Risk Factors" section.

Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We have never generated any revenue from product sales, and we may never generate product revenue or be profitable.

We have no products approved for commercial sale and have not generated any revenue from product sales. To obtain revenue from the sales of our product candidates that are significant or large enough to achieve profitability, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing therapies with significant commercial success.

Our ability to generate revenue and achieve profitability depends significantly on many factors, including:

- successfully completing research and preclinical and clinical development of our product candidates;
- obtaining regulatory approvals and marketing authorizations for product candidates for which we successfully complete clinical development and clinical trials;
- developing a sustainable and scalable manufacturing process for our product candidates, including those that utilize our TV platform, as well as establishing and maintaining commercially viable supply relationships with third parties that can provide adequate products and services to support clinical activities and commercial demand of our product candidates;
- identifying, assessing, acquiring and/or developing new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- launching and successfully commercializing product candidates for which we obtain regulatory and marketing approval, either by collaborating with a partner or, if launched independently, by establishing a sales, marketing and distribution infrastructure;
- obtaining and maintaining an adequate price for our product candidates, both in the United States and in foreign countries where our products are commercialized;
- obtaining adequate reimbursement for our product candidates from payors;
- obtaining market acceptance of our product candidates as viable treatment options;
- addressing any competing technological and market developments;
- maintaining, protecting, expanding and enforcing our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of our expenses, or when we will be able to generate any meaningful revenue or achieve or maintain profitability, if ever. In addition, our expenses could increase beyond our current expectations if we are required by the FDA, or foreign regulatory agencies, to perform studies in addition to those that we currently anticipate, or if there are any delays in any of our or our future collaborators' clinical trials or the development of any of our product candidates. Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate and ongoing compliance efforts.

Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations. Revenue from the sale of any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any price and whether we own the commercial rights for that territory. If the number of addressable patients is not as significant as we anticipate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of product candidates or continue our operations and cause a decline in the value of our common stock, all or any of which may adversely affect our viability.

If we fail to obtain additional financing, we may be unable to complete the development and, if approved, commercialization of our product candidates.

Our operations have required substantial amounts of cash since inception. We fund our operations primarily with the proceeds from our IPO, our follow-on offering completed in January 2020, the Stock Purchase Agreement with Biogen and payments received from our Takeda Collaboration Agreement, Sanofi Collaboration Agreement and Biogen Collaboration Agreement. We are currently advancing three product candidates, DNL151, DNL343, and DNL310 through clinical development, and have several other product candidates in preclinical development, as well as early-stage research projects. Developing our product candidates is expensive, and we expect to continue to spend substantial amounts as we fund our early-stage research projects, and continue to advance our programs through preclinical and clinical development. Even if we are successful in developing our product candidates, obtaining regulatory approvals and launching and commercializing any product candidate will require substantial additional funding.

As of September 30, 2020, we had $981.5 million in cash, cash equivalents and marketable securities. We believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our projected operations through at least the next 12 months. Our estimate as to how long we expect our existing cash, cash equivalents and marketable securities to be available to fund our operations is based on assumptions that may be proved inaccurate, and we could use our available capital resources sooner than we currently expect. In addition, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may need to raise additional funds sooner than we anticipate if we choose to expand more rapidly than we presently anticipate.

We will require additional capital for the further development and, if approved, commercialization of our product candidates. Additional capital may not be available when we need it, on terms acceptable to us or at all. We have no committed source of additional capital. If adequate capital is not available to us on a timely basis, we may be required to significantly delay, scale back or discontinue our research and development programs or the commercialization of any product candidates, if approved, or be unable to continue or expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition, results of operations, growth prospects and cause the price of our common stock to decline.

Due to the significant resources required for the development of our programs, and depending on our ability to access capital, we must prioritize development of certain product candidates. Moreover, we may expend our limited resources on programs that do not yield a successful product candidate and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We have a diversified portfolio with sixteen programs. These programs require significant capital investment. Our programs are at various stages of research, discovery, preclinical and early clinical development. We seek to maintain a process of prioritization and resource allocation to maintain an optimal balance between aggressively advancing lead programs and ensuring replenishment of our portfolio. We regularly review the programs in our portfolio, and terminate those programs which do not meet our development criteria, which we have done a number of times in the past.

Due to the significant resources required for the development of our programs, we must focus our programs on specific diseases and disease pathways and decide which product candidates to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect of certain programs may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our programs or product candidates or misread trends in the biopharmaceutical industry, in particular for neurodegenerative diseases, our business, financial condition, results of operations and growth prospects could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

Risks Related to the Discovery, Development and Commercialization of Our Product Candidates

Research and development of biopharmaceutical products is inherently risky. We are heavily dependent on the successful development of our BBB platform technology and the programs currently in our pipeline, which are in the early stages of preclinical and clinical development. We cannot give any assurance that any of our product candidates will receive regulatory, including marketing approval, which is necessary before they can be commercialized.

We are at an early stage of development of the product candidates currently in our programs and are further developing our BBB platform technology. To date, we have invested substantially all of our efforts and financial resources to identify, acquire intellectual property for, and develop our BBB platform technology and our programs, including conducting preclinical studies and early-stage clinical trials, and providing general and administrative support for these operations. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize our product candidates, and we may fail to do so for many reasons, including the following:

- our product candidates may not successfully complete preclinical studies or clinical trials;
- our drug delivery platform technology designed to deliver large molecule therapeutics across the BBB may not be clinically viable;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- our competitors may develop therapeutics that render our product candidates obsolete or less attractive;
- our competitors may develop platform technologies to deliver large molecule therapeutics across the BBB that render our platform technology obsolete or less attractive;

- the product candidates and BBB platform technology that we develop may not be sufficiently covered by intellectual property for which we hold exclusive rights;
- the product candidates and BBB platform technology that we develop may be covered by third parties' patents or other intellectual property or exclusive rights;
- the market for a product candidate may change so that the continued development of that product candidate is no longer reasonable or commercially attractive;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- if a product candidate obtains regulatory approval, we may be unable to establish sales and marketing capabilities, or successfully market such approved product candidate, to gain market acceptance; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations.

We may not be successful in our efforts to further develop our BBB platform technology and current product candidates. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. Each of our product candidates is in the early stages of development and will require significant additional clinical development, management of preclinical, clinical, and manufacturing activities, regulatory approval, adequate manufacturing supply, a commercial organization, and significant marketing efforts before we generate any revenue from product sales, if at all.

We have never completed a clinical development program. We have previously discontinued the development of certain molecules prior to completion of preclinical development because we did not believe they met our criteria for potential clinical success. None of our product candidates have advanced into late-stage development or a pivotal clinical trial and it may be years before any such trial is initiated, if at all. Further, we cannot be certain that any of our product candidates will be successful in clinical trials. For instance, in 2016, we initiated a Phase 1 clinical trial in a former RIPK1 inhibitor product candidate, DNL104, which we subsequently discontinued based on liver test abnormalities in some clinical trial healthy volunteer participants. Further, in June 2020, together with our collaboration partner Sanofi, we paused clinical activities with DNL747 to accelerate development of DNL788, in part due to DNL747 preclinical chronic toxicity studies. We may in the future advance product candidates into clinical trials and terminate such trials prior to their completion.

If any of our product candidates successfully complete clinical trials, we generally plan to seek regulatory approval to market our product candidates in the United States, the European Union, and in additional foreign countries where we believe there is a viable commercial opportunity. We have never commenced, compiled or submitted an application seeking regulatory approval to market any product candidate. We may never receive regulatory approval to market any product candidates even if such product candidates successfully complete clinical trials, which would adversely affect our viability. To obtain regulatory approval in countries outside the United States, we must comply with numerous and varying regulatory requirements of such other countries regarding safety, efficacy or potency, purity, chemistry, manufacturing and controls, clinical trials, commercial sales, pricing, and distribution of our product candidates. We may also rely on our collaborators or partners to conduct the required activities to support an application for regulatory approval, and to seek approval, for one or more of our product candidates. We cannot be sure that our collaborators or partners will conduct these activities or do so within the time frame we desire. Even if we (or our collaborators or partners) are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. If we are unable to obtain approval for our product candidates in multiple jurisdictions, our revenue, business, financial condition, results of operations and growth prospects could be negatively affected.

Even if we receive regulatory approval to market any of our product candidates, whether for the treatment of neurodegenerative diseases or other diseases, we cannot assure you that any such product candidate will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives.

Investment in biopharmaceutical product development involves significant risk that any product candidate will fail to demonstrate adequate efficacy or potency, or an acceptable safety profile, gain regulatory approval, and become commercially viable. We cannot provide any assurance that we will be able to successfully advance any of our product candidates through the development process or, if approved, successfully commercialize any of our product candidates.

We may not be successful in our efforts to continue to create a pipeline of product candidates or to develop commercially successful products. If we fail to successfully identify and develop additional product candidates, our commercial opportunity may be limited.

One of our strategies is to identify and pursue clinical development of additional product candidates. We currently have several programs in the research, discovery and preclinical stages of development. Identifying, developing, obtaining regulatory approval and commercializing additional product candidates for the treatment of neurodegenerative diseases will require substantial additional funding and is prone to the risks of failure inherent in drug development. We cannot provide you any assurance that we will be able to successfully identify or acquire additional product candidates, advance any of these additional product candidates through the development process, successfully commercialize any such additional product candidates, if approved, or assemble sufficient resources to identify, acquire, develop or, if approved, commercialize additional product candidates. If we are unable to successfully identify, acquire, develop and commercialize additional product candidates, our commercial opportunity may be limited.

We have concentrated a substantial portion of our research and development efforts on the treatment of neurodegenerative diseases, a field that has seen limited success in drug development. Further, our product candidates are based on new approaches and novel technology, which makes it difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval.

We have focused our research and development efforts on addressing neurodegenerative diseases. Collectively, efforts by biopharmaceutical companies in the field of neurodegenerative diseases have seen limited success in drug development. There are few effective therapeutic options available for patients with Alzheimer's disease, Parkinson's disease, ALS and other neurodegenerative diseases. Our future success is highly dependent on the successful development of our BBB platform technology and our product candidates for treating neurodegenerative diseases. Developing and, if approved, commercializing our product candidates for treatment of neurodegenerative diseases subjects us to a number of challenges, including engineering product candidates to cross the BBB to enable optimal concentration of the therapeutic in the brain and obtaining regulatory approval from the FDA and other regulatory authorities who have only a limited set of precedents to rely on.

Our approach to the treatment of neurodegenerative diseases aims to identify and select targets with a genetic link to neurodegenerative diseases, identify and develop molecules that engage the intended target, identify and develop biomarkers, which are biological molecules found in blood, other bodily fluids or tissues that are signs of a normal or abnormal process or of a condition or disease, to select the right patient population and demonstrate target engagement, pathway engagement and impact on disease progression of our molecules, and engineer our molecules to cross the BBB and act directly in the brain. This strategy may not prove to be successful. We may not be able to discover, develop and utilize biomarkers to demonstrate target engagement, pathway engagement and the impact on disease progression of our molecules. We cannot be sure that our approach will yield satisfactory therapeutic products that are safe and effective, scalable, or profitable. Moreover, public perception of drug safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical trials, or if approved, of physicians to subscribe to novel treatments.

We may encounter substantial delays in our clinical trials, or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all.

Clinical testing is expensive, time consuming, and subject to uncertainty. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. We cannot be sure that submission of an investigational new drug application ("IND"), or a clinical trial application ("CTA"), will result in the FDA or European Medicines Agency ("EMA"), as applicable, allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could suspend or terminate such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. Events that may prevent successful or timely initiation or completion of clinical trials include:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- delays in confirming target engagement, patient selection or other relevant biomarkers to be utilized in preclinical and clinical product candidate development;
- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- delays in obtaining required Institutional Review Board ("IRB") approval at each clinical trial site;

- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND or amendment, CTA or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical trial operations or study sites; developments on trials conducted by competitors for related technology that raises FDA or EMA concerns about risk to patients of the technology broadly; or if the FDA or EMA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;

- delays in identifying, recruiting and enrolling suitable patients to participate in our clinical trials, and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;

- difficulty collaborating with patient groups and investigators;

- failure by our CROs, other third parties, or us to adhere to clinical trial requirements;

- failure to perform in accordance with the FDA's or any other regulatory authority's current good clinical practices ("cGCPs") requirements, or applicable EMA or other regulatory guidelines in other countries;

- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;

- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;

- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;

- the cost of clinical trials of our product candidates being greater than we anticipate;

- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development programs;

- transfer of manufacturing processes from our academic collaborators to larger-scale facilities operated by a CDMO or by us, and delays or failure by our CDMOs or us to make any necessary changes to such manufacturing process;

- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing; and

- delays associated with the COVID-19 global pandemic.

Any inability to successfully initiate or complete clinical trials could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board for such trial or by the FDA, EMA or any other regulatory authority, or if the IRBs of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

DNL201, a former LRRK2 inhibitor product candidate, recently completed a Phase 1b clinical trial in Parkinson's disease patients with and without the genetic LRRK2 mutation. This program was previously subject to a partial clinical hold due to preclinical toxicity data. The partial clinical hold was removed in December 2017 based on additional clinical and preclinical data provided to the FDA. In our recently completed Phase 1b clinical trial of DNL201 in patients with Parkinson’s disease, there was one SAE considered unrelated to drug, and at the high dose, there was one severe AE (headache) leading to dose reduction and one study withdrawal (headache and nausea). Our clinical-stage product candidates are DNL151 for Parkinson's disease, DNL343 for ALS and FTD, and DNL310 for Hunter syndrome. In the nonclinical safety studies for these product candidates, toxicities were observed at high doses in rat and/or cynomolgus monkey above doses and exposures that will be tested in the clinic. We cannot assure you that DNL151, DNL343 and DNL310, or our other product candidates will not be subject to new, partial or full clinical holds in the future.

We may in the future advance product candidates into clinical trials and terminate such trials prior to their completion, such as we did for DNL104, which could adversely affect our business. Further, after the commencement of clinical trials, we may pause the advancement of lead molecules in favor of a backup molecule with a superior safety or efficacy profile, such as we recently did in our RIPK1 program, switching our focus from DNL747 to DNL788.

Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

We may encounter difficulties enrolling and/or retaining patients in our clinical trials, and our clinical development activities could thereby be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment and retention in our clinical trials for a variety of reasons, including:

- inability or delay in enrollment of patients due to a variety of reasons, including outbreaks and public health crises, such as the COVID-19 global pandemic;
- the size and nature of the patient population;
- the patient eligibility criteria defined in the protocol, including biomarker-driven identification and/or certain highly-specific criteria related to stage of disease progression, which may limit the patient populations eligible for our clinical trials to a greater extent than competing clinical trials for the same indication that do not have biomarker-driven patient eligibility criteria;
- the size of the study population required for analysis of the trial’s primary endpoints;

- the proximity of patients to a trial site;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or targeting patient populations meeting our patient eligibility criteria;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies and product candidates;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will not complete such trials, for any reason, including the risk of higher drop-out rates if participants become infected with the COVID-19 virus or other infectious diseases that impact their participation in our trials.

Our inability to enroll and retain a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining participation in our clinical trials through the treatment and any follow-up periods, which could delay or negatively impact the anticipated readouts from our clinical trials, delay our regulatory submissions, and increase the costs of the clinical trials.

Our clinical trials may reveal significant adverse events, toxicities, or other side effects and may fail to demonstrate substantial evidence of the safety and efficacy or potency of our product candidates, which would prevent, delay or limit the scope of regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. For those product candidates that are subject to regulation as biological drug products, we will need to demonstrate that they are safe, pure, and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies of our product candidates may not be predictive of the results of early-stage or later-stage clinical trials, and results of early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. The results of clinical trials in one set of patients or disease indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety or efficacy or potency results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. Open-label extension studies may also extend the timing and increase the cost of clinical development substantially. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy or potency profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or potency or unacceptable safety issues, notwithstanding promising results in earlier trials. This is particularly true in neurodegenerative diseases, where failure rates historically have been higher than in many other disease areas. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. We cannot be certain that our current clinical trials or any other future clinical trials will be successful. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, or that the product candidates will be approved for the currently proposed indications, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval, such as requiring us to narrow our indications to smaller subset of patient population, may limit the scope and use of our product candidate, which may also limit its commercial potential.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available, and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary, interim or topline data from our nonclinical studies and clinical trials. These interim updates are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse changes between interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. You or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the preliminary or topline data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer, more advanced or more effective than ours, which may negatively impact our ability to successfully market or commercialize any product candidates we may develop and ultimately harm our financial condition.

The development and commercialization of new drug products is highly competitive. Moreover, the neurodegenerative field is characterized by strong and increasing competition, and a strong emphasis on intellectual property. We may face competition with respect to any product candidates that we seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

There are a number of large pharmaceutical and biotechnology companies that are currently pursuing the development of products for the treatment of the neurodegenerative disease indications for which we have research programs, including Alzheimer’s disease, Parkinson’s disease and ALS. Companies that we are aware are developing therapeutics in the neurodegenerative disease area include companies with significant financial resources, such as AbbVie, Alector, AstraZeneca, Biogen, Bristol-Myers Squibb, Eli Lilly, E-Scape Bio, GlaxoSmithKline, Ionis, JCR Pharmaceuticals, Johnson & Johnson, Novartis, Prevail Therapeutics, Roche, Sanofi and Takeda. In addition to competition from other companies targeting neurodegenerative indications, any products we may develop may also face competition from other types of therapies, such as gene-editing therapies.

Many of our current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Furthermore, currently approved products could be discovered to have application for treatment of neurodegenerative disease indications, which could give such products significant regulatory and market timing advantages over any of our product candidates. Our competitors also may obtain FDA, EMA or other regulatory approval for their products more rapidly than we may obtain approval for ours and may obtain orphan product exclusivity from the FDA for indications our product candidates are targeting, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, products or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates we may develop against competitors.

In addition, we could face litigation or other proceedings with respect to the scope, ownership, validity and/or enforceability of our patents relating to our competitors' products and our competitors may allege that our products infringe, misappropriate or otherwise violate their intellectual property. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize. See "Risks Related to Our Intellectual Property."

The manufacture of our product candidates, particularly those that utilize our BBB platform technology, is complex and we may encounter difficulties in production. If we or any of our third-party manufacturers encounter such difficulties, or fail to meet rigorously enforced regulatory standards, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

The processes involved in manufacturing our drug and biological product candidates, particularly those that utilize our BBB platform technology, are complex, expensive, highly regulated and subject to multiple risks. Additionally, the manufacture of biologics involves complex processes, including developing cells or cell systems to produce the biologic, growing large quantities of such cells, and harvesting and purifying the biologic produced by them. As a result, the cost to manufacture a biologic is generally far higher than traditional small molecule chemical compounds, and the biologics manufacturing process is less reliable and is difficult to reproduce. Manufacturing biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. Further, as product candidates are developed through preclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials.

In order to conduct clinical trials of our product candidates, or supply commercial products, if approved, we will need to manufacture them in small and large quantities. Our manufacturing partners may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If our manufacturing partners are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or become infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. The same risks would apply to our internal manufacturing facilities, should we in the future decide to build internal manufacturing capacity. In addition, building internal manufacturing capacity would carry significant risks in terms of being able to plan, design and execute on a complex project to build manufacturing facilities in a timely and cost-efficient manner.

In addition, the manufacturing process, including any material modifications in the manufacturing process, for any products that we may develop is subject to FDA, EMA and foreign regulatory authority approval processes, and continuous oversight, and we will need to contract with manufacturers who can meet all applicable FDA, EMA and foreign regulatory authority requirements, including complying with current good manufacturing practices ("cGMPs"), on an ongoing basis. If we or our third-party manufacturers are unable to reliably produce products to specifications acceptable to the FDA, EMA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CDMOs will be able to manufacture the approved product to specifications acceptable to the FDA, EMA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects.

If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product candidates we may develop, we may not be successful in commercializing those product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing, or distribution of pharmaceutical products. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a focused sales, marketing, and commercial support infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if and when they are approved.

There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our commercialization personnel.

Factors that may inhibit our efforts to commercialize any approved product on our own include:

- our inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs, and other support personnel;

- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future approved products;

- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement, and other acceptance by payors;
- the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability;
- restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

If we enter into arrangements with third parties to perform sales, marketing, commercial support, and distribution services, our product revenue or the profitability of product revenue may be lower than if we were to market and sell any products we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates if approved.

Even if any product candidates we develop receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors, and others in the medical community necessary for commercial success.

The commercial success of any of our product candidates will depend upon its degree of market acceptance by physicians, patients, third-party payors, and others in the medical community. Even if any product candidates we may develop receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors, and others in the medical community. The degree of market acceptance of any product candidates we may develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy or potency and safety of such product candidates as demonstrated in pivotal clinical trials and published in peer-reviewed journals;
- the potential and perceived advantages compared to alternative treatments;
- the ability to offer our products for sale at competitive prices;
- the ability to offer appropriate patient access programs, such as co-pay assistance;
- the extent to which physicians recommend our products to their patients;
- convenience and ease of dosing and administration compared to alternative treatments;
- the clinical indications for which the product candidate is approved by FDA, EMA or other regulatory agencies;
- product labeling or product insert requirements of the FDA, EMA or other comparable foreign regulatory authorities, including any limitations, contraindications or warnings contained in a product's approved labeling;

- restrictions on how the product is distributed;
- the timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- the strength of marketing and distribution support;
- sufficient third-party coverage or reimbursement; and
- the prevalence and severity of any side effects.

If any product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenue, and we may not become profitable.

Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices, or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, and reimbursement for new drugs vary widely from country to country. In the United States, recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

Our ability to successfully commercialize any products that we may develop also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Government authorities currently impose mandatory discounts for certain patient groups, such as Medicare, Medicaid and Veterans Affairs ("VA"), hospitals, and may seek to increase such discounts at any time. Future regulation may negatively impact the price of our products, if approved. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In order to get reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower-priced generic versions of standard of care drugs. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the medicine is approved by the FDA, EMA or other comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates, and our overall financial condition.

If any of our product candidates that are small molecules obtain regulatory approval, additional competitors could enter the market with generic versions of such drugs, which may result in a material decline in sales of affected products.

Under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), a pharmaceutical manufacturer may file an abbreviated new drug application ("ANDA") seeking approval of a generic copy of an approved, small molecule innovator product. Under the Hatch-Waxman Act, a manufacturer may also submit a new drug application ("NDA") under section 505(b)(2) that references the FDA's prior approval of the small molecule innovator product. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. The Hatch-Waxman Act also provides for certain periods of regulatory exclusivity, which preclude FDA approval (or in some circumstances, FDA filing and reviewing) of an ANDA or 505(b)(2) NDA. These include, subject to certain exceptions, the period during which an FDA-approved drug is subject to orphan drug exclusivity. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." If there are patents listed in the Orange Book, a generic or 505(b)(2) applicant that seeks to market its product before expiration of the patents must include in the ANDA a "Paragraph IV certification," challenging the validity or enforceability of, or claiming non-infringement of, the listed patent or patents. Notice of the certification must be given to the innovator, too, and if within 45 days of receiving notice the innovator sues to protect its patents, approval of the ANDA is stayed for 30 months, or as lengthened or shortened by the court.

Accordingly, if any of our small molecule product candidates are approved, competitors could file ANDAs for generic versions of our small molecule drug products or 505(b)(2) NDAs that reference our small molecule drug products, respectively. If there are patents listed for our small molecule drug products in the Orange Book, those ANDAs and 505(b)(2) NDAs would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict which, if any, patents in our current portfolio or patents we may obtain in the future will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents, or the outcome of any such suit.

We may not be successful in securing or maintaining proprietary patent protection for products and technologies we develop or license. Moreover, if any of our owned or in-licensed patents that are listed in the Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, the affected product could immediately face generic competition and its sales would likely decline rapidly and materially. Should sales decline, we may have to write off a portion or all of the intangible assets associated with the affected product and our results of operations and cash flows could be materially and adversely affected. See "Risks Related to Our Intellectual Property."

Our biologic, or large molecule, product candidates for which we intend to seek approval may face competition sooner than anticipated.

Even if we are successful in achieving regulatory approval to commercialize a product candidate faster than our competitors, our large molecule product candidates may face competition from biosimilar products. In the United States, our large molecule product candidates are regulated by the FDA as biologic products and we intend to seek approval for these product candidates pursuant to the biologics license application ("BLA"), pathway. The Biologics Price Competition and Innovation Act of 2009 (the "BPCIA"), created an abbreviated pathway for the approval of biosimilar and interchangeable biologic products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our large molecule product candidates.

We believe that any of our large molecule product candidates approved as a biologic product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. In addition, a competitor could decide to forego the biosimilar approval path and submit a full BLA after completing its own preclinical studies and clinical trials. In such cases, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its product as soon as it is approved.

In Europe, the European Commission has granted marketing authorizations for several biosimilar products pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In Europe, a competitor may reference data supporting approval of an innovative biological product, but will not be able to get it on the market until 10 years after the time of approval of the innovative product. This 10-year marketing exclusivity period will be extended to 11 years if, during the first eight of those 10 years, the marketing authorization holder obtains an approval for one or more new therapeutic indications that bring significant clinical benefits compared with existing therapies. In addition, companies may be developing biosimilar products in other countries that could compete with our products, if approved.

If competitors are able to obtain marketing approval for biosimilars referencing our large molecule product candidates, if approved, such products may become subject to competition from such biosimilars, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our product candidates may have received approval.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk when and if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit testing and commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased or interrupted demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaborators. Our insurance policies may have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

The regulatory approval processes of the FDA, EMA and comparable foreign regulatory authorities are lengthy, time consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.

The time required to obtain approval by the FDA, EMA and comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials, and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Moreover, the FDA, EMA or other regulatory authorities may fail to approve companion diagnostics that we contemplate using with our therapeutic product candidates. We have not submitted for, or obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Applications for our product candidates could fail to receive regulatory approval in an initial or subsequent indication for many reasons, including but not limited to the following:

- the FDA, EMA or comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA, EMA or comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical program may not be sufficiently broad or representative to assure efficacy or potency and safety in the full population for which we seek approval;
- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio when compared to the standard of care is acceptable;
- the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA, BLA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA, EMA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA, EMA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects.

Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences.

Adverse events or other undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, EMA or other comparable foreign regulatory authorities.

Our most advanced product candidates, DNL151, DNL343 and DNL310 are currently our only clinical stage product candidates. In our recently completed Phase 1b clinical trial of former product candidate DNL201 in patients with Parkinson's disease, there was one SAE considered unrelated to drug, and at the high dose, there was one severe AE (headache) leading to dose reduction and one study withdrawal (headache and nausea). Adverse events and other side effects may result from higher dosing, repeated dosing and/or longer-term exposure to DNL151, DNL343 and/or DNL310 and could lead to delays and/or termination of the development of these product candidates.

In 2016, we initiated a Phase 1 clinical trial in a former RIPK1 inhibitor product candidate, DNL104, which we subsequently discontinued based on liver function test abnormalities in some clinical trial healthy volunteer participants. In 2020, we paused clinical studies with DNL747 in our RIPK1 program. Chronic toxicity studies with DNL747 in cynomolgus monkeys showed dose- and duration-dependent adverse preclinical findings at exposures higher than those tested in the clinic. These findings, which are considered off-target and molecule-specific, may impact the ability to increase the dose of DNL747 and achieve higher levels of target inhibition without time consuming additional clinical safety studies in patients to evaluate the long-term safety and tolerability.

Drug-related side effects could affect patient recruitment, the ability of enrolled patients to complete the study, and/or result in potential product liability claims. We are required to maintain product liability insurance pursuant to certain of our license agreements. We may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical trial participants, costs due to related litigation, distraction of management's attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates, and decreased demand for our product candidates, if approved for commercial sale.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of such product and cause us to recall our product;
- regulatory authorities may require additional warnings on the label;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
- we may be required to create a Risk Evaluation and Mitigation Strategy plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements, such as boxed warning on the packaging, to assure safe use;
- we could be sued and held liable for harm caused to patients; and

- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, financial condition, results of operations, and growth prospects. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on nonclinical studies or early-stage clinical trials.

We may in the future conduct clinical trials for our product candidates outside the United States, and the FDA, EMA and applicable foreign regulatory authorities may not accept data from such trials.

We may in the future choose to conduct one or more of our clinical trials outside the United States, including in Europe. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA, EMA or applicable foreign regulatory authority may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to cGCP regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA or any applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA or EMA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any partner we work with fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to extensive regulatory scrutiny.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy or potency, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

While healthcare professionals are free to use and prescribe drug products for off-label uses, FDA strictly regulates manufacturers' promotional claims of drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the FDA-approved labeling. The FDA, the Department of Justice, the Inspector General of the Department of Health and Human Services, among other government agencies, actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including large civil and criminal fines, penalties, and enforcement actions. If we cannot successfully manage the promotion of our approved product candidates, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Manufacturers and manufacturers' facilities are required to comply with extensive requirements imposed by the FDA, EMA and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, BLA or marketing authorization application ("MAA"). Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our product candidates will be subject to limitations on the approved indicated uses for which the product may be marketed and promoted or to the conditions of approval (including the requirement to implement a Risk Evaluation and Mitigation Strategy) or contain requirements for potentially costly post-marketing testing. We will be required to report certain adverse reactions and production problems, if any, to the FDA, EMA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have approval. The holder of an approved NDA, BLA, or MAA must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our non-biologic products or safety, purity, and potency for our biologic products, in general or in specific patient subsets. If original marketing approval was obtained via the accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to confirm clinical benefit for our products. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters that would result in adverse publicity;
- impose civil or criminal penalties;

- suspend or withdraw regulatory approvals;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities;
- seize or detain products; and/or
- require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

We plan to seek orphan drug designation for some product candidates, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug status, including market exclusivity, which may cause our revenue, if any, to be reduced.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting an NDA or BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. In February 2019, the FDA granted orphan drug designation for our DNL310 program in Hunter syndrome. We plan to seek orphan drug designations for some other product candidates and may be unable to obtain such designations.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other NDA or BLA applications to market the same drug or biologic for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan exclusivity or if FDA finds that the holder of the orphan exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even though DNL310 has been granted orphan drug designation and even if one of our product candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product.

Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

We may face difficulties from changes to current regulations and future legislation. Current and future legislation may increase the difficulty and cost for us to commercialize our drugs, if approved, and affect the prices we may obtain, including changes in coverage and reimbursement policies in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates, if approved, profitably. Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the Affordable Care Act ("ACA"), was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research. Recent changes in the U.S. administration could lead to repeal of or changes in some or all of the ACA, and complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business. Until the ACA is fully implemented or there is more certainty concerning the future of the ACA, it will be difficult to predict its full impact and influence on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in 2013, and will remain in effect through 2030 unless additional Congressional action is taken. The CARES Act, which was signed into law on March 27, 2020, and designed to provide financial support and resources to individuals and businesses affected by COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020, through December 31, 2020, and extended the sequester by one year, through 2030, in order to offset the added expense of the 2020 cancellation. The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to receive or set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement, and new payment methodologies. This could lower the price that we receive for any approved product. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our product candidates, if approved.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the laws of the FDA, EMA and other comparable foreign regulatory authorities; provide true, complete and accurate information to the FDA, EMA and other comparable foreign regulatory authorities; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. In particular, research, sales, marketing, education and other business arrangements in the healthcare industry are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, educating, marketing and promotion, sales and commission, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by employees and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

If we fail to comply with healthcare laws, we could face substantial penalties and our business, operations and financial conditions could be adversely affected.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations will be subject to various federal and state fraud and abuse laws. The laws that may impact our operations include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The intent standard under the federal Anti-Kickback Statute was amended by the ACA to eliminate the need to prove specific intent and actual knowledge to establish an Anti-Kickback Statute violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- federal civil and criminal false claims laws, including the False Claims Act, which can be enforced through civil “qui tam” or “whistleblower” actions, and civil monetary penalty laws generally prohibit individuals or entities, among other things, from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third-party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;

- the federal Physician Payment Sunshine Act, created under the ACA, and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program to report annually to the U.S. Department of Health and Human Services under the Open Payments Program, information related to payments or other transfers of value made to physicians, as defined by law, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Additionally, President Trump signed into law in 2018 the “Substance Use-Disorder Prevention that Promoted Opioid Recovery and Treatment for Patients and Communities Act” which, under the provision entitled “Fighting the Opioid Epidemic with Sunshine,” in part, extends the reporting and transparency requirements for physicians under the Physician Payments Sunshine Act to physician assistants, nurse practitioners and other mid-level practitioners, with reporting requirements going into effect in 2022 for payments made in 2021;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payer, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could, despite our efforts to comply, be subject to challenge under one or more of such laws. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Our business is subject to complex and evolving U.S. and foreign laws and regulations, information security policies and contractual obligations relating to privacy and data protection, including the use, processing, and cross-border transfer of personal information. These laws and regulations are subject to change and uncertain interpretation, and could result in claims, changes to our business practices, or monetary penalties, and otherwise may harm our business.

We receive, generate and store significant and increasing volumes of sensitive information and business-critical information, including employee and personal data (including protected health information), research and development information, commercial information, and business and financial information. We heavily rely on external security and infrastructure vendors to manage our information technology systems and data centers. We face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate use or disclosure, inappropriate modification, and the risk of our being unable to adequately monitor, audit and modify our controls over our critical information. This risk extends to the third-party vendors and subcontractors we use to manage this sensitive data.

A wide variety of provincial, state, national, and international laws, and regulations apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data. These data protection and privacy-related laws and regulations are evolving and may result in ever-increasing regulatory and public scrutiny and escalating levels of enforcement and sanctions. For example, the collection and use of personal data in the European Union are governed by the European Union General Data Protection Regulation ("GDPR"), which became fully effective on May 25, 2018. The GDPR imposes stringent data protection requirements, including, for example, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categories of data, such as health data, and additional obligations when we contract with third-party processors in connection with the processing of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States and other third countries and in the context of clinical trials, we currently rely on patient informed consent as the legal basis for such transfers. In addition, the GDPR provides that European Union member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data. The GDPR provides for penalties for noncompliance of up to the greater of €20 million or four percent of worldwide annual revenues. The GDPR applies extraterritorially, and we may be subject to the GDPR because of our data processing activities that involve the personal data of individuals located in the European Union, such as in connection with any European Union clinical trials. GDPR regulations may impose additional responsibility and liability in relation to the personal data that we process and we may be required to put in place additional mechanisms to ensure compliance with the new data protection rules. This may be onerous and may interrupt or delay our development activities, and adversely affect our business, financial condition, results of operations and prospects.

Further, various states, such as California and Massachusetts, have implemented similar privacy laws and regulations that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. These laws and regulations are not necessarily preempted by HIPAA, particularly if a state affords greater protection to individuals than HIPAA. Where state laws are more protective, we have to comply with the stricter provisions. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. For example, California recently enacted legislation, the California Consumer Privacy Act ("CCPA"), that will, among other things, require covered companies to provide new disclosures to California consumers, and afford such consumers new abilities to opt-out of certain sales of personal information, that became effective on January 1, 2020. The CCPA was amended several times throughout 2018 and 2019, and it is unclear whether further modifications will be made to this legislation or how it will be interpreted. In addition, the CCPA requires covered companies to provide new disclosures to individuals and consumers in California, and afford such individuals and consumers new data protection rights, including the ability to opt-out of certain sales of personal information. The GDPR, CCPA and many other laws and regulations relating to privacy and data protection are still being tested in courts, and they are subject to new and differing interpretations by courts and regulatory officials. Additionally, the interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and data we receive, use and share, potentially exposing us to additional expense, adverse publicity and liability. We are working to comply with the GDPR, CCPA and other privacy and data protection laws and regulations that apply to us, and we anticipate needing to devote significant additional resources to complying with these laws and regulations.

It is possible that the GDPR, CCPA or other laws and regulations relating to privacy and data protection may be interpreted and applied in a manner that is inconsistent from jurisdiction to jurisdiction or inconsistent with our current policies and practices and compliance with such laws and regulations could require us to change our business practices and compliance procedures in a manner adverse to our business. We cannot guarantee that we are in compliance with all such applicable data protection laws and regulations and we cannot be sure how these regulations will be interpreted, enforced or applied to our operations. Furthermore, other jurisdictions outside the European Union are similarly introducing or enhancing privacy and data security laws, rules, and regulations, which could increase our compliance costs and the risks associated with noncompliance. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices and our efforts to comply with the evolving data protection rules may be unsuccessful. We cannot guarantee that we or our vendors may be in compliance with all applicable international laws and regulations as they are enforced now or as they evolve. For example, our privacy policies may be insufficient to protect any personal information we collect, or may not comply with applicable laws. Our non-compliance could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems. In addition, if we are unable to properly protect the privacy and security of protected health information, we could be found to have breached our contracts.

Our actual or perceived failure to adequately comply with applicable laws and regulations relating to privacy and data protection, or to protect personal data and other data we process or maintain, could result in regulatory enforcement actions against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, other lawsuits or reputational and damage, all of which could materially affect our business, financial condition, results of operations and growth prospects.

If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state, and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air, and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Our business activities may be subject to the Foreign Corrupt Practices Act and similar anti-bribery and anti-corruption laws, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations.

Our business activities may be subject to the Foreign Corrupt Practices Act of 1977, as amended (the "FCPA"), and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the Securities and Exchange Commission (the "SEC"), and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

In addition, in the future once we enter a commercialization phase, our products may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, we may be fined or other penalties could be imposed, including a denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or technologies targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to existing or potential customers with international operations. Any limitation on our ability to export or sell access to our products would likely adversely affect our business.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including from December 22, 2018 until January 25, 2019, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to Our Reliance on Third Parties

We expect to depend on collaborations with third parties for the research, development and commercialization of certain of the product candidates we may develop. If any such collaborations are not successful, we may not be able to realize the market potential of those product candidates.

We anticipate seeking third-party collaborators for the research, development, and commercialization of certain of the product candidates we may develop. For example, we have collaborations with F-star, Takeda, Sanofi, Biogen and others, to further our development of product candidates and to enhance our research efforts directed to better understanding neurodegenerative diseases. Our likely collaborators for any other collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies, biotechnology companies and academic institutions. If we enter into any such arrangements with any third parties, we will likely have shared or limited control over the amount and timing of resources that our collaborators dedicate to the development or potential commercialization of any product candidates we may seek to develop with them. Our ability to generate revenue from these arrangements with commercial entities will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into.

Collaborations involving our research programs, or any product candidates we may develop, pose the following risks to us:

- collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not properly obtain, maintain, enforce, or defend intellectual property or proprietary rights relating to our product candidates or research programs or may use our proprietary information in such a way as to expose us to potential litigation or other intellectual property related proceedings, including proceedings challenging the scope, ownership, validity and enforceability of our intellectual property;
- collaborators may own or co-own intellectual property covering our product candidates or research programs that results from our collaboration with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property or such product candidates or research programs;
- we may need the cooperation of our collaborators to enforce or defend any intellectual property we contribute to or that arises out of our collaborations, which may not be provided to us;

- collaborators may control certain interactions with regulatory authorities, which may impact on our ability to obtain and maintain regulatory approval of our products candidates;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development, or commercialization of our product candidates or research programs or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborators may decide to not pursue development and commercialization of any product candidates we develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates or research programs if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators may restrict us from researching, developing or commercializing certain products or technologies without their involvement;
- collaborators with marketing and distribution rights to one or more product candidates may not commit sufficient resources to the marketing and distribution of such product candidates;
- we may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control;
- collaborators may grant sublicenses to our technology or product candidates or undergo a change of control and the sublicensees or new owners may decide to take the collaboration in a direction which is not in our best interest;
- collaborators may become bankrupt, which may significantly delay our research or development programs, or may cause us to lose access to valuable technology, know-how or intellectual property of the collaborator relating to our products, product candidates or research programs;
- key personnel at our collaborators may leave, which could negatively impact our ability to productively work with our collaborators;
- collaborations may require us to incur short and long-term expenditures, issue securities that dilute our stockholders, or disrupt our management and business;
- if our collaborators do not satisfy their obligations under our agreements with them, or if they terminate our collaborations with them, we may not be able to develop or commercialize product candidates as planned;
- collaborations may require us to share in development and commercialization costs pursuant to budgets that we do not fully control and our failure to share in such costs could have a detrimental impact on the collaboration or our ability to share in revenue generated under the collaboration;

- collaborations may be terminated in their entirety or with respect to certain product candidates or technologies and, if so terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates or technologies, including our BBB platform technology; and

- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our development or commercialization program under such collaboration could be delayed, diminished, or terminated.

We may face significant competition in seeking appropriate collaborations. Recent business combinations among biotechnology and pharmaceutical companies have resulted in a reduced number of potential collaborators. In addition, the negotiation process is time-consuming and complex, and we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop product candidates or bring them to market and generate product revenue.

If we enter into collaborations to develop and potentially commercialize any product candidates, we may not be able to realize the benefit of such transactions if we or our collaborator elects not to exercise the rights granted under the agreement or if we or our collaborator are unable to successfully integrate a product candidate into existing operations and company culture. The failure to develop and commercialize a product candidate pursuant to our agreements with our current or future collaborators could prevent us from receiving future payments under such agreements, which could negatively impact our revenues. In addition, if our agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely. We may also find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. Many of the risks relating to product development, regulatory approval, and commercialization described in this "Risk Factors" section also apply to the activities of our collaborators and any negative impact on our collaborators may adversely affect us.

We expect to rely on third parties to conduct our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research, or testing.

We currently rely and expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct some aspects of our research and preclinical testing and our clinical trials. Any of these third parties may terminate their engagements with us or be unable to fulfill their contractual obligations. If we need to enter into alternative arrangements, it would delay our product development activities.

Our reliance on these third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with cGCPs for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible, reproducible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database within certain time frames. Failure to do so can result in fines, adverse publicity, and civil and criminal sanctions.

Our third-party service providers are not our employees, and we are therefore unable to directly monitor whether or not they devote sufficient time and resources to our clinical and nonclinical programs. These third-party service providers may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for any product candidates we may develop and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors, including with the shipment of any drug supplies, could delay clinical development or marketing approval of any product candidates we may develop or commercialization of our medicines, producing additional losses and depriving us of potential product revenue.

We contract with third parties for the manufacture of materials for our research programs, preclinical studies and clinical trials and expect to continue to do so for commercialization of any product candidates that we may develop. This reliance on third parties may increase the risk that we will not have sufficient quantities of such materials, product candidates, or any medicines that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.

We do not have any manufacturing facilities. We currently rely on third-party manufacturers for the manufacture of our materials for preclinical studies and clinical trials and expect to continue to do so for preclinical studies, clinical trials and for commercial supply of any product candidates that we may develop.

We may be unable to establish any further agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the possible breach of the manufacturing agreement by the third party;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;
- reliance on the third party for regulatory compliance, quality assurance, safety, and pharmacovigilance and related reporting; and
- the inability to produce required volume in a timely manner and to quality standards.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in clinical holds on our trials, sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or medicines, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our medicines and harm our business, financial condition, results of operations and growth prospects.

Any medicines that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply for any of our product candidates. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer and may incur added costs and delays in identifying and qualifying any such replacement. Furthermore, securing and reserving production capacity with contract manufacturers may result in significant costs.

Our current and anticipated future dependence upon others for the manufacture of any product candidates we may develop or medicines may adversely affect our future profit margins and our ability to commercialize any medicines that receive marketing approval on a timely and competitive basis.

We depend on third-party suppliers for key raw materials used in our manufacturing processes, and the loss of these third-party suppliers or their inability to supply us with adequate raw materials could harm our business.

We rely on third-party suppliers for the raw materials required for the production of our product candidates. Our dependence on these third-party suppliers and the challenges we may face in obtaining adequate supplies of raw materials involve several risks, including limited control over pricing, availability, quality and delivery schedules. As a small company, our negotiation leverage is limited and we are likely to get lower priority than our competitors who are larger than we are. We cannot be certain that our suppliers will continue to provide us with the quantities of these raw materials that we require or satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole sourced raw materials could materially harm our ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and potential commercialization of our product candidates, including limiting supplies necessary for clinical trials and regulatory approvals, which would have a material adverse effect on our business.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for any product candidates we develop or for our BBB platform technology, our competitors could develop and commercialize products or technology similar or identical to ours, and our ability to successfully commercialize any product candidates we may develop, and our technology may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our BBB platform technology and any proprietary product candidates and other technologies we may develop. We seek to protect our proprietary position by in-licensing intellectual property and filing patent applications in the United States and abroad relating to our BBB platform technology, programs and product candidates, as well as other technologies that are important to our business. Given that the development of our technology and product candidates is at an early stage, our intellectual property portfolio with respect to certain aspects of our technology and product candidates is also at an early stage. For example, as of September 30, 2020, we do not own or in-license any issued patents in the United States directed to the composition of matter of any of the antibodies or enzymes that we have thus far developed using our BBB platform technology. In addition, we cannot be certain that any patents we own or in-license in the United States adequately cover the Fc domain portion of our BBB platform technology that binds to transferrin receptor, or adequately cover the antibodies, enzymes or proteins being developed in our ATV:TREM2, ETV:IDS or PTV:PGRN programs. We have filed or intend to file patent applications on these aspects of our technology and product candidates; however, there can be no assurance that any such patent applications will issue as granted patents. Furthermore, in some cases, we have only filed provisional patent applications on certain aspects of our technology and product candidates and each of these provisional patent applications is not eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of the filing date of the applicable provisional patent application. Any failure to file a non-provisional patent application within this timeline could cause us to lose the ability to obtain patent protection for the inventions disclosed in the associated provisional patent applications. Furthermore, in some cases, we may not be able to obtain issued claims covering compositions relating to our BBB platform technology, programs and product candidates, as well as other technologies that are important to our business, and instead may need to rely on filing patent applications with claims covering a method of use and/or method of manufacture for protection of such BBB platform technology, programs, product candidates and other technologies. There can be no assurance that any such patent applications will issue as granted patents, and even if they do issue, such patent claims may be insufficient to prevent third parties, such as our competitors, from utilizing our technology. Any failure to obtain or maintain patent protection with respect to our BBB platform technology, programs and product candidates could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

If any of our owned or in-licensed patent applications do not issue as patents in any jurisdiction, we may not be able to compete effectively.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. With respect to both in-licensed and owned intellectual property, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into nondisclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in any of our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical technology and product candidates would be adversely affected.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our owned or in-licensed pending and future patent applications may not result in patents being issued which protect our BBB platform technology, product candidates or other technologies or which effectively prevent others from commercializing competitive technologies and product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether our BBB platform technology, product candidates or other technologies will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and growth prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We or our licensors may be subject to a third-party preissuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review, or interference proceedings or other similar proceedings challenging our owned or licensed patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our owned or in-licensed patent rights, allow third parties to commercialize our BBB platform technology, product candidates or other technologies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we, or one of our licensors, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our or our licensor's priority of invention or other features of patentability with respect to our owned or in-licensed patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our BBB platform technology, product candidates and other technologies. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. If we or our collaborators are unsuccessful in any such proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the product candidates we may develop. The loss of exclusivity or the narrowing of our owned and licensed patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products.

In addition, given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Some of our owned and in-licensed patents and patent applications are, and may in the future be, co-owned with third parties. For example, we may currently, and may in the future, co-own certain patents and patent applications relating to our BBB platform technology with F-star. In addition, certain of our licensors co-own the patents and patent applications we in-license with other third parties with whom we do not have a direct relationship. Our exclusive rights to certain of these patents and patent applications are dependent, in part, on inter-institutional or other operating agreements between the joint owners of such patents and patent applications, who are not parties to our license agreements. If our licensors do not have exclusive control of the grant of licenses under any such third-party co-owners' interest in such patents or patent applications or we are otherwise unable to secure such exclusive rights, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and growth prospects.

Our rights to develop and commercialize our BBB platform technology and product candidates are subject, in part, to the terms and conditions of licenses granted to us by others or licenses granted by us to others.

We are heavily reliant upon licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the development of our BBB platform technology and product candidates. For example, in June 2016, we entered into a license agreement with Genentech pursuant to which we received an exclusive license to certain of Genentech's intellectual property relating to our LRRK2 program, including our DNL151 product candidate.

Our agreements with F-star and other license agreements may not provide exclusive rights to use certain licensed intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. For example, F-star retains the right to use itself, and to license to others, its modular antibody technology for any purpose other than the targets which we have agreed with F-star would or may be exclusively available to us. As a result, we may not be able to prevent competitors or other third parties from developing and commercializing competitive products that also utilizes technology that we have in-licensed.

In addition, subject to the terms of any such license agreements, we do not have the right to control the preparation, filing, prosecution and maintenance, and we may not have the right to control the enforcement, and defense of patents and patent applications covering the technology that we license from third parties. For example, under our agreements with F-star and Genentech, the licensors control prosecution and, in the case of F-star and in specified circumstances, enforcement of certain of the patents and patent applications licensed to us. Also, under our agreements with Takeda, Sanofi and Biogen, they control prosecution, and in specified circumstances, enforcement of certain of the patents and patent applications licensed to them. We cannot be certain that our in-licensed or out-licensed patents and patent applications that are controlled by our licensors or licensees will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our licensors or licensees fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, our right to develop and commercialize our BBB platform technology and any of our product candidates that are subject of such licensed rights could be adversely affected, and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. For example, our license to certain intellectual property owned by Genentech is subject to certain research rights Genentech granted to third parties prior to our license agreement. In addition, certain of our in-licensed intellectual property relating to RIPK1 was funded in part by the U.S. government. As a result, the U.S. government may have certain rights to such intellectual property. When new technologies are developed with U.S. government funding, the U.S. government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the U.S. government to use the invention or to have others use the invention on its behalf. The U.S. government's rights may also permit it to disclose the funded inventions and technology to third parties and to exercise march-in rights to use or allow third parties to use the technology we have licensed that was developed using U.S. government funding. The U.S. government may exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, or because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States in certain circumstances and if this requirement is not waived. Any exercise by the U.S. government of such rights or by any third party of its reserved rights could have a material adverse effect on our competitive position, business, financial condition, results of operations and growth prospects.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We have entered into license agreements with third parties and may need to obtain additional licenses from others to advance our research or allow commercialization of product candidates we may develop or our BBB platform technology. It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates or continue to utilize our existing BBB platform technology, which could harm our business, financial condition, results of operations and growth prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, including our BBB platform technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

In addition, each of our license agreements, and we expect our future agreements, will impose various development, diligence, commercialization, and other obligations on us. Certain of our license agreements also require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. In spite of our efforts, our licensors might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization of certain of our product candidates or of our current BBB platform technology. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and growth prospects.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and growth prospects.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting, and defending patents on our BBB platform technology, product candidates and other technologies in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Further, our ability to pursue patents throughout the world may be delayed or affected due to the COVID-19 global pandemic. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and growth prospects may be adversely affected.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and applications. In certain circumstances, we rely on our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act (the "America Invents Act"), enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our BBB platform technology, product candidates or other technologies or (ii) invent any of the inventions claimed in our or our licensor’s patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

Issued patents covering our BBB platform technology, product candidates and other technologies could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

If we or one of our licensors initiated legal proceedings against a third party to enforce a patent covering our BBB platform technology, product candidates or other technologies, the defendant could counterclaim that such patent is invalid or unenforceable or raise a defense to infringement. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of subject matter eligibility for patenting, novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Grounds for defenses to infringement include statutory exemptions to patent infringement for uses related to submitting information to regulatory authorities to seek certain regulatory approvals. Third parties may raise claims challenging the validity or enforceability of our owned or in-licensed patents before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our BBB platform technology, product candidates or other technologies. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, a judge or jury could find that our patent claims laws of nature or are otherwise ineligible for patenting, and we cannot be certain that there is no invalidating prior art, of which we or our licensing partners and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our BBB platform technology, product candidates or other technologies. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and growth prospects.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our owned or in-licensed U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permit a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar extensions as compensation for patent term lost during regulatory review processes are also available in certain foreign countries and territories, such as in Europe under a Supplementary Patent Certificate. However, we may not be granted an extension in the United States and/or foreign countries and territories because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is shorter than what we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and growth prospects could be materially harmed.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our BBB platform technology, product candidates or other technologies. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our BBB platform technology, product candidates and other technologies. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for our BBB platform technology, product candidates and other technologies, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. Trade secrets and know-how can be difficult to protect. We expect our trade secrets and know-how to over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel from academic to industry scientific positions.

We seek to protect these trade secrets and other proprietary technology, in part, by entering into nondisclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants as well as train our employees not to bring or use proprietary information or technology from former employers to us or in their work, and remind former employees when they leave their employment of their confidentiality obligations. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite our efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

We may not be successful in obtaining, through acquisitions, in-licenses or otherwise, necessary rights to our BBB platform technology, product candidates or other technologies.

We currently have rights to intellectual property, through licenses from third parties, to identify and develop our BBB platform technology and product candidates. Many pharmaceutical companies, biotechnology companies, and academic institutions are competing with us in the field of neurodegeneration and BBB technology and may have patents and have filed and are likely filing patent applications potentially relevant to our business. In order to avoid infringing these third-party patents, we may find it necessary or prudent to obtain licenses to such patents from such third-party intellectual property holders. We may also require licenses from third parties for certain BBB technologies that we are evaluating for use with our current or future product candidates. In addition, with respect to any patents we co-own with third parties, we may require licenses to such co-owners' interest to such patents. However, we may be unable to secure such licenses or otherwise acquire or in-license any compositions, methods of use, processes, or other intellectual property rights from third parties that we identify as necessary for our current or future product candidates and our BBB platform technology. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants, and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our licensors, competitors and potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Third party claims of intellectual property infringement, misappropriation or other violation against us, our licensors or our collaborators may prevent or delay the development and commercialization of our BBB platform technology, product candidates and other technologies.

The field of discovering treatments for neurodegenerative diseases, especially using BBB technology, is highly competitive and dynamic. Due to the focused research and development that is taking place by several companies, including us and our competitors, in this field, the intellectual property landscape is in flux, and it may remain uncertain in the future. As such, there may be significant intellectual property litigation and proceedings relating to our owned and in-licensed, and other third-party intellectual property and proprietary rights in the future.

Our commercial success depends in part on our, our licensors' and our collaborators' ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. As discussed above, recently, due to changes in U.S. law referred to as patent reform, new procedures including *inter partes* review and post-grant review have been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patents in the future.

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist relating to BBB technology and in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our BBB platform technology, product candidates and other technologies may give rise to claims of infringement of the patent rights of others. We cannot assure you that our BBB platform technology, product candidates and other technologies that we have developed, are developing or may develop in the future will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued and that a third party, for example, a competitor in the fields in which we are developing our BBB platform technology, product candidates, and other technologies might assert are infringed by our current or future BBB platform technology, product candidates or other technologies, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our BBB platform technology, product candidates or other technologies. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our BBB platform technology, product candidates or other technologies, could be found to be infringed by our BBB platform technology, product candidates or other technologies. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our BBB platform technology, product candidates or other technologies may infringe.

Third parties may have patents or obtain patents in the future and claim that the manufacture, use or sale of our BBB platform technology, product candidates or other technologies infringes upon these patents. In the event that any third-party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by our BBB platform technology, product candidates or other technologies. In this case, the holders of such patents may be able to block our ability to commercialize the applicable product candidate or technology unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our BBB platform technology, product candidates or other technologies, or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing our infringing BBB platform technology, product candidates or other technologies. In addition, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing product candidates or technologies, which may be impossible or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our BBB platform technology, product candidates or other technologies, which could harm our business significantly.

Engaging in litigation to defend against third parties alleging that we have infringed, misappropriated or otherwise violated their patents or other intellectual property rights is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings against us could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations or growth prospects.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time consuming, and unsuccessful.

Competitors may infringe our patents or the patents of our licensing partners, or we may be required to defend against claims of infringement. In addition, our patents or the patents of our licensing partners also may become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time consuming. In an infringement proceeding, a court may decide that a patent in which we have an interest is invalid or unenforceable, the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1), or may refuse to stop the other party from using the technology at issue on the grounds that our owned and in-licensed patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and growth prospects.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our product candidates or utilize similar technology but that are not covered by the claims of the patents that we license or may own;

- we, or our current or future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or own now or in the future;
- we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our current or future pending owned or licensed patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Risks Related to Our Operations

We are highly dependent on our key personnel, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, particularly our Chief Executive Officer, Dr. Ryan Watts, and our scientific and medical personnel. The loss of the services provided by any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements, could result in delays in the development of our product candidates and harm our business.

We conduct our operations at our facility in South San Francisco, California, in a region that is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel is intense and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We expect that we may need to recruit talent from outside of our region, and doing so may be costly and difficult.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided restricted stock and stock option grants that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key man" insurance policies on the lives of all of these individuals or the lives of any of our other employees. If we are unable to attract and incentivize quality personnel on acceptable terms, or at all, it may cause our business and operating results to suffer.

We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth.

As of September 30, 2020, we had 281 employees, all of whom were full-time. As our development plans and strategies develop, we must add a significant number of additional managerial, operational, financial, and other personnel. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, retaining, and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our current and future product candidates, while complying with our contractual obligations to contractors and other third parties;
- expanding our operational, financial and management controls, reporting systems, and procedures; and
- managing increasing operational and managerial complexity.

Our future financial performance and our ability to continue to develop and, if approved, commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to manage these growth activities. Our ability to successfully manage our expected growth is uncertain given the fact that all of our executive officers have joined us since February 2015. This lack of long-term experience working together as a company may adversely impact our senior management team's ability to effectively manage our business and growth.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. There can be no assurance that the services of these independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop our product candidates and, accordingly, may not achieve our research, development, and commercialization goals.

We have engaged in and may in the future engage in acquisitions or strategic partnerships, which may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We have in the past engaged in acquisitions and strategic partnerships, and we may engage in various acquisitions and strategic partnerships in the future, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. For instance, in January 2018 we entered into the Takeda Collaboration Agreement, as amended in February 2019, and in connection therewith we issued and sold to Takeda 4,214,559 shares of our common stock for an aggregate purchase price of $110.0 million in February 2018. On May 30, 2018, we exercised our buy-out option in connection with the F-star Collaboration Agreement and entered into a Purchase Agreement pursuant to which we acquired all of the outstanding shares of F-star Gamma. Further, on October 29, 2018, we entered into the Sanofi Collaboration Agreement. In August 2020, we entered into the Provisional Biogen Collaboration Agreement, and in connection therewith we sold $13,310,243 shares of our common stock to Biogen in September 2020 for an aggregate purchase price of $465.0 million. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent liabilities;
- the issuance of our equity securities which would result in dilution to our stockholders;
- assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such an acquisition or strategic partnership;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired intellectual property, technology and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs.

In addition, if we undertake such a transaction, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

Our internal computer systems, or those used by our third-party research institution collaborators, CROs or other contractors or consultants, may fail or suffer other breakdowns, cyberattacks or information security breaches that could compromise the confidentiality, integrity, and availability of such systems and data, expose us to liability, and affect our reputation.

We are increasingly dependent upon information technology systems, infrastructure, and data to operate our business. We also rely on third-party vendors and their information technology systems. Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants may be vulnerable to damage from computer viruses or unauthorized access, or breached due to operator error, malfeasance or other system disruptions. As the cyber-threat landscape evolves, these attacks are growing in frequency, sophistication and intensity, and are becoming increasingly difficult to detect. These threats can come from a variety of sources, ranging in sophistication from an individual hacker to a state-sponsored attack. Cyber threats may be generic, or they may be custom-crafted against our information systems. Over the past few years, cyber-attacks have become more prevalent, intense, sophisticated and much harder to detect and defend against. Such attacks could include the use of key loggers or other harmful and virulent malware, including ransomware or other denials of service, and can be deployed through malicious websites, the use of social engineering and/or other means. We and our third-party vendors may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources. Although to our knowledge we and our vendors have not experienced any such material system failure or security breach to date, if a breakdown, cyberattack or other information security breach were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations , whether due to a loss of trade secrets or other proprietary information or other similar disruption and we could incur liability and reputational damage. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on our third-party research institution collaborators for research and development of our product candidates and other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business.

Cyber-attacks, breaches, interruptions or other data security incidents could result in legal claims or proceedings, liability under federal or state laws that protect the privacy of personal information, regulatory penal-ties, significant remediation costs, disrupt key business operations and divert attention of management and key information technology resources. In the United States, notice of breaches must be made to affected individuals, the U.S. Secretary of the Department of Health and Human Services ("HHS"), and for extensive breaches, notice may need to be made to the media or U.S. state attorneys general. Such a notice could harm our reputation and our ability to compete. The HHS has the discretion to impose penalties without attempting to resolve violations through informal means. In addition, U.S. state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. There can be no assurance that we, our collaborators, CROs, vendors, and any other business counterparties will be successful in efforts to detect, prevent, protect against or fully recover systems or data from all break-downs, service interruptions, attacks or breaches of systems. In addition, we do not maintain standalone cyber-security insurance and have limited insurance coverage in the event of any breach or disruption of our or our collaborators', CROs', or vendors' systems, including any unauthorized access or loss of any personal data that we may collect, store or otherwise process. The costs related to significant security breaches or disruptions could be material and exceed the limits of any insurance coverage we may have. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary information, including data related to our personnel, we could incur liability and the further development and commercialization of our product candidates could be delayed and our business and operations could be adversely affected and/or could result in the loss or disclosure of critical or sensitive data, which could result in financial, legal, business or reputational harm to us.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our third-party research institution collaborators, CROs, CDMOs, suppliers, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics such as COVID-19, and other natural or man-made disasters or business interruptions, for which we are partly uninsured. In addition, we rely on our third-party research institution collaborators for conducting research and development of our product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

All of our operations including our corporate headquarters are located in a single facility in South San Francisco, California. Damage or extended periods of interruption to our corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

Our business is subject to economic, political, regulatory and other risks associated with international operations.

Our business is subject to risks associated with conducting business internationally. Some of our suppliers and collaborative relationships are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- differing and changing regulatory requirements in non-U.S. countries;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- difficulties in compliance with non-U.S. laws and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- difficulties associated with staffing and managing international operations, including differing labor relations;

- potential liability under the FCPA, UK Bribery Act or comparable foreign laws;
- business interruptions resulting from geo-political actions, including war and terrorism, natural disasters including earthquakes, typhoons, floods and fires, or health epidemics such as COVID-19; and
- cyberattacks, which are growing in frequency, sophistication and intensity, and are becoming increasingly difficult to detect.

These and other risks associated with our planned international operations may materially adversely affect our ability to attain profitable operations.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2019, we had federal net operating loss carryforwards of approximately $221.5 million, federal research and development tax credit carryforwards of approximately $14.5 million, and orphan tax credit carryforwards of approximately $1.7 million, some of which will begin to expire in 2035. Under Sections 382 and 383 of the United States Internal Revenue Code of 1986, as amended, (the "Code"), if a corporation undergoes an “ownership change” (generally defined as a greater than 50-percentage-point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three-year period), the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change taxable income or taxes may be limited. As a result of our IPO in December 2017, our follow-on offering in January 2020, and private placements and other transactions that have occurred since our incorporation, we may have experienced such an ownership change. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. As a result, our ability to use our pre-change net operating loss carryforwards and other pre-change tax attributes to offset post-change taxable income or taxes may be subject to limitation.

We may be subject to adverse legislative or regulatory tax changes that could negatively impact our financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the IRS and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our stockholders or us. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, in December 2017, Congress passed the Tax Cuts and Jobs Act, which made broad and complex changes to the tax laws. We cannot predict whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or decided, which could result in an increase in our, or our stockholders’, tax liability or require changes in the manner in which we operate in order to minimize increases in our tax liability.

Risks Related to Ownership of Our Common Stock

The market price of our common stock has been and may continue to be volatile, which could result in substantial losses for investors.

The trading price of our common stock has been and may continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this report, these factors include:

- the success of existing or new competitive products or technologies;

- the timing and results of clinical trials for our current product candidates and any future product candidates that we may develop;
- commencement or termination of collaborations for our product development and research programs;
- failure to achieve development, regulatory or commercialization milestones under our collaborations;
- failure or discontinuation of any of our product development and research programs;
- failure to develop our BBB platform technology;
- results of preclinical studies, clinical trials, or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents, or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our research programs, clinical development programs, or product candidates that we may develop;
- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines, or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders, or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- adoption of new accounting standards or changes in accounting standards;
- ineffectiveness of our internal controls;
- significant lawsuits, including patent or stockholder litigation;
- market conditions in the pharmaceutical and biotechnology sectors; and
- general economic, industry, and market conditions, including those caused by the COVID-19 pandemic.

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. In the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of any such lawsuits could be costly and divert the time and attention of our management and harm our operating results, regardless of the merits of such a claim.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock and trading volume could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price or trading volume to decline.

Sales of substantial amounts of our common stock in the public markets, or the perception that such sales might occur, could cause the market price of our common stock to decline significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

Sales of our common stock by current stockholders may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate, and make it more difficult for you to sell shares of our common stock.

Certain holders of shares of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Registration of these shares under the Securities Act would result in the shares becoming freely tradeable in the public market, subject to the restrictions of Rule 144 in the case of our affiliates. Any sales of securities by these stockholders could have a material adverse effect on the market price for our common stock.

We have registered on Form S-8 all shares of common stock that are issuable under our 2017 Equity Incentive Plan and 2017 Employee Stock Purchase Plan. As a consequence, these shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. For example, in August 2020, we entered into the Provisional Biogen Collaboration Agreement, and in connection therewith issued and sold 13,310,243 shares of our common stock to Biogen in September 2020 for an aggregate purchase price of $465 million. We, and indirectly, our stockholders, will bear the cost of issuing and servicing all such securities.

Because our decision to issue debt or equity securities in any future offering will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of any future offerings. To the extent that we raise additional capital through the sale of equity or debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

On March 12, 2019, we filed a shelf registration statement on Form S-3 (File No. 333-230232) with the Securities and Exchange Commission, which became effective upon filing. In January 2020, we sold 9.0 million shares of common stock in a follow-on offering pursuant to this registration statement. The shelf registration continues to allow us to sell, from time to time, an unspecified number of shares of common stock; shares of preferred stock; debt securities; warrants to purchase shares of common stock, preferred stock, or other securities; purchase contracts; and units representing two or more of the foregoing securities. Additionally, collaborations we enter into with third parties may provide capital in the near term but limit our potential cash flow and revenue in the future. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

As of September 30, 2020, our directors, executive officers, holders of more than 5% of our outstanding stock and their respective affiliates beneficially own shares representing more than 50.0% of our outstanding common stock. As a result, these stockholders, if they act together, may significantly influence all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control of our company that our other stockholders may believe is in their best interests. This in turn could have a material adverse effect on our stock price and may prevent attempts by our stockholders to replace or remove the board of directors or management.

If we are unable to maintain effective internal controls, our business, financial position and results of operations and growth prospects could be adversely affected.

As a public company, we are subject to reporting and other obligations under the Securities Exchange Act of 1934, as amended, (the "Exchange Act"), including the requirements of Section 404 of the Sarbanes-Oxley Act, which require annual management assessments of the effectiveness of our internal control over financial reporting.

The rules governing the standards that must be met for management and our auditors to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During the course of its testing, our management or auditors may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act. These reporting and other obligations place significant demands on our management and administrative and operational resources, including accounting resources.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Any failure to maintain effective internal controls could have an adverse effect on our business, financial position, results of operations and growth prospects.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

We have not paid and do not expect to pay any dividends for the foreseeable future. Any return on investment may be limited to the value of our common stock. Investors may never obtain a return on their investment.

We have never paid cash dividends on our common stock and do not anticipate that we will pay any dividends in the foreseeable future. We currently intend to retain our future earnings, if any, to maintain and expand our existing operations. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if our stock price appreciates, which may never occur.

Delaware law and provisions in our charter documents might discourage, delay, or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay, or prevent a merger, acquisition, or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our charter documents:

- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three-year terms;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may only be removed for cause;
- eliminate cumulative voting in the election of directors;

- authorize our board of directors to issues shares of preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;
- provide our board of directors with the exclusive right to elect a director to fill a vacancy or newly created directorship;
- permit stockholders to only take actions at a duly called annual or special meeting and not by written consent;
- prohibit stockholders from calling a special meeting of stockholders;
- require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;
- authorize our board of directors, by a majority vote, to amend the bylaws; and
- require the affirmative vote of at least 66 2/3% or more of the outstanding shares of common stock to amend many of the provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware, (the "DGCL"), prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15.0% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws, or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of fiduciary duty;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

Our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action or we do not enforce such provision, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Recent Sales of Unregistered Securities

On September 22, 2020, we issued and sold 13,310,243 shares of our common stock to Biogen for an aggregate purchase price of $465.0 million pursuant to the terms of a common stock purchase agreement with Biogen and in connection with the Biogen Collaboration Agreement. No underwriters were involved in the sale and the book entry position representing the securities sold and issued contain legends restricting transfer of the securities without registration under the Securities Act or an applicable exemption from registration.

The offer, sale and issuance of the securities described above was exempt from registration under the Securities Act under Section 4(a)(2) of the Securities Act as a transaction by an issuer not involving a public offering. The recipient of securities in this transaction acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in this transaction. The recipient of securities in this transaction was an accredited person and had adequate access, through employment, business or other relationships, to information about the registrant.

Use of Proceeds from Registered Securities

On December 7, 2017, our Registration Statement on Form S-1 (File No. 333-221522) was declared effective by the SEC for our initial public offering of common stock. We started trading on The NASDAQ Global Select Market on December 8, 2017, and the transaction formally closed on December 12, 2017. In connection with the initial public offering, we sold an aggregate of 15,972,221 shares of common stock at a price to the public of $18.00 per share, for net proceeds of $264.3 million. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10.0% or more of any class of our equity securities or to any of our affiliates. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC on December 8, 2017 pursuant to Rule 424(b)(4). We invested the funds received in short-term, interest-bearing investment-grade securities and government securities.

On January 28, 2020, we sold 9.0 million shares of common stock (inclusive of shares sold pursuant to an overallotment option granted to the underwriters in connection with the offering) through an underwritten public offering at a price of $23.00 per share for aggregate net proceeds of $193.9 million. There has been no material change in the planned use of the net proceeds from the follow-on public offering as described in our final prospectus supplement filed with the SEC on January 29, 2020. We invested the funds received in short-term, interest-bearing investment-grade securities and government securities.

Issuer Purchases of Equity Securities

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

EXHIBIT INDEX

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Number	Filing Date
10.1	Common Stock Purchase Agreement between the Registrant and Biogen Inc., dated August 5, 2020.	—	—	—	Filed herewith
10.2#	Provisional LRRK2 Collaboration and License Agreement between the Registrant and Biogen Inc., dated August 5, 2020.	—	—	—	Filed herewith
10.3	Standstill and Stock Restriction Agreement between the Registrant and Biogen Inc., dated September 22, 2020.	—	—	—	Filed herewith
10.4#	Definitive LRRK2 Collaboration and License Agreement between the Registrant and Biogen Inc., dated October 4, 2020.	—	—	—	Filed herewith
10.5#	Definitive Right of First Negotiation, Option and License Agreement between the Registrant and Biogen Inc., dated October 6, 2020.	—	—	—	Filed herewith
10.6#	Form of Amended and Restated Change in Control and Severance Plan.	—	—	—	Filed herewith
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act.	—	—	—	Filed herewith
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act.	—	—	—	Filed herewith
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act.	—	—	—	Furnished herewith
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act.	—	—	—	Furnished herewith
101.INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Incline XBRL document	—	—	—	Furnished herewith
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	—	—	—	Furnished herewith
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	—	—	—	Furnished herewith
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	—	—	—	Furnished herewith
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	—	—	—	Furnished herewith
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	—	—	—	Furnished herewith
104	The cover page from the Company's Quarterly Report on Form 10-Q for the three months ended September 30, 2020, formatted in Inline XBRL (contained in Exhibit 101)	—	—	—	Furnished herewith

* The certifications attached as Exhibits 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Denali Therapeutics Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.

\# Portions of this exhibit (indicated by asterisks) have been omitted in connection with the rules of the SEC.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

DENALI THERAPEUTICS INC.

Date: November 5, 2020

By: /s/ Ryan J. Watts
Ryan J. Watts, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 5, 2020

By: /s/ Steve E. Krognes
Steve E. Krognes
Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)

Exhibit 10.1

Execution Version

COMMON STOCK PURCHASE AGREEMENT

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EXHIBITS

COMMON STOCK PURCHASE AGREEMENT

THIS COMMON STOCK PURCHASE AGREEMENT (this "**Agreement**"), is made as of August 5, 2020 by and among Denali Therapeutics Inc., a Delaware corporation (the "**Company**"), and Biogen MA Inc., a Massachusetts corporation (the "**Investor**").

The parties hereby agree as follows:

1. Defined Terms Used in this Agreement. In addition to the terms defined above, the following terms used in this Agreement shall be construed to have the meanings set forth or referenced below.

(a) "**Accredited Investor**" means an "accredited investor" within the meaning of SEC Rule 501 of Regulation D, as presently in effect.

(b) "**Affiliate**" means, with respect to a Person, any other Person that, directly or indirectly, through one (1) or more intermediaries, controls, is controlled by or is under common control with such Person. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" means (a) the possession, directly or indirectly, of the power to direct the management or policies of a Person, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise; or (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of a Person (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity). The parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that, in such case, such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management or policies of such entity.

(c) "**Antitrust Clearance Date**" means the date that is the date on which all of the following conditions have been met: (i) the waiting periods under the HSR Act and any other Antitrust Law, to the extent applicable to the transactions contemplated by this Agreement, the Provisional Collaboration and License Agreement and/or the Definitive Collaboration Agreement, shall have expired or earlier been terminated; (ii) no judicial or administrative proceeding opposing consummation of all or any part of this Agreement, the Provisional Collaboration and License Agreement or the Definitive Collaboration Agreement shall be pending; (iii) no law, order or injunction (whether temporary, preliminary or permanent) prohibiting consummation of the transactions contemplated by this Agreement, the Provisional Collaboration and License Agreement or the Definitive Collaboration Agreement, or any material portion hereof or thereof shall be in effect (each of clauses (i) through (iii), collectively, the "**Antitrust Conditions**"), unless either party earlier exercises its termination right under Section 9.4 at any time prior to the Antitrust Clearance Date.

(d) "**Antitrust Law**" means the HSR Act, the Sherman Antitrust Act, as amended, the Clayton Act, as amended, the Federal Trade Commission Act, as amended, and any other applicable law designed to prohibit, restrict or regulate actions or transactions having the purpose or effect of monopolization, restraint of trade or harm to competition.

(e) "**Board**" means the Board of Directors of the Company.

(f) "**Business Day**" means a day, other than a Saturday or Sunday, on which banking institutions in San Francisco, California, U.S.A. are open for business.

(g) "**Closing**" has the meaning set forth in Section 2.2(a).

(h) "**Code**" means the Internal Revenue Code of 1986, as amended.

(i) "**Common Stock**" has the meaning set forth in Section 3.2(a)(i).

(j) "**Company SEC Reports**" has the meaning set forth in Section 3.12(a).

(k) "**Definitive LRRK2 Collaboration and License Agreement**" has the meaning set forth in the Provisional Collaboration and License Agreement.

(l) "**Denali IP**" has the meaning set forth in the Provisional Collaboration and License Agreement.

(m) "**Denali Know-How**" has the meaning set forth in the Provisional Collaboration and License Agreement.

(n) "**Denali Patents**" has the meaning set forth in the Provisional Collaboration and License Agreement.

(o) "**DOJ**" means the U.S. Department of Justice.

(p) "**Exchange Act**" means the Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

(q) "**Financial Statements**" has the meaning set forth in Section 3.10(b).

(r) "**FTC**" means the U.S. Federal Trade Commission.

(s) "**GAAP**" means U.S. generally accepted accounting principles.

(t) "**HSR Act**" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder.

(u) "**Knowledge,**" including the phrase "to the Company's knowledge," shall mean the actual knowledge (after reasonable inquiry of their direct reports) of the President and Chief Executive Officer, Chief Operating Officer, Chief Financial Officer and Chief Medical Officer of the Company.

(v) "**Material Adverse Effect**" means a material adverse effect on the business, assets (including intangible assets), liabilities, financial condition, property, or results of operations of the Company, taken as a whole; provided however, that, none of the following (alone or when aggregated any other effects), shall be deemed to be a Material Adverse Effect, and none of the following (alone or when aggregated any other effects), shall be taken into account: (A) (1) general market, economic or political conditions that do not have a disproportionate effect on the Company relative to other companies operating in the Company's industry or (2) conditions (or any changes therein) in the industries in which the Company conducts business, including any acts of terrorism or war, weather conditions, global virus epidemics or other force majeure events that do not have a disproportionate effect on the Company relative to other companies operating in the Company's industry; (B) the execution of this Agreement, the Provisional Collaboration and License Agreement, the Definitive LRRK2 Collaboration and License Agreement and the pendency of the transactions contemplated hereby and thereby; or (C) (1) regulatory, manufacturing or clinical changes resulting from any studies conducted or sponsored by the Company, or clinical trial meetings (and communications related thereto), and including, for the avoidance of doubt, any increased incidence or severity of any side effects, adverse effects, adverse events or safety observations (new or previously identified); (2) any determination (or delay thereof), positive or negative, with respect to the acceptance, filing, designation, approval, or clearance of any of the Company's product candidates; (3) approval (or other clinical or regulatory developments), market entry (or threat thereof) of competitive products, or any regulatory developments, guidance, announcement or publication relating to any of the Company's product candidates; or (4) changes in the trading price or volume of the company's Common Stock.

(w) "**Outside Date**" has the meaning set forth in Section 9.4.

(x) "**Per Share Purchase Price**" shall mean $34.9355, which amount is equal to 140% of the BLOOMBERG daily volume-weighted average per share price of the Common Stock on Nasdaq over the thirty (30) trading day period ending on and including the last trading day prior to the date hereof.

(y) "**Permits**" has the meaning set forth in Section 3.9.

(z) "**Person**" means any individual, corporation, partnership, trust, limited liability company, association or other entity.

(aa) "**Preferred Stock**" has the meaning set forth in Section 3.2(a)(ii).

(bb) "**Provisional Collaboration and License Agreement**" means that certain Provisional Collaboration and License Agreement, dated August 5, 2020, by and between the Company, the Investor and Biogen International GmbH, a Gesellschaft mit beschränkter Haftung organized under the laws of Switzerland.

(cc) "**Purchase Price**" has the meaning set forth in Section 2.1.

(dd) "**Required Filings**" has the meaning set forth in Section 9.3(a).

(ee) "**Restated Certificate**" means the current Amended and Restated Certificate of Incorporation of the Company.

(ff) "**Rule 144**" has the meaning set forth in Section 4.6.

(gg) "**SEC**" means the U.S. Securities and Exchange Commission.

(hh) "**Securities Act**" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

(ii) "**Shares**" has the meaning set forth in Section 2.1.

(jj) "**Standstill and Stock Restriction Agreement**" means the agreement between the Company and the Investor in the form of Exhibit A attached to this Agreement.

(kk) "**Transaction Agreements**" means this Agreement and the Standstill and Stock Restriction Agreement.

2. Purchase and Sale of Common Stock.

2.1 Sale and Issuance of Common Stock. Subject to the terms and conditions of this Agreement, Investor agrees to purchase at the Closing, and the Company agrees to sell and issue to Investor at the Closing, 13,310,243 shares of Common Stock (the "**Shares**") at the Per Share Purchase Price for an aggregate purchase price of $464,999,994.33 (the "**Purchase Price**"), payable by wire transfer to a bank account designated by the Company in writing to Investor at least three (3) Business Days prior to the Closing.

2.2 Closing; Delivery; Adjustments.

(a) The purchase and sale of the Shares shall take place remotely via the exchange of documents and signatures on the third (3rd) Business Day after the final condition set forth in Sections 7 and 8 is satisfied or waived (other than those conditions that by their nature are to be satisfied or waived at the Closing) or at such other time and place as the Company and the Investor mutually agree upon, orally or in writing (which time and place are designated as the "**Closing**"). At the Closing, the Company shall sell, and the Investor shall purchase, the Shares.

(b) At the Closing, the Company shall instruct its transfer agent to deliver confirmation of book-entry issuance of the Shares being purchased by Investor at such Closing against payment of the Purchase Price therefor.

(c) All numbers of shares and dollar amounts set forth in this Agreement are subject to appropriate adjustment in the event of any stock dividend, stock split, recapitalization, merger, consolidation, or similar event affecting such shares.

3. Representations and Warranties of the Company. The Company hereby represents and warrants to the Investor that:

3.1 Organization, Good Standing, Corporate Power and Qualification. The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware and has all requisite corporate power and authority to carry on its business as presently conducted and as proposed to be conducted. The Company is duly qualified to transact business and is in good standing in each jurisdiction in which the failure to so qualify would have a Material Adverse Effect.

3.2 Company Capitalization and Voting Rights.

(a) The authorized and issued capital of the Company consists, as of July 31, 2020, of:

(i) 400,000,000 shares of Common Stock, $0.01 par value per share, of the Company (the "**Common Stock**"), of which (i) 105,984,031 shares are issued and outstanding, (ii) 4,498,311 shares are reserved for issuance pursuant to the Company's stock incentive plans, (iii) 2,457,049 shares are reserved for issuance pursuant to the Company's employee stock purchase plan and (iv) 15,573,822 shares are issuable upon the exercise of stock options outstanding, vesting of restricted stock awards outstanding and vesting of restricted stock unit awards outstanding. All of the outstanding shares of Common Stock have been duly authorized, are fully paid and nonassessable and were issued in compliance with all applicable federal and state securities laws.

(ii) 40,000,000 shares of Preferred Stock, $0.01 par value per share, of the Company (the "**Preferred Stock**"), none of which are issued and outstanding.

(b) All of the authorized shares of Common Stock are entitled to one (1) vote per share.

(c) Except as described or referred to in the Company SEC Reports, there were not any outstanding equity securities, options, warrants, rights (including conversion or preemptive rights) or other agreements pursuant to which the Company is or may become obligated to issue, sell or repurchase any shares of its capital stock or any other securities of the Company other than equity securities that may have been granted pursuant to its stock incentive plans, which plans are described in the Company SEC Reports.

(d) Except as described or referred to in the Company SEC Reports, the Company is not a party to or subject to any agreement or understanding relating to the voting of shares of capital stock of the Company or the giving of written consents by a stockholder or director of the Company.

3.3 Subsidiaries. The Company currently has one wholly owned subsidiary, Denali BBB Holding Limited, a company organized under the laws of the United Kingdom. Except as otherwise disclosed in the Company SEC Reports, the Company is not a participant in any joint venture, partnership or similar arrangement.

3.4 Authorization. The Company has all requisite corporate power and authority to enter into and to perform its obligations under the Transaction Agreements, to consummate the transactions contemplated by the Transaction Agreements and to issue the Shares in accordance with the terms of this Agreement. All corporate action required to be taken by the Company's Board and stockholders in order to enter into the Transaction Agreements and to issue the Shares at the Closing, has been taken. All action on the part of the officers of the Company necessary for the execution and delivery of the Transaction Agreements, the performance of all obligations of the Company under the Transaction Agreements to be performed as of the Closing and the issuance and delivery of the Shares has been taken or will be taken prior to the Closing. The Transaction Agreements, when executed and delivered by the Company, shall constitute valid and legally binding obligations of the Company, enforceable against the Company in accordance with their respective terms except (a) as limited by applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance, or other laws of general application relating to or affecting the enforcement of creditors' rights generally, or (b) as limited by laws relating to the availability of specific performance, injunctive relief, or other equitable remedies.

3.5 Valid Issuance of Shares. The Shares have been duly authorized and, when issued, sold and delivered in accordance with the terms and for the consideration set forth in this Agreement, will be (a) validly issued, fully paid and nonassessable, (b) free of restrictions on transfer other than restrictions on transfer under the Transaction Agreements, applicable state and federal securities laws and liens or encumbrances created by or imposed by any Investor and (c) not subject to preemptive rights or other similar rights of stockholders of the Company. Assuming the accuracy of the representations of the Investor in Section 4 of this Agreement and subject to Section 3.6 below, the Shares will be issued in compliance with all applicable federal and state securities laws.

3.6 Governmental Consents and Filings. Assuming the accuracy of the representations made by the Investor in Section 4 of this Agreement, no consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with any federal, state, local or foreign governmental authority is required on the part of the Company in connection with the consummation of the transactions contemplated by this Agreement, except for filings pursuant to applicable federal or state securities laws, which have been made or will be made in a timely manner, and compliance with the HSR Act and such other Antitrust Law as may be applicable to this Agreement, the Provisional Collaboration and License Agreement and/or the Definitive Collaboration Agreement.

3.7 Litigation. There is no claim, action, suit, proceeding, arbitration, complaint, charge or, to the Company's knowledge, investigation pending or, to the Company's knowledge, currently threatened in writing against the Company or any officer or director of the Company that questions the validity of the Transaction Agreements or the right of the Company to enter into them, or to consummate the transactions contemplated by the Transaction Agreements, or would reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect.

3.8 Compliance with Other Instruments. The Company is not in conflict, violation, breach or default (a) of any provisions of its Restated Certificate or Bylaws, (b) of any instrument, judgment, order, writ or decree, (c) under any investor rights agreement, other material agreement, note, indenture, deed of trust, license, lease agreement or mortgage where such conflict, violation, breach or default would have a Material Adverse Effect, or (d) to the Company's knowledge, of any provision of federal or state statute, rule or regulation applicable to the Company, the violation of which would have a Material Adverse Effect. The execution, delivery and performance of the Transaction Agreements and the consummation of the transactions contemplated by the Transaction Agreements will not result in (x) any such conflict, violation, breach or default described in Section 3.8(a)-(d) above, or (y) an event which results in the creation of any lien, charge or encumbrance upon any assets of the Company or the suspension, revocation, forfeiture, or nonrenewal of any material permit or license applicable to the Company.

3.9 Licenses and Other Rights; Compliance with Laws. The Company has all franchises, permits, licenses and other rights and privileges ("**Permits**") necessary to permit it to own its properties and to conduct its business as presently conducted and is in compliance thereunder, except where the failure to be in compliance would not reasonably be expected to have a Material Adverse Effect. To the Company's knowledge, the Company has not taken any action that would interfere with its ability to renew all such Permit(s), except where the failure to renew such Permit(s) would not reasonably be expected to have a Material Adverse Effect. The Company is and has been in compliance with all laws applicable to its business, properties and assets, except where the failure to be in compliance has not had and would not reasonably be expected to have a Material Adverse Effect.

3.10 Property. The property and assets that the Company owns are free and clear of all mortgages, deeds of trust, liens, loans and encumbrances, except for statutory liens for the payment of current taxes that are not yet delinquent and encumbrances and liens that arise in the ordinary course of business and do not materially impair the Company's ownership or use of such property or assets. With respect to the property and assets it leases, the Company is in compliance with such leases and, to the Company's knowledge, holds a valid leasehold interest free of any liens, claims or encumbrances other than those of the lessors of such property or assets. The Company does not own any real property.

3.11 Intellectual Property.

(a) No claim, suit, proceeding, settlement, arbitration, citation, summons, or subpoena of any nature, civil, criminal, regulatory or otherwise, in law or in equity, has been brought or obtained against the Company or any of its affiliates relating to the Denali IP. No claim, suit, proceeding, arbitration, citation, summons, or subpoena of any nature, civil, criminal, regulatory or otherwise, in law or in equity, to the Company's knowledge, has been threatened in writing by any person: (i) challenging the ownership, scope, duration, validity, enforceability, priority or right to use the Denali Patents (including, by way of example, through the institution of or written threat of institution of interference, *inter partes* review, reexamination, protest, opposition, nullity, or similar invalidity proceeding before the United States Patent and Trademark Office or any foreign patent authority or court) or (ii) alleging that the Denali IP, or the disclosing, copying, making, or licensing of the Denali IP, or the Development or Commercialization of the Compounds or Products (each, as defined in the Provisional Collaboration and License Agreement) contemplated by the Provisional Collaboration and License Agreement, does or will violate, infringe, misappropriate or otherwise conflict or interfere with, any patent or other intellectual property or proprietary right of any person.

(b) To the Company's knowledge, (i) the Company has the right to use all Denali Know-How and Denali Patents necessary to conduct the activities under the LRRK2 Program with respect to LRRK2 Licensed Compounds and LRRK2 Licensed Products (each as defined in the Provisional Collaboration and License Agreement) and (ii) the Development or Commercialization of the LRRK2 Licensed Compounds and LRRK2 Licensed Products as contemplated by the Provisional Collaboration and License Agreement will not conflict with any other license or agreement to which the Company or any of its affiliates is a party.

(c) To the Company's knowledge, the Denali Patents with respect to which the Company controls prosecution and maintenance activities are being prosecuted in the respective patent offices worldwide in accordance with applicable law.

(d) To the Company's knowledge, all fees required to be paid by the Company in any jurisdiction where a Denali Patent with respect to which the Company controls prosecution and maintenance activities has issued in order to maintain such Denali Patent in such jurisdiction have been timely paid and to the Company's knowledge, the Denali Patents that have issued are subsisting, valid and enforceable.

(e) The inventorship of the Denali Patents is properly identified on each issued patent or patent application (in the form such patent application exists as of the date hereof) in the Denali Patents for which all inventors were employees of the Company or its affiliates at the time of such invention.

(f) The Company has not previously assigned, transferred, conveyed or granted any license or other rights under the Denali IP that would conflict with or limit the scope of any of the rights or licenses granted to the Investor under the Provisional Collaboration and License Agreement.

(g) To the Company's knowledge, no person is infringing or threatening to infringe or misappropriating or threatening to misappropriate or otherwise violating or threatening to violate the Denali IP.

(h) The Company's rights, title and interests to all Denali IP are free of any lien or security interest.

(i) No written claim has been filed, or to the Company's knowledge, threatened in writing, against it by any third party alleging that the conception, development, or reduction to practice of the Denali IP owned by the Company involve the misappropriation of trade secrets or other violation of the rights or property of any person.

(j) The Company has obtained, or caused its affiliates, as applicable, to obtain, assignments from the inventors of any Denali IP who were employees of the Company or its affiliates at the time of the invention, of all inventorship rights to such Denali IP, and, to the Company's knowledge, all such assignments are valid and enforceable.

(k) Except for Existing LRRK2 Agreements and Existing Option Program Agreements (each as defined in the Provisional Collaboration and License Agreement), no third party has any rights, title or interests in or to, or any license under, any of the Denali IP that would conflict with the rights and licenses granted to Investor under the Provisional Collaboration and License Agreement.

(l) The Company and its affiliates have taken commercially reasonable measures consistent with industry practices to protect the secrecy, confidentiality and value of all Denali Know-How that constitutes trade secrets under applicable law (including requiring all employees, consultants and independent contractors to execute binding and enforceable agreements requiring all such employees, consultants, and independent contractors to maintain the confidentiality of such Denali Know-How) and, to the Company's knowledge, such Denali Know-How has not been used or disclosed to any third party except pursuant to such confidentiality agreements, and to the Company's knowledge, there has not been a breach by any party to such confidentiality agreements.

3.12 SEC Filings; Financial Statements.

(a) The Common Stock is registered pursuant to Section 12(b) of the Exchange Act. The Company has timely and properly filed all forms, schedules, reports, prospectuses, proxy statements and documents required to be filed by the Company with the SEC (the "**Company SEC Reports**"). The Common Stock is currently listed on the Nasdaq Global Select Market. The Company is not in violation of the listing requirements of the Nasdaq Stock Market LLC, has no Knowledge of any facts that would reasonably lead to delisting or suspension of its Common Stock from the Nasdaq Stock Market LLC and has not received any written notification that, and has no Knowledge that, the SEC or the Nasdaq Stock Market LLC is contemplating terminating such listing. The Company SEC Reports (i) at the time they were filed (or if amended or superseded by a filing prior to the date of this Agreement, then on the date of such filing) complied in all material respects with the requirements of the Securities Act or the Exchange Act, as the case may be, and the rules and regulations promulgated thereunder, and (ii) did not at the time they were filed (or if amended or superseded by a filing prior to the date of this Agreement, then on the date of such filing) contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The Company makes no representation or warranty whatsoever concerning the Company SEC Reports as of any time other than the time they were filed, amended or superseded.

(b) Each of the consolidated financial statements (including, in each case, any related notes thereto) (the "**Financial Statements**") contained in the Company SEC Reports has been prepared in accordance with GAAP applied on a consistent basis throughout the period involved (except as may be indicated in the notes thereto) and complied in all material respects with the rules and regulations of the SEC and all applicable accounting requirements. Each of the Financial Statements fairly presents in all material respects the consolidated financial position of the Company at the respective dates thereof and the consolidated results of its operations and cash flows for the periods indicated, except that the unaudited interim financial statements were or are subject to normal and recurring year-end adjustments which have not had or are not expected to have, individually or in the aggregate, a Material Adverse Effect.

3.13 Internal Controls; Disclosure Controls and Procedures. The Company maintains internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. The Company has implemented the "disclosure controls and procedures" (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) required in order for the principal executive officer and principal financial officer of the Company to engage in the review and evaluation process mandated by the Exchange Act, and is in compliance with such disclosure controls and procedures in all material respects. Each of the principal executive officer and the principal financial officer of the Company has made all certifications required by Sections 302 and 906 of the Sarbanes-Oxley Act of 2002 with respect to all reports, schedules, forms, statements and other documents required to be filed by the Company with the SEC.

3.14 Private Placement. Neither the Company nor any person acting on its behalf, has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under any circumstances that would require registration of the Shares under the Securities Act. Subject to the accuracy of the representations made by the Investor in Section 4, the Shares will be issued and sold to the Investor in compliance with applicable exemptions from the registration and prospectus delivery requirements of the Securities Act and the registration and qualification requirements of all applicable securities laws of the states of the United States. The Company has not engaged any brokers, finders or agents, or incurred, or will incur, directly or indirectly, any liability for brokerage or finder's fees or agents' commissions or any similar charges in connection with this Agreement and the transactions contemplated hereby.

3.15 Changes.

(a) Except as otherwise disclosed in the Company SEC Reports, since March 31, 2020, there has not been any change in the assets, liabilities, financial condition or operating results of the Company from that reflected in the Financial Statements, except changes or events in the ordinary course of business that have not caused a Material Adverse Effect.

(b) Except as set forth in the Company SEC Reports filed prior to March 31, 2020, the Company has not (i) declared or paid any dividends, or authorized or made any distribution upon or with respect to any class or series of its capital stock, or (ii) sold, exchanged or otherwise disposed of any of its material assets or rights.

(c) Since March 31, 2020, the Company has not admitted in writing its inability to pay its debts generally as they become due, filed or consented to the filing against it of a petition in bankruptcy or a petition to take advantage of any insolvency act, made an assignment for the benefit of creditors, consented to the appointment of a receiver for itself or for the whole or any substantial part of its property, or had a petition in bankruptcy filed against it, been adjudicated a bankrupt, or filed a petition or answer seeking reorganization or arrangement under the federal bankruptcy laws or any other laws of the United States or any other jurisdiction.

3.16 Not an Investment Company. The Company is not, and solely after receipt of the Purchase Price, will not be, an "investment company" as defined in the Investment Company Act of 1940, as amended.

4. Representations and Warranties of the Investor. The Investor hereby represents and warrants to the Company that:

4.1 Authorization. The Investor has all requisite corporate power and authority to enter into the Transaction Agreements. The Transaction Agreements, when executed and delivered by the Investor, will constitute valid and legally binding obligations of the Investor, enforceable against the Investor in accordance with their respective terms, except (a) as limited by applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance, or other laws of general application relating to or affecting the enforcement of creditors' rights generally, or (b) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies.

4.2 No Conflicts; Government Consents and Filings. The execution, delivery and performance of the Transaction Agreements by the Investor and the consummation by the Investor of the transactions contemplated by the Transaction Agreements will not (i) conflict with or result in a violation of any provision of the Investors' certificate of incorporation, bylaws or equivalent organizational documents, (ii) violate or conflict with, or result in a breach of any provision of, or constitute a default under, any material agreement, indenture, or instrument to which the Investor is a party where such violation or conflict would have a Material Adverse Effect, or (iii) to the Investor's knowledge, result in a violation of any provision of federal or state statute, rule or regulation applicable to the Investor, the violation of which would have a Material Adverse Effect. Assuming the accuracy of the representations made by the Company in Section 3 of this Agreement, no consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with any federal, state, local or foreign governmental authority is required on the part of the Investor in connection with the consummation of the transactions contemplated by this Agreement, except for filings pursuant to applicable federal or state securities laws, which have been made or will be made in a timely manner, and compliance with the HSR Act and such other Antitrust Laws as may be applicable to this Agreement, the Provisional Collaboration and License Agreement and/or the Definitive Collaboration Agreement. Neither Investor nor any of its Affiliates owns, of record or beneficially, any voting securities of the Company, or any securities convertible into or exercisable for any voting securities of the Company.

4.3 Purchase Entirely for Own Account. The Shares to be acquired by the Investor will be acquired for Investor's own account, not as a nominee or agent, and not with a present view to the resale or distribution of any part thereof, and that Investor has no present intention of selling, granting any participation in, or otherwise distributing the same. The Investor does not presently have any contract, undertaking, agreement or arrangement with any Person to sell, transfer or grant participations to such Person or to any third Person, with respect to any of the Shares except as would not result in a violation of the Securities Act. The Investor has not been formed for the specific purpose of acquiring the Shares.

4.4 Disclosure of Information. The Investor has had access to all of the Company's SEC filings that Investor has requested. The Investor has had an opportunity to discuss the Company's business, management, financial affairs and the terms and conditions of the offering of the Shares with the Company's management. The foregoing, however, does not modify, amend or affect the Investor's right to rely on the truth, accuracy and completeness of the Company's SEC filings, or limit or modify the representations and warranties of the Company in Section 3 of this Agreement, or the right of the Investor to rely thereon.

4.5 Restricted Securities. The Investor understands that, except as set forth in Section 4 of the Standstill and Stock Restriction Agreement, the Shares have not been, and will not be, registered under the Securities Act, by reason of a specific exemption from the registration provisions of the Securities Act which depends upon, among other things, the bona fide nature of the investment intent and the accuracy of the Investor's representations as expressed herein. The Investor understands that the Shares are "restricted securities" under applicable U.S. federal and state securities laws and that, pursuant to these laws, the Investor must hold the Shares indefinitely unless they are registered with the SEC and qualified by state authorities, or an exemption from such registration and qualification requirements is available. The Investor acknowledges that, except as set forth in Section 4 of the Standstill and Stock Restriction Agreement, the Company does not have any obligation to register or qualify the Shares for resale. The Investor further acknowledges that if an exemption from registration or qualification is available, it may be conditioned on various requirements including, but not limited to, the time and manner of sale, the holding period for the Shares, and on requirements relating to the Company which, except as set forth in Section 4 of the Standstill and Stock Restriction Agreement, are outside of the Investor's control, and which the Company is not under an obligation, and may not be able, to satisfy.

4.6 Legends. The Investor understands that the Shares may bear the legends set forth in Section 6(b), and any legend required by the securities laws of any state to the extent such laws are applicable to the Shares. The Shares, when issued, shall not bear the restrictive legends set forth in Section 6(b): (i) following a sale of such Shares pursuant to a registration statement covering the resale of such Shares, while such registration statement is effective under the Securities Act, (ii) following any sale of such Shares pursuant to Rule 144 promulgated under the Securities Act ("**Rule 144**"), (iii) if such Shares are eligible for sale under Rule 144, without the requirement for the Company to be in compliance with the current public information required under Rule 144 as to such Shares and without volume or manner-of-sale restrictions or (iv) if any such legend is not required under applicable requirements of the Securities Act (including judicial interpretations and pronouncements issued by the staff of the Commission). The Company agrees that at such time as the restrictive legends set forth in Section 6(b) are no longer required, the Company will (x) no later than two (2) Business Days following the delivery by the Investor to the Company or the Company's transfer agent of a certificate representing Shares issued with such restrictive legends, deliver or cause to be delivered to the Investor a certificate representing such Shares that is free from any such restrictive legend, and (y), in the event that such shares are uncertificated, no later than two (2) Business Days following the delivery of a written request by the Investor to the Company to remove any such restrictive legend, remove, or cause to be removed, any such restrictive legend in the Company's stock records; each party will be responsible for any fees it incurs in connection with such request and removal.

4.7 Accredited Investor. The Investor is an Accredited Investor.

4.8 United States Investor. The Investor is a United States person (as defined by Section 7701(a)(30) of the Code).

4.9 No General Solicitation. Neither the Investor, nor any of its officers, directors, employees, agents, stockholders or partners has either directly or indirectly, including, through a broker or finder (a) engaged in any general solicitation, or (b) published any advertisement in connection with the offer and sale of the Shares.

4.10 Exculpation. The Investor acknowledges that it is not relying upon any Person, other than the Company and its officers and directors, in making its investment or decision to invest in the Company.

4.11 Residence. The office or offices of the Investor in which its principal place of business is identified in the address or addresses of the Investor set forth on its signature page hereto.

5. Market Stand-off Agreement. Investor agrees that it will not, without the prior written consent of the managing underwriter, during the period commencing on the date of the final prospectus relating to the registration by the Company of any of the Company's equity securities under the Securities Act on a registration statement on Form S-1 or Form S-3 filed within eighteen (18) months after the Closing, and ending on the date specified by the Company and the managing underwriter, such period not to exceed the lesser of (a) ninety (90) days and (b) the number of days that the Company and each director and officer of the Company agree not to take certain actions following the date of such final prospectus, or such other period in each case as may be requested by the Company or an underwriter solely to comply with regulatory requirements, (i) lend; offer; pledge; sell; contract to sell; sell any option or contract to purchase; purchase any option or contract to sell; grant any option, right, or warrant to purchase; or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock or any securities convertible into or exercisable or exchangeable (directly or indirectly) for Common Stock held immediately before the effective date of the registration statement for such offering or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of such securities, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of Common Stock or other securities, in cash, or otherwise. The underwriters in connection with such registration are intended third-party beneficiaries of this Section 5 and shall have the right, power and authority to enforce the provisions hereof as though they were a party hereto. Investor further agrees to execute such agreements as may be reasonably requested by the underwriters in connection with such registration that are consistent with this Section 5 or that are necessary to give further effect thereto.

6. Restrictions on Transfer.

(a) The Shares shall not be sold, pledged, or otherwise transferred, and the Company shall not recognize and shall issue stop-transfer instructions to its transfer agent with respect to any such sale, pledge, or transfer, except upon the conditions specified in this Agreement, which conditions are intended to ensure compliance with the provisions of the Securities Act. Investor will cause any proposed purchaser, pledgee, or transferee of the Shares to agree to take and hold such securities subject to the provisions and upon the conditions specified in this Agreement.

(b) Each certificate, instrument, or book entry representing Shares, and any other securities issued in respect of such Shares upon any stock split, stock dividend, recapitalization, merger, consolidation, or similar event, shall (unless otherwise permitted by the provisions of Section 6(c)) be notated with a legend substantially in the following form:

THE SECURITIES REPRESENTED HEREBY HAVE BEEN ACQUIRED FOR INVESTMENT AND HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933. SUCH SHARES MAY NOT BE SOLD, PLEDGED, OR TRANSFERRED IN THE ABSENCE OF SUCH REGISTRATION OR A VALID EXEMPTION FROM THE REGISTRATION AND PROSPECTUS DELIVERY REQUIREMENTS OF SAID ACT.

THE SECURITIES REPRESENTED HEREBY MAY BE TRANSFERRED ONLY IN ACCORDANCE WITH THE TERMS OF AN AGREEMENT BETWEEN THE COMPANY AND THE STOCKHOLDER, A COPY OF WHICH IS ON FILE WITH THE SECRETARY OF THE COMPANY.

THE SECURITIES REPRESENTED HEREBY ARE SUBJECT TO CERTAIN VOTING RESTRICTIONS AS SET FORTH IN AN AGREEMENT BETWEEN THE COMPANY AND THE STOCKHOLDER, A COPY OF WHICH IS ON FILE WITH THE SECRETARY OF THE COMPANY.

Investor consents to the Company making a notation in its records and giving instructions to any transfer agent of the Company's securities in order to implement the restrictions on transfer set forth in this Section 6.

(c) Before any proposed sale, pledge, or transfer of any Shares, unless there is in effect a registration statement under the Securities Act covering the proposed transaction, Investor shall give notice to the Company of its intention to effect such sale, pledge, or transfer and, if reasonably requested by the Company, cause to be delivered at Investor's expense a written opinion of legal counsel who shall, and whose legal opinion shall, be reasonably satisfactory to the Company, addressed to the Company, to the effect that the proposed transaction may be effected without registration under the Securities Act, whereupon Investor shall be entitled to sell, pledge, or transfer such securities in accordance with the terms of the notice given by Investor to the Company. The Company will not require such a legal opinion (x) in any transaction in compliance with Rule 144; or (y) in any transaction in which the Investor distributes securities to an Affiliate of the Investor for no consideration; *provided* that each transferee agrees in writing to be subject to the terms of this Agreement, including Section 5 and Section 6. Each certificate, instrument, or book entry representing the Shares transferred as above provided shall be notated with, except if such transfer is made pursuant to Rule 144, the appropriate restrictive legend set forth in Section 6(b), except that such certificate instrument, or book entry shall not be notated with such restrictive legend if, in the opinion of counsel for Investor and the Company, such legend is not required in order to establish compliance with any provisions of the Securities Act

(d) Notwithstanding anything herein to the contrary, any transfer of Shares shall be subject to the Standstill and Stock Restriction Agreement.

7. Conditions to the Investor's Obligations. The obligation of the Investor to purchase Shares at the Closing is subject to the fulfillment, on or before the Closing, of each of the following conditions, unless otherwise waived.

7.1 Representations and Warranties. The representations and warranties of the Company contained in Section 3 hereof shall be true and correct in all respects as of the date hereof, except to the extent such representations and warranties are made as of another date, in which case such representations and warranties will be true and correct in all respects as of such other date. As of the Closing (or such other date as a representation and warranty is made), the representations and warranties of the Company contained in (i) Sections 3.1 (Organization, Good Standing, Corporate Power and Qualification), 3.2(a)(ii)–(b) (Company Capitalization and Voting Rights), 3.4 (Authorization), 3.5 (Valid Issuance of Shares), 3.14 (Private Placement) and 3.16 (Not an Investment Company) shall be true and correct in all respects, and (ii) Section 3, other than those in Sections 3.1, 3.2(a)(ii)-(b), 3.4, 3.5, 3.14 and 3.16, shall be true and correct in all respects, except for inaccuracies that have not, individually or in the aggregate, caused a Material Adverse Effect (disregarding all qualifications and exceptions contained therein relating to materiality or Material Adverse Effect).

7.2 Performance. The Company shall have performed and complied, in all material respects, with all covenants, agreements, obligations and conditions contained in this Agreement that are required to be performed or complied with by the Company on or before such Closing.

7.3 Standstill and Stock Restriction Agreement. The Company shall have executed and delivered the Standstill and Stock Restriction Agreement.

7.4 Proceedings and Documents. All corporate and other proceedings in connection with the transactions contemplated at the Closing and all documents incident thereto shall be reasonably satisfactory in form and substance to the Investor, and Investor (or its counsel) shall have received all such counterpart original and certified or other copies of such documents as reasonably requested.

7.5 Qualifications. All authorizations, approvals or permits, if any, of any governmental authority or regulatory body of the United States or of any state that are required in connection with the lawful issuance and sale of the Shares pursuant to this Agreement shall be obtained and effective as of the Closing.

7.6 Compliance Certificate. The President of the Company shall deliver to Investor a certificate certifying that the conditions specified in Section 7.1 and Section 7.2 with respect to the Company have been fulfilled.

7.7 Secretary's Certificate. The Secretary of the Company shall deliver to Investor a certificate certifying as to (a) the Company's certificate of incorporation and bylaws, (b) the resolutions of the Board approving this Agreement and the transactions contemplated hereby, and (c) good standing certificates with respect to the Company from the applicable authority(ies) in Delaware and any other jurisdiction in which the Company is qualified to do business, dated within three (3) Business Days of the Closing.

7.8 Cross-Receipt. The Company shall deliver to the Investor a duly executed cross-receipt in form and substance reasonably satisfactory to both parties.

7.9 Legal Opinion. Investor shall have received from Wilson Sonsini Goodrich and Rosati P.C., counsel for the Company, an opinion, dated as of the Closing, in a form reasonably satisfactory to the Investor.

7.10 No Governmental Prohibition; Antitrust Clearance. The sale of the Shares by the Company and the purchase of the Shares by the Investor will not be prohibited, enjoined or injuncted by any applicable law at the time of the Closing. Each of the Antitrust Conditions shall have been satisfied.

7.11 Collaboration Agreement. The Provisional Collaboration and License Agreement or, when executed, the Definitive LRRK2 Collaboration and License Agreement, shall be in full force and effect.

7.12 Nasdaq Qualification. Nasdaq shall have completed its review of the applicable listing of additional shares application and raised no objection to the consummation of the transactions contemplated by this Agreement.

7.13 Absence of Litigation. No proceeding initiated by a governmental authority and challenging this Agreement or the transactions contemplated hereby, or seeking to prohibit or prevent the Closing, will have been instituted or be pending before any court, arbitrator, governmental body, agency or official.

8. Conditions of the Company's Obligations. The obligations of the Company to sell Shares to the Investor at the Closing are subject to the fulfillment, on or before the Closing, of each of the following conditions, unless otherwise waived:

8.1 Representations and Warranties. The representations and warranties of the Investor contained in Section 4 shall be true and correct in all respects as of the date hereof and in all material respects as of the Closing (other than those set forth in Sections 4.1 (Authorization), 4.3 (Purchase Entirely for Own Account), 4.7 (Accredited Investor), 4.8 (United States Investor) and 4.9 (No General Solicitation), which shall be true in correct in all respects), except to the extent such representations and warranties are made as of another date, in which case such representations and warranties will be true and correct in all material respects as of such other date.

8.2 Performance. The Investor shall have performed and complied, in all material respects, with all covenants, agreements, obligations and conditions contained in this Agreement that are required to be performed or complied with by the Investor on or before such Closing.

8.3 Compliance Certificate. An authorized officer of the Investor shall deliver to the Company a certificate certifying that the conditions specified in Section 8.1 and Section 8.2 with respect to the Investor have been fulfilled.

8.4 Cross Receipt. The Investor shall deliver to the Company a duly executed cross-receipt in form and substance reasonably satisfactory to both parties.

8.5 Qualifications. All authorizations, approvals or permits, if any, of any governmental authority that are required in connection with the lawful issuance and sale of the Shares pursuant to this Agreement shall be obtained and effective as of the Closing.

8.6 Standstill and Stock Restriction Agreement. The Investor shall have executed and delivered the Standstill and Stock Restriction Agreement.

8.7 No Governmental Prohibition; Antitrust Clearance. The sale of the Shares by the Company and the purchase of the Shares by the Investor will not be prohibited, enjoined or injuncted by any applicable law at the time of the Closing. Each of the Antitrust Conditions shall have been satisfied.

8.8 Collaboration Agreement. The Provisional Collaboration and License Agreement or, when executed, the Definitive LRRK2 Collaboration and License Agreement, shall be in full force and effect.

8.9 Absence of Litigation. No proceeding initiated by a governmental authority and challenging this Agreement or the transactions contemplated hereby, or seeking to prohibit or prevent the Closing, will have been instituted or be pending before any court, arbitrator, governmental body, agency or official.

9. Miscellaneous.

9.1 Successors and Assigns. The terms and conditions of this Agreement shall inure to the benefit of and be binding upon the respective successors and assigns of the parties. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and assigns any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement. The Company will not assign this Agreement or any rights or obligations hereunder without the prior written consent of the Investor, and the Investor will not assign this Agreement or any rights or obligations hereunder without the prior written consent of the Company; provided, however, that the Investor may assign this Agreement together with all of the Shares it then owns to any wholly-owned subsidiary and any such assignee may assign this Agreement together with all of the Shares it then owns to the Investor or any other subsidiary wholly-owned by the Investor.

9.2 Governing Law. This Agreement shall be governed by the internal law of the State of Delaware without regard to principles of conflicts of law.

9.3 Antitrust Matters.

(a) Subject to the terms and conditions of this Agreement, each of the Company and the Investor will use its reasonable best efforts to take, or cause to be taken, all actions and to do, or cause to be done, all things necessary, proper or advisable under applicable law to consummate the acquisition of the Shares as soon as practicable after the date hereof, including taking all steps as may be necessary, subject to the limitations in this Section 9.3, to obtain all applicable waiting period expirations or terminations, consents, clearances, waivers, licenses, registrations, permits, authorizations, orders and approvals. In furtherance and not in limitation of the foregoing, each of the Company and the Investor agrees to (i) file or cause to be filed with (A) the FTC and the DOJ any notifications required to be filed under the HSR Act no later than ten (10) Business Days after the date of this Agreement, (B) the U.K. Competition and Markets Authority under the U.K. Enterprise Act 2002, as amended by the Enterprise and Regulatory Reform Act of 2013, and the rules and regulations promulgated thereunder as soon as practicable and advisable and (C) any other regulatory body any notifications or other filings required to be filed under any other Antitrust Law as soon as practicable and advisable (any filings required pursuant to clause (A), (B) or (C), the "**Required Filings**"), and (ii) use reasonable best efforts to obtain as promptly as practicable approvals, clearances, consents, decisions not to assume jurisdiction, and/or the termination or expiration of any waiting period as applicable under the HSR Act or other applicable Antitrust Law, including by filing as soon as practicable and advisable any supplemental or additional information which may reasonably be requested by the FTC or the DOJ or any other governmental authority in connection with applicable Antitrust Law. Each party hereto shall be responsible for its own costs in connection with the Required Filings, except that the Investor shall be responsible for the payment of all applicable filing fees payable under the HSR Act and other applicable Antitrust Law.

(b) Each of the Company and the Investor shall use reasonable best efforts to provide or cause to be provided promptly all assistance and cooperation to allow the Company and the Investor to prepare and submit any Required Filings, including providing to the Company and the Investor, as applicable, any information that it may require for the purpose of any filing, notification, application or request for further information made in respect of any such filing.

(c) Each of the Company and the Investor shall, in connection with the transactions contemplated hereby, and the obtaining of all waiting period expirations or terminations, consents, clearances, waivers, licenses, orders, registrations, approvals, permits and authorizations under the HSR Act or any other Antitrust Law, with respect to actions taken on or after the date of this Agreement, without limitation: (i) promptly notify the other of, and if in writing, furnish the other with copies of (or, in the case of oral communications, advise the other of) any material communications from or with any governmental authority, including the FTC and the DOJ, with respect to this Agreement, (ii) cooperate in all respects and consult with each other in connection with any filing or submission and in connection with any investigation or other inquiry, (iii) permit the other to review and discuss in advance, and consider in good faith the view of the other in connection with, any proposed written or oral communication with any governmental authority, (iv) not participate in any substantive meeting or have any substantive communication with any governmental authority unless it has given the other party a reasonable opportunity to consult with it in advance and, to the extent permitted by such governmental authority, gives the other the opportunity to attend and participate therein, (v) furnish the other party's outside legal counsel with copies of all supplemental filings and substantive communications between it and any such governmental authority with respect to this Agreement; *provided* that any materials subject to this Section 9.3(c) may be restricted to outside counsel and may be redacted or withheld as necessary (A) to comply with contractual arrangements, (B) to address good faith legal privilege or confidentiality concerns and (C) to comply with applicable law, (vi) furnish the other party's outside legal counsel with such necessary information and reasonable assistance as the other party's outside legal counsel may reasonably request in connection with its preparation of necessary submissions of information to any such governmental authority, and (vii) use reasonable best efforts to respond as soon as practicable to reasonable requests from the other party hereto.

(d) Notwithstanding anything herein to the contrary, nothing in this Agreement will require the Company or the Investor to (i) sell, hold separate, license or otherwise dispose of any assets or conduct its business in a specified manner, (ii) agree or proffer to sell, hold separate, license or otherwise dispose of any assets or conduct their business in a specified manner or (iii) permit or agree to the sale, holding separate, licensing or other disposition of, any assets of such party, whether as a condition to obtaining any approval from, or to avoid potential litigation or administrative action by, a governmental authority or any other Person or for any other reason.

9.4 Termination. This Agreement may be terminated prior to the Closing (a) at any time by mutual written consent of the Company and the Investor or (b) by either the Company or the Investor, upon written notice to the other, if the Antitrust Clearance Date has not occurred on or before the date that is nine (9) months after the date of this Agreement (the "**Outside Date**"), provided, however, that if as of the Outside Date, each of the Antitrust Conditions has been not satisfied but all other closing conditions set forth in Sections 7 and 8 shall have been satisfied or waived (other than those conditions that by their nature are to be satisfied or waived at the Closing, which shall remain capable of being satisfied) and the Antitrust Condition remains capable of being satisfied, then either party may elect to extend the Outside Date for sixty (60) days following the expiration of the original Outside Date upon written notice to the other party provided such electing party is acting in good faith to satisfy the Antitrust Condition; provided, further, however that the Outside Date may thereafter be further extended by consecutive 30-day increments upon the written agreement and consent of the Company and the Investor. This Agreement shall terminate automatically in the event that the Provisional Collaboration and License Agreement, or, if executed, the Definitive LRRK2 Collaboration and License Agreement, is terminated prior to the Closing. In the event of the termination of this Agreement pursuant to Section 9.4, this Agreement (except for Section 9.1, Section 9.2 and Sections 9.4 through 9.13 and any definitions set forth in this Agreement and used in such Sections) shall forthwith become void and have no effect, without any liability on the part of any party hereto or its Affiliates, and all filings, applications and other submissions made pursuant to this Agreement, to the extent practicable, shall be withdrawn from the agency or other person to which they were made or appropriately amended to reflect the termination of the transactions contemplated hereby; *provided*, *however*, that nothing contained in this Section 9.4 shall relieve any party from liability for fraud or any intentional or willful breach of this Agreement.

9.5 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered electronic mail (including .pdf or any electronic signature) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

9.6 Titles and Subtitles. The titles and subtitles used in this Agreement are used for convenience only and are not to be considered in construing or interpreting this Agreement.

9.7 Notices. All notices and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effectively given upon the earlier of actual receipt, or (a) personal delivery to the party to be notified, (b) when sent, if sent by electronic mail during normal business hours of the recipient, and if not sent during normal business hours, then on the recipient's next business day, (c) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one (1) business day after deposit with a nationally recognized overnight courier, freight prepaid, specifying next business day delivery, with written verification of receipt. All communications shall be sent to the respective parties at their address as set forth on the signature page hereto, or to such e-mail address or address as subsequently modified by written notice given in accordance with this Section 9.7. If notice is given to the Company, a copy shall also be sent to Wilson Sonsini Goodrich and Rosati, P.C., 650 Page Mill Road, Palo Alto, CA 94304, Attn: Tony Jeffries, Esq., tjeffries@wsgr.com, and if notice is given to the Investor, a copy shall also be given to Ropes & Gray LLP, Prudential Tower, 800 Boylston Street, Boston, MA 02199, Attn: Zachary Blume, zachary.blume@ropesgray.com.

9.8 No Finder's Fees. Each party represents that it neither is nor will be obligated for any finder's fee or commission in connection with this transaction. The Investor agrees to indemnify and to hold harmless the Company from any liability for any commission or compensation in the nature of a finder's or broker's fee arising out of this transaction (and the costs and expenses of defending against such liability or asserted liability) for which the Investor or any of its officers, employees or representatives is responsible. The Company agrees to indemnify and hold harmless the Investor from any liability for any commission or compensation in the nature of a finder's or broker's fee arising out of this transaction (and the costs and expenses of defending against such liability or asserted liability) for which the Company or any of its officers, employees or representatives is responsible.

9.9 Amendments and Waivers. Any term of this Agreement may be amended, terminated or waived only with the written consent of the Company and the Investor. Any amendment or waiver effected in accordance with this Section 9.9 shall be binding upon the Investor and each transferee of the Shares, each future holder of all such securities, and the Company.

9.10 Severability. The invalidity or unenforceability of any provision hereof shall in no way affect the validity or enforceability of any other provision.

9.11 Delays or Omissions. No delay or omission to exercise any right, power or remedy accruing to any party under this Agreement, upon any breach or default of any other party under this Agreement, shall impair any such right, power or remedy of such non-breaching or non-defaulting party nor shall it be construed to be a waiver of any such breach or default, or an acquiescence therein, or of or in any similar breach or default thereafter occurring; nor shall any waiver of any single breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. Any waiver, permit, consent or approval of any kind or character on the part of any party of any breach or default under this Agreement, or any waiver on the part of any party of any provisions or conditions of this Agreement, must be in writing and shall be effective only to the extent specifically set forth in such writing. All remedies, either under this Agreement or by law or otherwise afforded to any party, shall be cumulative and not alternative.

9.12 Entire Agreement. This Agreement (including the Exhibits hereto), the Provisional Collaboration and License Agreement or, when executed, the Definitive LRRK2 Collaboration and License Agreement, and the Standstill and Stock Restriction Agreement, constitute the full and entire understanding and agreement between the parties with respect to the subject matter hereof, and any other written or oral agreement relating to the subject matter hereof existing between the parties are expressly canceled.

9.13 Dispute Resolution. The parties (a) hereby irrevocably and unconditionally submit to the jurisdiction of the state courts of the state of Delaware and to the jurisdiction of the United States District Court for the District of Delaware for the purpose of any suit, action or other proceeding arising out of or based upon this Agreement, (b) agree not to commence any suit, action or other proceeding arising out of or based upon this Agreement except in the state courts of the state of Delaware or the United States District Court for the District of Delaware, and (c) hereby waive, and agree not to assert, by way of motion, as a defense, or otherwise, in any such suit, action or proceeding, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper or that this Agreement or the subject matter hereof may not be enforced in or by such court.

WAIVER OF JURY TRIAL: EACH PARTY HEREBY WAIVES ITS RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT AND THE SECURITIES ISSUED HEREUNDER, THE STANDSTILL AND STOCK RESTRICTION AGREEMENT, OR THE SUBJECT MATTER HEREOF OR THEREOF. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL-ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT AND THAT RELATE TO THE SUBJECT MATTER OF THIS AGREEMENT, INCLUDING, WITHOUT LIMITATION, CONTRACT CLAIMS, TORT CLAIMS (INCLUDING NEGLIGENCE), BREACH OF DUTY CLAIMS, AND ALL OTHER COMMON LAW AND STATUTORY CLAIMS. THIS SECTION HAS BEEN FULLY DISCUSSED BY EACH OF THE PARTIES HERETO AND THESE PROVISIONS WILL NOT BE SUBJECT TO ANY EXCEPTIONS. EACH PARTY HERETO HEREBY FURTHER WARRANTS AND REPRESENTS THAT SUCH PARTY HAS REVIEWED THIS WAIVER WITH ITS LEGAL COUNSEL, AND THAT SUCH PARTY KNOWINGLY AND VOLUNTARILY WAIVES ITS JURY TRIAL RIGHTS FOLLOWING CONSULTATION WITH LEGAL COUNSEL.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties have executed this Common Stock Purchase Agreement as of the date first written above.

COMPANY:
DENALI THERAPEUTICS INC.

By: /s/ Ryan J. Watts
Name: Ryan Watts, Ph.D.
Title: President and CEO

Address:
161 Oyster Point Boulevard
South San Francisco, CA 94080

E-mail:

IN WITNESS WHEREOF, the parties have executed this Common Stock Purchase Agreement as of the date first written above.

INVESTOR:
BIOGEN MA INC.

By: /s/ Alfred W. Sandrock, Jr.
Name: Alfred W. Sandrock, Jr.
Title: EVP, R&D

Address:
225 Binney Street
Cambridge, MA 02142

E-mail:

EXHIBIT A

Form of Standstill and Stock Restriction Agreement

[See attached.]

Exhibit 10.2

Provisional Collaboration and License Agreement

Between

Denali Therapeutics, Inc.,

Biogen MA, Inc.

and

Biogen International GmbH

Dated August 5, 2020

PROVISIONAL COLLABORATION AND LICENSE AGREEMENT

This Provisional Collaboration and License Agreement ("**Provisional Collaboration and License Agreement**") is entered into as of August 5, 2020 (the "**Execution Date**") by and between Denali Therapeutics Inc., a Delaware corporation with its principal place of business located at 161 Oyster Point Blvd., South San Francisco, California 94080 ("**Denali**"), Biogen MA, Inc., a corporation organized under the laws of the Commonwealth of Massachusetts having an office at 225 Binney Street, Cambridge, MA 02142 ("**BIMA**"), and Biogen International GmbH, a Gesellschaft mit beschränkter Haftung organized under the laws of Switzerland, whose registered office is at Neuhofstrasse 30, 6340 Baar, Switzerland ("**BIG**", together with BIMA, collectively, "**Biogen**"). Biogen and Denali are each individually referred to as a "**Party**" and collectively as the "**Parties**."

In consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

ARTICLE 1
OVERVIEW

1.1 Binding Nature of this Provisional Collaboration and License Agreement. The Parties hereby enter into this Provisional Collaboration and License Agreement, which constitutes a binding contract between the Parties. In conjunction with this Provisional Collaboration and License Agreement, the parties are entering into that certain stock purchase agreement dated as of the date hereof (the "**Stock Purchase Agreement**"). This Section 1.1 (Binding Nature of this Provisional Collaboration and License Agreement), Article 2 (Definitions), and Sections 3.2 (Exclusive Collaboration), the last sentence of 3.3.1 (Development and Regulatory Activities), 3.10 (Termination), 3.11 (Effects of Termination), 4.1.4 (Selection of Option TV Target), 5.1 (Term and Termination of this Provisional Collaboration and License Agreement), 5.2 (Indemnification and Limitation of Liability), 5.3 (Representations, Warranties and Covenants), 5.4 (Confidentiality and Non-Disclosure), 5.5 (Governing Law; Dispute Resolution), 5.7 (Antitrust Matters), 5.8 (Assignment), 5.9 (Force Majeure), 5.10 (Counterparts; Electronic Signatures), 5.11 (Severability), 5.12 (Entire Agreement; Amendments), 5.13 (Notices), 5.14 (Performance by Biogen), 5.15 (Coordination between BIMA and BIG), 5.16 (Retained Rights), 5.17 (Interpretation), 5.18 (Injunctive Relief), 5.19 (No Benefit to Third Parties) and 5.20 (Other Terms) of this Provisional Collaboration and License Agreement (together with the Schedules referenced in such sections) shall be effective as of the Execution Date; all other terms shall be automatically effective as of the Effective Date without any further action on the part of any person. As further provided in Section 5.6 (Definitive Agreement Terms) below, the Parties shall negotiate and execute one or more agreements containing (a) a more detailed set of terms governing the collaboration with respect to the LRRK2 Program established under Article 3 (LRRK2 Program) of this Provisional Collaboration and License Agreement (which agreement shall be consistent with all of the applicable terms of this Provisional Collaboration and License Agreement) (such expanded version of such terms, the "**Definitive LRRK2 Collaboration and License Agreement**") and (b) a more detailed set of terms governing the option and right of first negotiation granted to Biogen as provided in Article 4 (Option Programs and ROFN Programs) of this Provisional Collaboration and License Agreement (which agreement(s) shall be consistent with all of the applicable terms of this Provisional Collaboration and License Agreement) (such expanded version of such terms, the "**Definitive ROFN and Option Agreement**"), in each case, subject to Section 5.5 (Governing Law; Dispute Resolution) of this Provisional Collaboration and License Agreement.

1.2 LRRK2 Program. Denali and Biogen will collaborate with respect to Denali's LRRK2 program as described below ("**LRRK2 Program**") in accordance with the applicable terms set forth in this Provisional Collaboration and License Agreement and the Definitive LRRK2 Collaboration and License Agreement. With respect to such LRRK2 Program:

1.2.1 Denali and Biogen will share the responsibility for, and will jointly Develop, the LRRK2 Licensed Compounds and the LRRK2 Licensed Products in the Territory and share costs and expenses at a ratio of 1.5:1 (Biogen 60% / Denali 40%), in accordance with an agreed plan and budget for all such Development and as further described below;

1.2.2 Denali and Biogen will jointly Commercialize LRRK2 Licensed Products in the U.S. and China and will share in the profits/losses with respect to the Commercialization of LRRK2 Licensed Products in the U.S. and China, in accordance with an agreed plan and budget for such Commercialization in the Co-Commercialization Territory and as further described below; and

1.2.3 Biogen will [***] with respect to the Commercialization of LRRK2 Licensed Products in all other jurisdictions worldwide, at its cost and expense, subject to payments to Denali as further described below.

1.3 ROFN Programs and Option Programs. Additionally, Denali will grant to Biogen certain rights of first negotiation with respect to the ROFN Programs and certain option rights to the Option Programs, each in accordance with the applicable terms set forth in this Provisional Collaboration and License Agreement and the Definitive ROFN and Option Agreement.

ARTICLE 2
DEFINITIONS

2.1 "**Allowable Overruns**" means any costs or expenses incurred by or on behalf of a Party in the performance of activities allocated to such Party under the Global Development Plan/Budget or Co-Commercialization Plan/Budget in a given calendar year that (a) are not [***] any breach of this Provisional Collaboration and License Agreement or the Definitive LRRK2 Collaboration and License Agreement, and (b) are in excess of the aggregate amount budgeted in the Global Development Plan/Budget or Co-Commercialization Plan/Budget (as applicable) for such Party in such calendar year (a) by an amount not to exceed [***] of such amount budgeted for such Party in such calendar year in the aggregate or (b) otherwise approved by a unanimous decision of the JSC, or a finance working group established by the JSC.

2.2 "**ATV:Abeta Program**" means all ATV:Abeta Therapeutics that are [***]Controlled by or on behalf of Denali or its affiliates prior to the Effective Date or during the Option Term, and pharmaceutical products containing such ATV:Abeta Therapeutics.

2.3 "**ATV:Abeta Therapeutic**" means [***] that incorporates (a) [***] and (b) [***].

2.4 "**Biogen IP**" means Biogen Know-How and Biogen Patents.

2.5 "**Biogen Know-How**" means [***].

2.6 "**Biogen Patents**" means [***].

2.7 [***]

2.8 "**Biogen Program Patent**" means [***].

2.9 "**Co-Commercialization Territory**" means U.S. and China.

2.10 "**Combination Product**" means a LRRK2 Licensed Product that is (a) sold in the form of a combination that contains or comprises a LRRK2 Licensed Compound together with one or more other therapeutically active pharmaceutical agents (whether coformulated or copackaged or otherwise sold together as a single unit) ("**Other Component**"), and (b) sold for a single invoice price. For purposes of the foregoing, none of the following shall be deemed to be an Other Component [***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

2.11 "**Commercialization**" means with respect to any product, any and all activities directed to: the marketing, advertising, promotion, distribution, pricing, reimbursement, import, export, offering for sale, and sale of such product, product samples, pre-launch activities to prepare a market for potential sales, pricing and reimbursement activities, [***] modeling and pharmaco-economic studies, epidemiological studies, expanded access programs and registries and activities required to fulfill ongoing regulatory obligations, adverse event reporting, and interacting with regulatory authorities regarding the foregoing, including seeking and maintaining any required pricing or reimbursement approval, but excluding any activities directed to Manufacturing, Development, or Medical Affairs. "**Commercialize**," "**Commercializing**," and "**Commercialized**" will be construed accordingly.

2.12 "**Commercially Reasonable Efforts**" means, [***].

2.13 "**Committee**" means the JSC, JDC, JCC, CMC Working Group or any other joint subcommittee established by the Parties or the JSC under the Definitive LRRK2 Collaboration and License Agreement.

2.14 "**Compound**" means a LRRK2 Licensed Compound, Option Compound or ROFN Compound, as applicable.

2.15 "**Control**" or "**Controlled**" means the possession by a Party or its affiliate (whether by ownership, license or otherwise other than pursuant to this Provisional Collaboration and License Agreement or any Definitive Agreement) of (a) with respect to any tangible know-how, the legal authority or right to physical possession of such tangible know-how, with the right to provide such tangible know-how to the other Party on the terms set forth herein, or (b) with respect to patent rights, Regulatory Approvals, regulatory submissions, intangible know-how or other intellectual property or subject matter, the legal authority or right to grant a license, sublicense, access, or right to use (as applicable) to the other Party under such patent rights, Regulatory Approvals, regulatory submissions, intangible know-how or other intellectual property or subject matter on the terms set forth herein, in each case ((a) and (b)), without breaching or otherwise violating the terms of any arrangement or agreement with a third party in existence as of the time such Party or its affiliates would first be required hereunder to grant the other Party such access, right to use, licenses or sublicense, and (c) with respect to any product, the possession by a Party of the ability (whether by sole or joint ownership, license or otherwise, other than pursuant to the license grants under this Provisional Collaboration and License Agreement or any Definitive Agreement) to grant a license or sublicense of patent rights within clause (b) above that claim such product or proprietary know-how within clause (a) or (b) above that is used in connection with the exploitation of such product. Notwithstanding any provision to the contrary set forth in this Provisional Collaboration and License Agreement, a Party and its affiliates will not be deemed to "Control" any patent rights, Regulatory Approvals, regulatory submissions, know-how or other intellectual property or subject matter that is [***].

2.16 "**Development**" means, with respect to any product, any and all internal and external research, development or regulatory activities regarding such product, including (a) research, process development, non-clinical testing, toxicology, non-clinical activities, IND-Enabling Studies, and clinical trials[***], (b) test method development and stability testing, and toxicology, and (c) preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct clinical trials and to obtain Regulatory Approval of such product and interacting with Regulatory Authorities regarding any of the foregoing, but excluding any activities directed to Manufacturing, Medical Affairs, or Commercialization. Development will include research, development, and regulatory activities for additional presentations or indications for a product after receipt of Regulatory Approval of such product, including clinical trials initiated following receipt of Regulatory Approval or to be conducted after receipt of Regulatory Approval, in each case, that was mandated by the applicable Regulatory Authority as a condition of such Regulatory Approval with respect to an approved indication (such as post-marketing approval studies and observational studies, if required by any Regulatory Authority in any country in the Territory to support or maintain Regulatory Approval for a product in such country). "**Develop**," "**Developing**," and "**Developed**" will be construed accordingly.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

2.17 "**Effective Date**" means the date on which all of the Antitrust Conditions (as defined in the Stock Purchase Agreement) have been met, unless [***].

2.18 "**Excluded Targets**" means [***].

2.19 "**Exploit**" means to make, have made, use, import, export, offer to sell, sell, Develop, Manufacture, perform Medical Affairs activities, Commercialize or otherwise exploit. "**Exploitation**" will be construed accordingly.

2.20 "**Field**" means any and all uses.

2.21 "**First Commercial Sale**" means, with respect to any Product in any country or region, the first sale of such Product to a third party (other than a Sublicensee) for distribution, use or consumption in such country or region after receipt of Regulatory Approval. First Commercial Sale excludes any *bona fide* transfers of Product to third parties for clinical trial purposes, any expanded access program, any compassionate sales or use program (including named patient program or single patient program), or any indigent program.

2.22 "**IND**" means an Investigational New Drug application as defined in 21 C.F.R. Part 312 or any comparable filings outside of the United States that are required to commence clinical trials in such country or region, and all supplements or amendments that may be filed with respect to the foregoing.

2.23 "**IND-Enabling Study**" means a toxicology study of a product (a) that is conducted in compliance with GLP regulations in an animal species appropriate to satisfy applicable regulatory requirements, (b) that is otherwise designed to satisfy applicable regulatory requirements and (c) the data and results from which are intended to support the filing of an IND for such product with the applicable Regulatory Authority.

2.24 "**Initiate**" or "**Initiation**" means, with respect to a clinical trial or IND-Enabling Study of a Product, the [***] in such clinical trial or the [***] in such IND-Enabling Study.

2.25 "**Joint Program Patents**" means any Program Patents that claim any inventions developed jointly by the Parties in the performance of activities under this Provisional Collaboration and License Agreement or the Definitive LRRK2 Collaboration and License Agreement.

2.26 "**LRRK2**" means a naturally occurring Leucine-rich repeat kinase 2 mRNA sequence or protein, [***].

2.27 "**LRRK2 Inhibitor**" means any small molecule compound: (a) [***]; and (b) [***].

2.28 "**LRRK2 IP**" means LRRK2 Know-How and LRRK2 Patents and Denali's interest in the Joint Program Patents.

2.29 "**LRRK2 Know-How**" means any and all know-how, data, materials and other information that are: (a) Controlled by Denali or its affiliates as of the Effective Date or during the term of the Provisional Collaboration and License Agreement or Definitive LRRK2 Collaboration and License Agreement; and (b) [***] for the Development, Manufacture or use of LRRK2 Licensed Compounds or LRRK2 Licensed Products or the Commercialization of LRRK2 Licensed Products[***].

2.30 "**LRRK2 Licensed Compound**" means the following small molecule compounds: (a) those compounds set forth in Schedule 2.30 (LRRK2 Licensed Compounds), including the compounds known internally at Denali as [***] "DNL151" and [***]; (b) all other LRRK2 Inhibitors [***]; and (c) [***].

2.31 "**LRRK2 Licensed Product**" means any product containing a LRRK2 Licensed Compound, alone or in combination with one or more other active ingredients, and in any formulation, dosage strength or method of delivery.

2.32 "**LRRK2 Patents**" means all patent applications and issued patents, including Denali's interest in any Joint Program Patents, that are: (a) Controlled by Denali or its affiliates as of the Effective Date or during the term of the Provisional Collaboration and License Agreement or Definitive LRRK2 Collaboration and License Agreement; and (b) [***] for the Development, Manufacture or use of LRRK2 Licensed Compounds or LRRK2 Licensed Products or the Commercialization of LRRK2 Licensed Products[***]. Such patent applications and issued patents existing as of the Execution Date are set forth in Schedule 2.32 (LRRK2 Patents).

2.33 "**Major Markets**" means the United States, France, Germany, United Kingdom, Italy, Spain, Japan, and China.

2.34 "**Manufacture**" means with respect to any product, any and all activities directed to manufacturing, processing, packaging, labeling, filling, finishing, assembly, quality assurance, quality control, testing, and release, shipping, supply, or storage of such product (or any components or process steps involving such product[***]), placebo, or comparator agent, as the case may be, including qualification, validation, and scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, quality assurance technical support activities qualification and audit of clinical and commercial manufacturing facilities, and stability testing, but excluding any activities directed to Development, Medical Affairs or Commercialization. "**Manufacturing**" and "**Manufactured**" will be construed accordingly.

2.35 "**Medical Affairs**" means any and all activities conducted by or on behalf of a Party's or any of its affiliates' medical affairs departments interacting with physicians or other healthcare professionals who utilize or conduct research related to a drug or biological product, including communications with key opinion leaders, medical education, symposia, advisory boards (to the extent related to medical affairs or clinical guidance), and other medical programs and communications, including educational grants and fellowships, research grants (including conducting investigator-initiated studies following Regulatory Approval), charitable donations, medical resourcing and allocation, medical and scientific platform and communications, KME and KOL engagement, congress planning, real-world evidence generation through registry or [***], conducting advisory board meetings or other consultant programs, the purpose of which is to obtain advice and feedback related to the launch of a given product, post-approval investigator initiated trials or scientific research agreements, activities related to patient registries and patient advocacy engagement, patient services, education and support, in each case, to the extent related to medical affairs and not to activities that involve the promotion, marketing, sale, or other Commercialization of Products. Medical Affairs excludes any activities directed to Manufacturing, Development, or Commercialization.

2.36 "**Net Sales**" means with respect to a LRRK2 Licensed Product, the gross amount invoiced or received in a country by or on behalf of Biogen or its affiliates, or, outside of the Co-Commercialization Territory, its Sublicensees (each of the foregoing persons, a "**Selling Party**") for the sale or other disposition of such LRRK2 Licensed Product to third parties (including third party distributors, wholesalers and end-users) in *bona fide* arms' length transactions in the Territory, less the following deductions, in each case, pertaining specifically to such LRRK2 Licensed Product and actually allowed or taken by such third party and not otherwise received by or reimbursed to a Selling Party:

(a) sales returns and allowances actually paid, granted or accrued on such LRRK2 Licensed Product, including reasonable and customary trade, quantity, prompt pay and cash discounts, and any adjustments granted on account of price adjustments or billing errors;

(b) credits or allowances given or made for rejection, recall, return or wastage replacement of [***] such LRRK2 Licensed Product or for rebates or retroactive price reductions (including Medicare, Medicaid, copay assistance, managed care and similar types of rebates and chargebacks);

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(c) taxes, duties or other governmental charges levied on or measured by the billing amount for such LRRK2 Licensed Product, as adjusted for rebates and refunds, [***];

(d) charges for freight, customs [***] specifically related to the distribution of such LRRK2 Licensed Product [***]; and

(e) [***].

Such amounts will be determined consistent with a Selling Party's customary practices and in accordance with U.S. generally accepted accounting principles, consistently applied ("**GAAP**"). It is understood that any accruals for individual items reflected in Net Sales are periodically (at least quarterly) trued up and adjusted by each Selling Party consistent with its customary practices and in accordance with GAAP.

Notwithstanding anything to the contrary set forth in this Provisional Collaboration and License Agreement, Net Sales will not be imputed to transfers of LRRK2 Licensed Product to third parties as *bona fide* samples, as donations, for the performance of clinical trials, or for similar *bona fide* business purposes in accordance with applicable law pertaining to any expanded access program, any compassionate sales or use program (including named patient program or single patient program), or any indigent program.

Sale or transfer of LRRK2 Licensed Products between any of the Selling Parties will not result in any Net Sales, with Net Sales to be based only on any subsequent sales or dispositions to a non-Selling Party. To the extent that any Selling Party receives consideration other than or in addition to cash upon the sale or disposition of a LRRK2 Licensed Product to a non-Selling Party, Net Sales will be [***]. For clarity, and without limiting Schedule 3.8 (LRRK2 Financials), Net Sales will not include [***].

In the case of any Combination Product sold in a given country and reporting period, Net Sales for the purpose of determining royalties and sales milestones of the Combination Product in such country will be calculated by [***].

If, on a country-by-country basis in a particular reporting period, the LRRK2 Licensed Product is sold separately in the same indication in a country, but the Other Components in the Combination Product are not sold separately in the same indication in such country, then Net Sales for the purpose of determining royalties and sales milestones of the Combination Product for such country will be calculated by [***].

If, on a country-by-country basis in a particular reporting period, the LRRK2 Licensed Product in the Combination Product is not sold separately in the same indication in such country, but the Other Components included in the LRRK2 Licensed Product are sold separately in the same indication in such country, then Net Sales for the purpose of determining royalties and sales milestones of the Combination Product for such country will be [***].

If neither the LRRK2 Licensed Product nor the Other Components are sold separately in the same indication in a given country during a particular reporting period, then Net Sales [***].

[***]

2.37 "**Option Compound**" means any ATV:Abeta Therapeutic or Option TV Protein.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

2.38 "**Option Exercise Period**" means, with respect to an Option Program, the period beginning on the Effective Date and expiring upon the earliest of (a) [***] following the delivery of the Option Data Package or Partial Option Data Package, as the case may be, for such Option Program in accordance with Section 4.1.2(a) (Option Data Package), as such period may be extended in accordance with Section 4.1.2(b) (Incomplete Option Data Package), unless earlier terminated, (b) thirty (30) business days after the fifth (5th) anniversary of the Effective Date, (c) the termination of this Provisional Collaboration and License Agreement (other than as a result of the execution of the Definitive ROFN and Option Agreement) and (d) the termination of the Definitive ROFN and Option Agreement.

2.39 "**Option IP**" means Option Know-How and Option Patents.

2.40 "**Option Know-How**" means, with respect to an Option Program, any and all know-how, data, materials and other information that are: (a) Controlled by Denali or its affiliates as of the Effective Date or during the term of the Provisional Collaboration and License Agreement or the Definitive ROFN and Option Agreement; and (b) [***] for the Development, Manufacture or use of Option Compounds or Option Products, or Commercialization of Option Products in such Option Program[***]; but in each case, (a) and (b), excluding the TV Platform Know-How with respect to such Option Program.

2.41 "**Option Patents**" means, with respect to an Option Program, all patent applications and issued patents that are: (a) Controlled by Denali or its affiliates as of the Effective Date or during the term of the Provisional Collaboration and License Agreement or Definitive ROFN and Option Agreement; and (b) [***] for the Development, Manufacture or use or the Commercialization of Option Products in such Option Program[***]; but, in each case, (a) and (b), excluding the TV Platform Patents with respect to such Option Program.

2.42 "**Option Product**" means any product containing an ATV:Abeta Therapeutic or Option TV Protein, in each case, alone or in combination with one or more other active ingredients, and in any formulation, dosage strength or method of delivery.

2.43 "**Option Programs**" means either of the ATV:Abeta Program or the Option TV Program.

2.44 "**Option Term**" means, with respect to an Option Program, the period beginning on the Effective Date and expiring on the earliest of (a) the fifth (5th) anniversary of the Effective Date, (b) expiration of the Option Exercise Period for such Option Program, (c) the termination of this Provisional Collaboration and License Agreement (other than as a result of the execution of the Definitive ROFN and Option Agreement) and (d) the termination of the Definitive ROFN and Option Agreement.

2.45 "**Option TV Program**" means all Option TV Proteins that are [***] Controlled by or on behalf of Denali or its affiliates prior to the Effective Date or during the Option Term and pharmaceutical products containing such Option TV Proteins.

2.46 "**Option TV Protein**" means any [***] that (a) [***] and (b) is directed to the Option TV Target, [***].

2.47 "**Option TV Target**" means the target selected by Biogen pursuant to the procedures set forth in Section 4.1.4 (Selection of Option TV Target).

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

2.48 "**Other Income**" means (a) any payment received by a Party or its affiliate from a Sublicensee in consideration for the grant of rights (including an option to obtain rights) to Develop, Manufacture or Commercialize a LRRK2 Licensed Product (or a LRRK2 Licensed Compound included in such LRRK2 Licensed Product) in a country within the Co-Commercialization Territory and (b) to the extent not already described in clause (a), other payments (excluding Net Sales) when recognized as income or an offset to an expense (other than any shared Commercialization cost) in accordance with GAAP by a Party or its affiliate that is [***] a LRRK2 Licensed Product (or a LRRK2 Licensed compound included in a LRRK2 Licensed Product in a country in the Co-Commercialization Territory; *provided*, *however*, [***].

2.49 [***]

2.50 [***]

2.51 "**Product**" means a LRRK2 Licensed Product, a ROFN Product or Option Product, as applicable.

2.52 "**Program**" means the LRRK2 Program, a ROFN Program or Option Program, as applicable.

2.53 "**Region**" means each of the following: [***].

2.54 "**Regulatory Approval**" means, with respect to a particular country or other regulatory jurisdiction, all approvals, licenses, registrations or authorizations of any Regulatory Authority necessary to market and sell a pharmaceutical product or biologic in such country or regulatory jurisdiction, including, if legally required, pricing or reimbursement approvals in such country.

2.55 "**Regulatory Authority**" means any applicable supra-national, federal, national, regional, state, provincial or local governmental or Regulatory Authority, agency, department, bureau, commission, council or other entities (*e.g.*, the FDA, EMA and PMDA) regulating or otherwise exercising authority with respect to the Development, Manufacture or Commercialization of a pharmaceutical or biologic product in a particular country or other regulatory jurisdiction.

2.56 "**Regulatory Exclusivity**" means any exclusive marketing rights or exclusivity rights or protection conferred by any Regulatory Authority with respect to a pharmaceutical or biologic product in a particular country or other regulatory jurisdiction, including any regulatory protection exclusivity such as orphan drug designation or pediatric exclusivity, but in all cases excluding patent rights and patent term extensions.

2.57 "**Related Compound**" means [***].

2.58 "**Reserved Target**" means each of [***] and [***].

2.59 "**ROFN Compound**" means any protein-based molecule that (a) [***] and (b) is directed to a target (other than an Excluded Target) for which the primary indication is an indication within Alzheimer's Disease ("**AD**"), amyotrophic lateral sclerosis ("**ALS**"), multiple sclerosis ("**MS**") or PD, and for clarity, is not within lysosomal storage diseases or oncology indications (such target, the "**ROFN Compound Target**"), [***].

2.60 "**ROFN IP**" means ROFN Know-How and ROFN Patents.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

2.61 "**ROFN Know-How**" means, with respect to a ROFN Program, any and all know-how, data, materials and other information that are: (a) Controlled by Denali or its affiliates as of the Effective Date or during the term of the Provisional Collaboration and License Agreement or the Definitive ROFN and Option Agreement; and (b) [***] for the Development, Manufacture or use or Commercialization of ROFN Products in such ROFN Program[***]; but in each case, (a) and (b), excluding the TV Platform Know-How with respect to such ROFN Program.

2.62 "**ROFN Patents**" means, with respect to a ROFN Program, all patent applications and issued patents that are: (a) Controlled by Denali or its affiliates as of the Effective Date or during the term of the Provisional Collaboration and License Agreement or Definitive ROFN and Option Agreement; and (b) [***] for the Development, Manufacture or use of ROFN Compounds or ROFN Products in such ROFN Program, or the Commercialization of ROFN Products in such ROFN Program[***]; but in each case, (a) and (b), excluding the TV Platform Patents with respect to such ROFN Program.

2.63 "**ROFN Product**" means any product containing a ROFN Compound, alone or in combination with one or more other active ingredients, and in any formulation, dosage strength or method of delivery.

2.64 "**ROFN Program**" means, with respect to a ROFN Compound Target, all ROFN Compounds directed to such ROFN Compound Target that are developed and Controlled by or on behalf of Denali or its affiliates prior to the Effective Date or during the ROFN Term and pharmaceutical products containing such ROFN Compounds.

2.65 "**ROFN Term**" means the period beginning on the Effective Date and expiring on the earliest of (a) the seventh (7^{th}) anniversary of the Effective Date, (b) the date on which Biogen has provided ROFN Exercise Notices to Denali in respect of two (2) ROFN Programs in accordance with Section 4.2 (ROFN), (c) the termination of this Provisional Collaboration and License Agreement (other than as a result of the execution of the Definitive ROFN and Option Agreement) and (d) the termination of the Definitive ROFN and Option Agreement.

2.66 "**Subcontractor**" means a third party contractor (including contract research organizations or contract manufacturing organizations) engaged by a Party or its affiliates on a fee-for-service to perform certain services or activities on behalf of and for the benefit of such Party or its affiliates or exercise certain rights on behalf of such Party or its affiliates, in each case, under this Provisional Collaboration and License Agreement or the Definitive LRRK2 Collaboration and License Agreement.

2.67 "**Sublicensee**" means any third party to whom a Party or any of its affiliates grants a sublicense of its rights hereunder to Develop or Commercialize any Product, other than a Subcontractor that is granted any such sublicense.

2.68 "**Target-Specific Component**" means the component of an Option Compound or ROFN Compound that is specifically directed to amyloid beta the Option TV Target or the ROFN Compound Target, as the case maybe. For clarity, such component in an antibody directed to amyloid beta, the Option TV Target, or ROFN Compound Target is the binding portion of the complementarity-determining region of such antibody.

2.69 "**Tax**" means all forms of taxation whether direct or indirect and whether levied by reference to income, profits, gains, net wealth, asset values, turnover, added value or other reference and statutory, governmental, state, provincial, local or foreign governmental or municipal impositions, duties (including but not limited to stamp duties), contributions, rates and levies (including social security contributions and any other payroll taxes), whenever and wherever imposed (whether imposed by way of a withholding or deduction for or on account of tax or otherwise) and in respect of any person (including Taxes imposed on another person for which a person is liable by reason of being a member of a consolidated, combined, unitary or similar tax group, as a transferee or successor, by contract or otherwise) and all penalties, charges, costs and interest relating thereto.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

2.70 "**Territory**" means worldwide.

2.71 "**TV Platform**" means the proprietary platform technology Controlled by Denali or its affiliates that [***].

2.72 "**TV Platform IP**" means, with respect to an Option Program or a ROFN Program, the TV Platform Know-How and the TV Platform Patents, in each case, for such Option Program or such ROFN Program, as the case may be.

2.73 "**TV Platform Know-How**" means [***].

2.74 "**TV Platform Patents**" means [***].

2.75 "**Valid Claim**" means [***].

2.76 "**VAT**" means (a) in relation to any jurisdiction within the European Union, the tax imposed by the EC Council Directive on the common system of value added tax (2006/112/EC) and any successor or equivalent legislation and any national legislation implementing that directive together with legislation supplemental thereto and the equivalent tax (if any) in that jurisdiction; and (b) in any other jurisdiction, any other value added, goods and services, consumption or similar tax chargeable on the supply or deemed supply of goods or services under applicable legislation or regulation.

ARTICLE 3
LRRK2 PROGRAM

3.1 Governance.

3.1.1 Joint Development Committee. Activities under the Global Development Plan/Budget shall be managed jointly by the Parties under the guidance of a joint development committee ("**JDC**"), which will be composed of an equal number of representatives of each Party.

(a) **Responsibilities**. The JDC will: (i) review and approve any updates and amendments to the Global Development Plan/Budget (at least annually); (ii) monitor workflow and overall progress under the Global Development Plan/Budget and coordinate the activities of the Parties with respect thereto; and (iii) take such other actions as may be expressly delegated to the JDC in the Definitive LRRK2 Collaboration and License Agreement.

(b) **CMC Working Group**. The JDC will establish a chemistry, manufacturing and controls working group ("**CMC Working Group**") to coordinate the transfer of Manufacturing activities to Biogen and to assist the JDC in its responsibility with respect to the review and resolution of Manufacturing matters.

(c) **Decision-Making**. In the event the JDC is unable to reach a unanimous decision with respect to matters pertaining to the Development or regulatory activities for the LRRK2 Licensed Compounds and LRRK2 Licensed Products within the JDC's authority (including updates to the Global Development Plan/Budget), then the relevant matter will be submitted for resolution to the JSC pursuant to the procedures outlined in Section 3.1.3(b) (Decision Making), *provided* that the lead Party for the relevant activities will have final decision-making power, without escalation to the JSC, with respect to operational matters that are not Consent Matters.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

3.1.2 Joint Commercialization Committee.

(a) **Formation**. A joint commercialization committee ("**JCC**"), made up of an equal number of representatives from each Party, will be established to oversee Commercialization of the LRRK2 Licensed Products in the Co-Commercialization Territory and share information regarding the Commercialization of the LRRK2 Licensed Products outside of the Co-Commercialization Territory.

(b) **Responsibilities**. The JCC will (i) coordinate and manage the Parties' Commercialization activities for LRRK2 Licensed Products in the Co-Commercialization Territory, including approval of the Co-Commercialization Plan/Budget, and any updates or amendments thereto, as well as the [***], and (ii) [***].

(c) **Decision-Making**. If the JCC is unable to reach unanimous agreement on any Commercialization matters for LRRK2 Licensed Products in the Co-Commercialization Territory for which it exercises decision-making authority (including the Co-Commercialization Plan/Budget), then the matter will be submitted to the JSC for resolution, pursuant to the procedures outlined in Section 3.1.3(b) (Decision-Making).

3.1.3 Joint Steering Committee.

(a) **Formation and Responsibility**. The Parties will establish a joint steering committee ("**JSC**") responsible for overseeing the Development under the Global Development Plan/Budget in the Territory and Commercialization under the Co-Commercialization Plan/Budget in the Co-Commercialization Territory, in each case, of LRRK2 Licensed Compounds and LRRK2 Licensed Products, and for discussing and sharing information regarding the Parties' Development, Manufacturing, Medical Affairs and Commercialization activities in the Territory with respect to LRRK2 Licensed Compounds and LRRK2 Licensed Products. The JSC will be composed of an equal number of representatives of each Party. Each Party will designate one of its JSC members as a co-chair.

(b) **Decision-Making**. If the JSC is unable to agree on any matter within the scope of its authority (including a dispute referred to it by the JDC or JCC) within [***] after such matter was first referred to the JSC, then such dispute shall be referred to the Executive Officers to be resolved by good faith discussion and agreement between them. If the Executive Officers cannot reach agreement on such matter after a reasonable period (to be specified in the Definitive LRRK2 Collaboration and License Agreement), then:

(i) except as provided in clause (ii) below, [***]; and

(ii) [***].

3.2 Exclusive Collaboration.

3.2.1 Exclusivity. Except with respect to the [***] or in the performance of activities under this Provisional Collaboration and License Agreement or the Definitive LRRK2 Collaboration and License Agreement (in the case of either Party), beginning on the Execution Date and during the term of this Provisional Collaboration and Licensed Agreement and the term of the Definitive LRRK2 Collaboration and License Agreement, neither Party will (and will not permit its affiliates to), either alone or directly or indirectly with any third party, [***] (any such product, [***] a "**LRRK2 Alternative Product**"), *provided*, *however*, [***].

3.2.2 Acquisitions of LRRK2 Alternative Products. If either Party licenses, acquires or otherwise obtains Development or Commercialization rights from a third party for, any LRRK2 Alternative Product (such Party, the "**Acquiring Party**"), then such Acquiring Party shall promptly so notify the non-Acquiring Party. Within [***] from the closing date of such transaction pursuant to which the Acquiring Party obtained rights to such LRRK2 Alternative Product, as applicable, the Acquiring Party will notify the non-Acquiring Party in writing of its election to either (a) [***] or (b) [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

3.2.3 Acquisitions by a Third Party that Controls LRRK2 Alternative Products. If a Party is acquired by a third party (including through a merger with such third party) that owns or Controls one or more LRRK2 Alternative Products and one or more products that are not LRRK2 Alternative Products, in each case, pursuant to programs that are in existence as of the effective date of such transaction (such Party, the "**Acquired Party**"), then such Acquired Party shall promptly so notify the non-Acquired Party. [***]

3.2.4 Protective Provisions.

(a) Without limiting anything set forth in Section 3.2.2 (Acquisitions of LRRK2 Alternative Products) or Section 3.2.3 (Acquisitions by a Third Party that Controls LRRK2 Alternative Products) each Acquiring Party and Acquired Party will ensure that (a) [***]. Notwithstanding the foregoing clause (b) and without limiting the obligations under clause (a), [***].

(b) Notwithstanding any provision in this Provisional Collaboration and License Agreement to the contrary, nothing in this Section 3.2 (Exclusive Collaboration) shall [***](i) [***] and (ii) [***]. Notwithstanding the foregoing, [***].

3.3 Development and Regulatory.

3.3.1 Development and Regulatory Activities. The Parties will jointly be responsible for all Development activities with respect to the LRRK2 Licensed Compounds and LRRK2 Licensed Products (as further described below) for the Territory, and such activities will be conducted in accordance with the Global Development Plan/Budget (as defined below). Except as otherwise agreed by the Parties, [***]. Notwithstanding the foregoing, [***]. The Parties will reasonably cooperate and coordinate their respective regulatory interactions relating to the LRRK2 Licensed Compounds and LRRK2 Licensed Products pursuant to the procedures to be described in the Definitive LRRK2 Collaboration and Licensed Agreement. Notwithstanding any provision set forth in this Provisional Collaboration and License Agreement or the Definitive LRRK2 Collaboration and License Agreement, the Parties agree that (i) Denali shall conduct and control the Development of LRRK2 Licensed Compounds and LRRK2 Licensed Products following the Execution Date until the later of the execution of the Definitive LRRK2 Collaboration and License Agreement and the Effective Date, *provided* that following approval of the initial Global Development Plan/Budget by the JSC, such Development activities will be performed in accordance with such Global Development Plan/Budget; and (ii) no earlier than the date on which the initial Global Development Plan/Budget is approved Biogen shall reimburse Denali for the costs and expenses incurred in conducting Development activities for the LRRK2 Licensed Products during the period commencing on the Execution Date and ending upon the date on which the initial Global Development Plan/Budget is approved by the JSC (the "**Interim Development Period**"), *provided* that in no event will Biogen be required to reimburse Denali more than [***] in respect of such Development activities over any given [***] period during the Interim Development Period.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

3.3.2 Global Development Plan/Budget. Promptly following the Effective Date and in any event prior to execution of the Definitive LRRK2 Collaboration and License Agreement, the JSC will (a) consider in good faith (i) each Party's proposal for an initial plan for the Development of LRRK2 Licensed Compounds and LRRK2 Licensed Products for the Territory, and a budget for such activities and (ii) any feedback provided by a Regulatory Authority on such plan and (b) agree upon such plan and budget (the "**Global Development Plan/Budget**"), and such initial Global Development Plan/Budget approved by the JSC shall be attached to the Definitive LRRK2 Collaboration and License Agreement as an exhibit. Such Global Development Plan/Budget (as amended in accordance with the procedures outlined below) shall describe the Development activities (along with an estimated budget and timeline of such activities) with respect to the LRRK2 Licensed Compounds and LRRK2 Licensed Products to be conducted by or on behalf of each of Denali and Biogen to obtain Regulatory Approval of the LRRK2 Licensed Products in the Territory, and, unless otherwise agreed by the Parties, shall provide that a LRRK2 Licensed Product containing DNL-151 will be the subject of the initial clinical studies set forth in the initial Global Development Plan/Budget. The Global Development Plan/Budget will include a meaningful allocation of Development activities to each Party, *provided* that to the extent not specified in this Provisional Collaboration and License Agreement, the Definitive LRRK2 Collaboration and License Agreement or in the Global Development Plan/Budget, the JSC shall allocate responsibility as between the Parties with respect to the Development activities set forth in such Global Development Plan/Budget. In any event, the Global Development Plan/Budget will include timelines for the performance of each clinical study for a LRRK2 Licensed Product to be initiated and other material Development activities for the LRRK2 Licensed Products.

3.3.3 Independent Clinical Studies. If one Party proposes to pursue a clinical study [***] (such activities, collectively, an "**Independent Study**"), and, following discussion of such matter at the JSC, the other Party declines to include such Independent Study in the Global Development Plan/Budget [***], then the proposing Party may conduct such Independent Study at its own cost and expense and may seek and obtain Regulatory Approval for the applicable LRRK2 Licensed Product and indication; *provided* that, [***]. In such case, (a) if Regulatory Approval is obtained in any country utilizing the data the proposing Party generates from such Independent Study or (b) if the other Party elects to include such Independent Study under the Global Development Plan/Budget prior to such Regulatory Approval being obtained, then promptly upon receipt of such Regulatory Approval or prior to the inclusion of such Independent Study in the Global Development Plan/Budget (in the event of an earlier election date), as applicable, the non-proposing Party will reimburse the proposing Party an amount equal to that portion of the Development costs and expenses incurred with respect to the Independent Study (including the associated Manufacturing Costs (to be defined in the Definitive LRRK2 Collaboration and License Agreement)) prior to such Regulatory Approval or inclusion, as applicable, that would have been borne by the non-proposing Party if such Independent Study had been included in the Global Development Plan/Budget [***]. [***] The Definitive LRRK2 Collaboration and License Agreement will include a more detailed mechanism by which an Independent Study can be proposed by a Party and the costs and expenses of such Independent Study will be reimbursed, in each case, consistent with this Section 3.3.3 (Independent Clinical Studies) and will provide for any disputes regarding a Material Adverse LRRK2 Program Effect to be resolved pursuant to [***]. At its election, Biogen will [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

3.3.4 Denali Opt-Out.

(a) Denali Election to Opt-Out. Denali shall have the right to opt-out of further co-Development activities for the LRRK2 Program as a whole or [***] under the Global Development Plan/Budget for all countries or co-Commercialization activities for the LRRK2 Program or [***] for the U.S. or China (and the Development and Commercialization cost-sharing and Profit Share associated therewith), subject to a reasonable, [***] wind-down mechanism (or such shorter period as may be agreed to by the Parties) (to be further specified in the Definitive LRRK2 Collaboration and License Agreement), which such period shall not commence at any time during the [***] period prior to the anticipated commercial launch of any LRRK2 Licensed Product (in the case of an opt-out by Denali with respect to the LRRK2 Program as a whole) or [***] in either the U.S. or China, as applicable (any such LRRK2 Licensed Compound for which Denali exercises such opt-out right [***], together with all LRRK2 Licensed Products that contain such LRRK2 Licensed Compound, collectively, an "**Opt-Out Product**", and countries for which Denali has exercised its opt-out right[***], the "**Opt-Out Countries**"). In such case [***].

(b) [***]

3.3.5 Pharmacovigilance and Adverse Event Reporting. The Parties will cooperate with each other with regard to the reporting and handling of safety information involving the LRRK2 Licensed Products in accordance with applicable law, regulatory requirements, and regulations on pharmacovigilance and clinical safety. Within [***] following the Effective Date or as otherwise agreed by the Parties, the Parties will negotiate in good faith and enter into a pharmacovigilance agreement related to the LRRK2 Licensed Products, which will define the pharmacovigilance responsibilities of the Parties and include safety data exchange procedures governing the exchange of information affecting the class and products to enable each Party to comply with all of its legal and regulatory obligations related to such LRRK2 Licensed Products (the "**Pharmacovigilance Agreement**"). Following the execution of the Pharmacovigilance Agreement, Biogen will own and maintain the global safety database for all LRRK2 Licensed Products that is created by and held by Biogen, and following the execution of the Pharmacovigilance Agreement, Denali shall transfer the contents and ownership of the global safety database for all LRRK2 Licensed Products created by Denali pursuant to a mutually agreed plan in an electronic format agreed upon by the Parties.

3.4 Commercialization.

3.4.1 Co-Commercialization Plan/Budget. The Parties will jointly be responsible for the Commercialization of the LRRK2 Licensed Products in the Co-Commercialization Territory, and Biogen will [***] with respect to, the Commercialization of LRRK2 Licensed Products in all other countries of the Territory. Reasonably prior to First Commercial Sale of a LRRK2 Licensed Product in the Co-Commercialization Territory, the Parties shall agree on a written plan and budget for all Commercialization activities in the Co-Commercialization Territory for LRRK2 Licensed Products (the "**Co-Commercialization Plan/Budget**"), which [***]Biogen's global commercialization strategy with respect to the LRRK2 Licensed Products. In addition, the Co-Commercialization Plan/Budget will provide that:

(a) [***];
(b) [***].

Further, the Co-Commercialization Plan/Budget will describe the following with respect to LRRK2 Licensed Products in the Co-Commercialization Territory: [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

3.4.2 Commercialization Costs. The Parties will share the costs and expenses incurred in the performance of such Commercialization activities in the Co-Commercialization Territory to the extent in accordance with the Co-Commercialization Plan/Budget (including Allowable Overruns) and profits (or losses) with respect to the Commercialization of LRRK2 Licensed Products in the Co-Commercialization Territory in accordance with Section 4 of Schedule 3.8 (LRRK2 Financials). For the avoidance of doubt, the relevant Biogen entity will book sales of LRRK2 Licensed Products in the relevant Co-Commercialization Territory [***] Separate reporting for the co-Commercialization activities in the United States and China shall be maintained. [***]

3.4.3 Decision-Making. Biogen will [***] perform [***]and bear the costs and expenses of, Commercializing LRRK2 Licensed Products outside the Co-Commercialization Territory. Biogen will pay to Denali the milestones and royalties specified in Schedule 3.8 (LRRK2 Financials) achieved with respect to the LRRK2 Licensed Products. Biogen will share plans for, and information regarding activities with respect to, the Commercialization of LRRK2 Licensed Products outside the Co-Commercialization Territory through the JCC and JSC and the Commercialization of the LRRK2 Licensed Products outside of the Co-Commercialization Territory will be discussed by the Parties through the JCC and JSC, as to be further outlined in the Definitive LRRK2 Collaboration and License Agreement. [***]

3.5 Manufacturing. Denali shall be responsible for Manufacturing or having Manufactured LRRK2 Licensed Product for [***]. [***]with the intent of minimizing interruptions to the Development of LRRK2 Licensed Products but no later than [***], Denali will, no later than [***] after such request, transfer Manufacturing responsibilities of LRRK2 Licensed Compounds and LRRK2 Licensed Products to Biogen (or its designee) pursuant to a plan to be agreed by the Parties through the CMC Working Group (the "**Manufacturing Transition Plan**"), and the Parties will cooperate to effect such transition of Manufacturing responsibilities in accordance with such Manufacturing Transition Plan. [***] Following completion of such Manufacturing transfer, Biogen will have the sole right to perform, and will have final decision-making authority under the CMC Working Group with respect to, Manufacturing of all LRRK2 Licensed Compounds and LRRK2 Licensed Products, and Manufacturing Costs (to be defined in the Definitive LRRK2 Collaboration and License Agreement) charged by Biogen and shared by the Parties for all such LRRK2 Licensed Compounds and LRRK2 Licensed Products will be consistent with arms-length, commercial terms with a third party contract manufacturing organization.

3.6 Medical Affairs. The Parties' responsibilities to conduct Medical Affairs activities with respect to LRRK2 Licensed Products inside and outside of the Co-Commercialization Territory (and to bear the costs and expenses associated therewith) will apply *mutatis mutandis* to each Party's respective responsibilities to Commercialize LRRK2 Licensed Products set forth in Section 3.4 (Commercialization), *provided*, *however* that, unless otherwise agreed to by the JCC:

3.6.1 [***];

3.6.2 [***]; and

3.6.3 the JCC will oversee all Medical Affairs activities with respect to LRRK2 Licensed Products inside and outside of the Co-Commercialization Territory.

3.7 Diligence.

3.7.1 Global Development Plan/Budget. Each Party will use Commercially Reasonable Efforts to perform the activities allocated to such Party under the Global Development Plan/Budget in accordance with the timelines set forth therein.

3.7.2 Co-Commercialization Territory. Each Party will use Commercially Reasonable Efforts to: (a) seek and obtain Regulatory Approval for at least [***] and (ii) [***], in each case ((i) and (ii)), [***]; and (b) [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

3.7.3 Ex-Co-Commercialization Territory. Biogen will use Commercially Reasonable Efforts to: (a) seek and obtain Regulatory Approval for at least [***], in each case ((i) and (ii)), [***]; and (b) [***].

3.8 Financials. Following the date on which the Parties enter into the Definitive Agreements, Biogen shall pay Denali in accordance with the terms set forth in Schedule 3.8 (LRRK2 Financials).

3.9 License Grants; Intellectual Property.

3.9.1 License Grants.

(a) **License to Biogen**. Denali hereby grants to Biogen a worldwide, co-exclusive (with Denali) license under the LRRK2 IP to research, Develop, make, have made, use, Manufacture, and import LRRK2 Licensed Compounds and LRRK2 Licensed Products and perform Medical Affairs with respect to, offer for sale, sell, and Commercialize LRRK2 Licensed Products in the Field in the Territory, all on the terms described in this Provisional Collaboration and License Agreement (as it may be superseded by, the Definitive LRRK2 Collaboration and License Agreement). Biogen agrees to be bound by and comply with obligations under the agreements listed on Schedule 3.9.1 (Existing LRRK2 Agreements) that are applicable to Biogen and the Parties activities under the LRRK2 Program ("**Existing LRRK2 Agreements**").

(b) **License to Denali**. The Definitive LRRK2 Collaboration and License Agreement will also include a grant of non-exclusive licenses by Biogen to Denali under Biogen IP solely to the extent necessary to enable Denali to jointly Develop such LRRK2 Licensed Compounds and LRRK2 Licensed Products in accordance with the Global Development Plan/Budget, to perform Medical Affairs with respect to LRRK2 Licensed Products in accordance with the Co-Commercialization Plan/Budget and to co-Commercialize LRRK2 Licensed Products in the Co-Commercialization Territory in accordance with the Co-Commercialization Plan/Budget, all as described in this Provisional Collaboration and License Agreement.

(c) **Sublicensing**. [***] Denali shall have the right to grant sublicenses to [***]. Except as expressly set forth in the previous sentence, without the other Party's prior written consent, neither Party may grant sublicenses to any third party Sublicensee to (i) [***] or (ii) [***]. Biogen may grant sublicenses to [***]. Any such (sub)license will be [***].

3.9.2 Patent Prosecution and Enforcement. As between the Parties [***]

3.10 Termination.

3.10.1 Termination for Convenience. Beginning on the date that is [***] following the Effective Date, and on not less than [***] prior written notice to Denali, Biogen will have the right, at its sole discretion, to terminate Article 3 (LRRK2 Program) of this Provisional Collaboration and License Agreement (including the appendices referenced in Article 3 (LRRK2 Program) or the Definitive LRRK2 Collaboration and License Agreement (as applicable)) for convenience (a) in its entirety or (b) with respect to any Region. Any such Region for which Article 3 (LRRK2 Program) of this Provisional Collaboration and License Agreement or the Definitive LRRK2 Collaboration and License Agreement (as applicable) is terminated will be referred to hereunder as a "**Terminated Region**" (and if Article 3 (LRRK2 Program) of this Provisional Collaboration and License Agreement or the Definitive LRRK2 Collaboration and License Agreement is terminated in its entirety, then all Regions in the world will be referred to herein as Terminated Regions).

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

3.10.2 Termination for Material Breach. Each Party shall have the right to terminate Article 3 (LRRK2 Program) of this Provisional Collaboration and License Agreement (including the appendices referenced in Article 3 (LRRK2 Program) or the Definitive LRRK2 Collaboration and License Agreement (as applicable)) for material breach in accordance with the terms set forth in Section 5.1.2 (Termination).

3.10.3 Additional Termination Rights. Denali will have right to terminate Article 3 (LRRK2 Program) of this Provisional Collaboration and License Agreement (including the appendices referenced in Article 2 (LRRK2 Program) or the Definitive LRRK2 Collaboration and License Agreement (as applicable)):

(a) in its entirety upon [***] written notice, if Biogen has not conducted any [***] activities to advance the [***] for at least [***], and such [***] is not (i) [***], (ii) [***], (iii) [***], (iv) [***] or (v) [***]; *provided* that [***]; or

(b) [***]

3.10.4 The Definitive LRRK2 Collaboration and License Agreement will contain additional customary provisions regarding termination rights, including termination rights for insolvency of a Party on terms equivalent to those in Section 5.1.2 (Termination).

3.11 Effects of Termination. In the event of termination of this Provisional Collaboration and License Agreement in its entirety, with respect to the LRRK2 Program by Biogen pursuant to Section 3.10.1 (Termination for Convenience), or by Denali pursuant to Section 3.10.2 (Termination for Material Breach) or Section 3.10.3 (Additional Termination Rights), in each case, prior to the execution of the Definitive LRRK2 Collaboration and License Agreement, the LRRK2 Licensed Compounds and LRRK2 Licensed Products and will become "**Terminated Compounds**" and "**Terminated Products**", and the following terms of this Section 3.11 (Effects of Termination) shall apply.

3.11.1 Transition. [***]

3.11.2 License. Biogen shall grant, and does hereby grant, effective as of the termination date, to Denali:

(a) an exclusive license, with the right to grant multiple tiers of sublicenses, to Develop, Manufacture, perform Medical Affairs activities and Commercialize the Terminated Compounds and Terminated Products and, to the extent Controlled by Denali following the effective date of termination hereof, other LRRK2 Inhibitors and products containing such LRRK2 Inhibitors in or for the Terminated Regions under (i) that know-how Controlled by Biogen or its affiliates [***] to Develop, Manufacture, perform Medical Affairs activities or Commercialize Terminated Compounds or Terminated Products and (ii) patents Controlled by Biogen or its affiliates [***];

(b) to the extent not licensed under Section 3.11.2(a), a non-exclusive license, with the right to grant multiple tiers of sublicenses, to Develop, Manufacture, perform Medical Affairs activities and Commercialize the Terminated Compounds and Terminated Products and, to the extent Controlled by Denali following the effective date of termination hereof, other LRRK2 Inhibitors and products containing such LRRK2 Inhibitors in or for the Terminated Regions, under (i) the know-how Controlled by Biogen or its affiliates [***], and (ii) patents Controlled by Biogen or its affiliates [***].

3.11.3 [***]:

(a) [***];

(b) [***];

(c) [***];

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(d) [***];

[***]. In addition, Denali would have the right to use and disclose for any purpose any Results that are [***] to the Terminated Products and Terminated Regions and, following the effective date of such termination, the foregoing Results shall constitute Denali's Confidential Information subject to Section 5.4 (Confidentiality and Non-Disclosure).

3.12 Other Terms. The Definitive LRRK2 Collaboration and License Agreement will contain additional comparable provisions to those set forth above and such provisions regarding effects of expiration or termination of such agreement, including additional terms and conditions to more fully implement the transfer of Biogen's rights and activities with respect to the LRRK2 Program to Denali to enable Denali to continue the Development, Manufacture and Commercialization of LRRK2 Licensed Compounds and LRRK2 Licensed Products throughout the Territory following such termination or expiration.

ARTICLE 4
OPTION AND ROFN PROGRAMS

4.1 Option.

4.1.1 Grant of Option. Denali hereby grants to Biogen during the applicable Option Exercise Period (x) an exclusive option to obtain an exclusive license under Option IP for the ATV:Abeta Program, and (y) an exclusive option to obtain an exclusive license under Option IP for the Option TV Program (each such exclusive option described in the foregoing clauses (x) and (y), an "**Option**"). Biogen will have the right to exercise each Option by providing to Denali written notice ("**Option Exercise Notice**") prior to the expiration of the Option Exercise Period for the Option Program covered by such Option. Each license agreement pursuant to which the foregoing licenses would be granted to Biogen shall include the following terms (and the full terms of each such license agreement will be set forth in the Definitive ROFN and Option Agreement):

(a) The grant of an exclusive license by Denali to Biogen under Option IP specifically for the purposes of the Option Program for which an Option Exercise Notice has been provided, consistent with the licenses granted by Denali to Biogen under the LRRK2 IP under the Definitive LRRK2 Collaboration and License Agreement to Develop or Manufacture Option Compounds and Option Products with respect to such Option Program and to perform Medical Affairs with respect to or Commercialize such Option Products;

(b) The grant of a non-exclusive license by Denali to Biogen under TV Platform IP with respect to the Option Program for which an Option Exercise Notice has been provided to Develop or Manufacture Option Compounds and Option Products with respect to such Option Program and to perform Medical Affairs with respect to or Commercialize such Option Products;

(c) With respect to the Option Program for which an Option Exercise Notice has been provided: (i) [***] and (ii) [***], and (iii) [***];

(d) Following Biogen's exercise of an Option, exclusivity commitments prohibiting each Party and their respective affiliates from, whether independently or with a third party, Developing, Commercializing or otherwise Exploiting any therapeutic products directed to (i) in the case of the ATV:Abeta Program, amyloid beta [***] or (ii) in the case of the Option TV Program, the Option TV Target that include [***], in each case ((i) and (ii)), consistent with the scope of the exclusivity provisions set forth herein with respect to the LRRK2 Program and the exceptions described in Section 3.2.1 (Exclusivity), Section 3.2.2 (Acquisition of LRRK2 Alternative Products), Section 3.2.3 (Acquisitions by a Third Party that Controls LRRK2 Alternative Products) and Section 3.2.4 (Protective Provisions), *mutatis mutandis*;

(e) [***];

(f) Agreement by Biogen that it will be subject to the provisions that are applicable to Biogen's activities or are required to be incorporated into any sublicense granted under any Option IP consistent with the agreements listed on Schedule 4.1.1(f) (Existing Option Program Agreements) (such agreements, the "**Existing Option Program Agreements**"); and

(g) [***].

4.1.2 Option Data Package; Due Diligence.

(a) **Option Data Package**. On an Option Program-by-Option Program basis, Denali will deliver to Biogen a data package regarding [***] to be identified in the Definitive ROFN and Option Agreement (the "**Option Data Package**") as soon as reasonably practicable after Denali's completion of the activities required to generate and review such data if such activities are completed prior to the expiration of the Option Term, but no later than [***] prior to the Initiation of IND-Enabling Studies under a given Option Program. Without limiting the foregoing, the Option Data Package for each Option Program shall contain such data that is [***]. On an Option-Program-by-Option Program basis, [***], then no later than [***] prior to [***] anniversary of the Effective Date Denali shall deliver to Biogen a data package that includes the data available to Denali at such time that would have been included in the Option Data Package (the "**Partial Option Data Package**").

(b) **Incomplete Option Data Package**. Following receipt of an Option Data Package for an Option Program, Biogen shall have the one-time right (subject to the remainder of this Section 4.1.2(b) (Incomplete Option Data Package)) to promptly (but in any event, within [***] of its receipt of the Option Data Package) notify Denali if such Option Data Package is missing any [***]. Denali shall provide Biogen with such missing [***] identified in such notice within [***] after the date of Biogen's request (if and to the extent that such [***] is available to Denali at such time). If, following any such request from Biogen, Denali does provide any such missing [***] that is available to Denali at such time within such [***], then the Option Exercise Period with respect to a given Option Program shall be extended to end [***] after delivery of such missing [***]. If Denali does not provide such missing [***] within such [***] period and does not otherwise confirm in writing to Biogen that such data is unavailable to Denali, then Biogen shall have the right to request such information from Denali again in accordance with this Section 4.1.2(b) (Incomplete Option Data Package) and the terms of this Section 4.1.2(b) (Incomplete Option Data Package) shall again apply. For clarity, Denali shall not be obligated to perform or reperform any Development activities pursuant to this Section 4.1.2(b) (Incomplete Option Data Package).

(c) **Due Diligence**. During the Option Exercise Period for a given Option Program, to assist Biogen in conducting thorough due diligence to decide whether to exercise an Option for such Option Program, at least once every [***], Denali will provide a written summary of material Development activities conducted with respect to such Option Program and afford to Biogen and its representatives an opportunity to discuss such activities with Denali personnel during normal business hours. In addition, during the Option Exercise Period following delivery of the Option Data Package or Partial Option Data Package for an Option Program, as the case may be, upon Biogen's request, (i) Denali will afford to Biogen and its representatives reasonable access during normal business hours to Denali's personnel, records and data, offices and laboratories, in each case, that Biogen may reasonably request related to such Option Program to conduct customary and reasonable due diligence of such Option Program and (ii) Denali will promptly provide through an electronic data room copies of (A) any documents reasonably requested by Biogen, (B) any patent or regulatory information and (C) any results of preclinical activities relating to such Option Program, in each case ((A) – (C)), (x) then available to Denali, (y) to the extent that such information has not been previously provided by Denali to Biogen and pertains to such Option Program, as the case may be, for such Option Program and (z) subject to customary and reasonable due diligence procedures to preserve the confidential nature of any such information.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

4.1.3 Denali Diligence and Restrictions. During the Option Term for a given Option Program: (a) Denali will use Commercially Reasonable Efforts to [***]; (b) except with Biogen's consent, Denali will not [***]; and (c) other than with the prior written consent of Biogen, [***].

4.1.4 Selection of Option TV Target.

(a) **Option TV Target Notice**. During the period commencing on the Execution Date and ending upon the [***] following the Execution Date (the "**Option TV Target Selection Period**"), Biogen shall have a one-time right (but not the obligation) to select one (1) Reserved Target as the Option TV Target by sending written notice to Denali, which notice will identify such proposed target (such notice, a "**TV Target Notice**"). The target nominated by Biogen shall become the Option TV Target upon Denali's receipt of such TV Target Notice in accordance with this Section 4.1.4(a) (Option TV Target Notice).

(b) **Reserved Targets**. During the period commencing on the Execution Date and ending upon the earlier of (i) the end of the Option TV Target Selection Period, (ii) the date on which Biogen delivers a TV Target Notice to Denali in accordance with Section 4.1.4(a) (Option TV Target Notice), (iii) termination of the Provisional Collaboration and License Agreement (other than as a result of the execution of the Definitive ROFN and Option Agreement) and (iv) the termination of the Definitive ROFN and Option Agreement, Denali will not assign, transfer, convey or grant any license or other rights to its rights, title and interests in or to the Option IP (as if a Reserved Target were the Option TV Target for purposes of such definition) that would conflict with or limit the scope of the Option granted to Biogen pursuant to Section 4.1.1 (Grant of Option) with respect to any Reserved Target if such Reserved Target to become the Option TV Target. Notwithstanding the foregoing, nothing in this Section 4.1.4(b) (Reserved Targets) shall restrict Denali's ability to grant non-exclusive licenses under the Option IP to Subcontractors to Development and Manufacture Option Compounds or Option Products, *provided*, that each such non-exclusive license will be granted pursuant to a written agreement that is consistent with the terms of this Definitive LRRK2 Collaboration and License Agreement and the Definitive ROFN and Option Agreement and that requires each such licensee to [***].

4.1.5 Termination of Option. If Biogen does not provide an Option Exercise Notice in respect of a given Option Program prior to the expiration of the Option Exercise Period for such Option Program, then Biogen's Option with respect to such Option Program shall terminate and Denali shall have no further obligations to Biogen with respect to such Option Program that is the subject of such Option.

4.2 ROFN.

4.2.1 ROFN Program; Procedures.

(a) **Grant of ROFN**. During the ROFN Term, if with respect to a given ROFN Program, Denali or its affiliates intends to enter into material negotiations with any third party to grant to such third party the right (or any option or other contingent rights) to Commercialize ROFN Products that are the subject of such ROFN Program, whether by license, sale of assets or otherwise, then Denali agrees to [***]. Biogen will have an exclusive right of first negotiation ("**ROFN**") to negotiate the terms and conditions of a definitive agreement pursuant to which Denali would grant exclusive rights to Biogen with respect to such ROFN Program to Develop, Commercialize or otherwise Exploit ROFN Products, which terms shall be consistent with the terms applicable to the LRRK2 Program, as set forth in this Provisional Collaboration and License Agreement or, when applicable, the Definitive LRRK2 Collaboration and License Agreement ("**ROFN Exercise Agreement**") subject to the time periods described in Section 4.2.1(b) (Failure to Enter into ROFN Exercise Agreement) below. Biogen may exercise the ROFN with respect to the applicable ROFN Program by notifying Denali in writing (a "**ROFN Exercise Notice**") no later than [***] following its receipt of the [***], *provided* that, for clarity, Biogen may not provide ROFN Exercise Notices to Denali for more than two (2) ROFN Programs during the ROFN Term. During such [***] period, Denali shall, upon Biogen's request, (i) Denali will afford to Biogen and its representatives reasonable access during normal business hours to Denali's personnel, records and data, offices and

laboratories, in each case, that Biogen may reasonably request related to such ROFN Program to conduct customary and reasonable due diligence of such ROFN Program and (ii) promptly provide through an electronic data room copies of (A) any documents reasonably requested by Biogen, (B) any patent or regulatory information and (C) any results of preclinical activities relating to such ROFN Program, in each case ((A) – (C)), (x) then available to Denali, (y) to the extent that such information has not been previously provided by Denali to Biogen and pertains to such ROFN Program, and (z) subject to customary and reasonable due diligence procedures to preserve the confidential nature of any such information. Until the expiration of the [***] period within which Biogen may issue a ROFN Exercise Notice for such ROFN, or if Biogen issues a ROFN Exercise Notice within such [***] period, the expiration of the [***] period or [***] period, as applicable, specified in Section 4.2.1(b) (Failure to Enter into ROFN Exercise Agreement) below for such ROFN Program, Denali and its affiliates will not enter into negotiations or any agreement with any third party relating to any license, sale or other transfer of rights with respect to such ROFN Program. If Biogen so provides a ROFN Exercise Notice to Denali for such ROFN Program during such [***] period, then Biogen and Denali shall exclusively negotiate in good faith with one another the potential terms of a ROFN Exercise Agreement in respect of such ROFN Program.

(b) **Failure to Enter into ROFN Exercise Agreement**. If (i) Biogen does not provide a ROFN Exercise Notice in respect of such ROFN Program to Denali within such [***] period, (ii) the Parties do not agree on the terms of a non-binding term sheet in respect of such ROFN Exercise Agreement [***] following Biogen's delivery of a ROFN Exercise Notice for such ROFN Program to Denali or (iii) the Parties have agreed on such terms of a non-binding term sheet within [***], but have not executed a ROFN Exercise Agreement in respect of such ROFN Program within [***] following Biogen's delivery of a ROFN Exercise Notice for such ROFN Program to Denali, then Denali and its affiliates shall be free to grant to any third party any rights to such ROFN Program or any portion thereof, without further obligations to Biogen, and on any terms that Denali and a third party considers appropriate[***].

4.2.2 Additional ROFN Details.

(a) Without limiting Section 4.2.1(a) (Grant of ROFN) above, during the ROFN Term, Denali shall provide a written pipeline overview of its ROFN Programs then-subject to the ROFN at least once every [***].

(b) [***].

(c) [***]

(d) It is understood and agreed that certain product(s) included in a program that is the subject of the ROFN may or may not be discovered or reduced to practice to any particular degree or at all at the time of [***] and that further modification or variations of a product (or products within such program) may be developed after the date of [***]. Accordingly, following delivery of [***], then [***], the requirements of the ROFN shall be deemed satisfied with respect to any and all products within such ROFN Program or otherwise directed to the applicable target (and mutants or variants thereof), whether developed or reduced to practice before or after the date of [***]. Further, because Denali will provide [***] for a particular ROFN Program to Biogen prior to the commencement of material negotiations with third parties with respect to such ROFN Program [***], then Denali and its affiliates shall be deemed to have satisfied its obligations to Biogen under this provision with respect to the applicable ROFN Program, and Denali need only provide one [***] before engaging in such material negotiations with the first third party for a particular ROFN, even if Denali subsequently engages in discussions with more than one third party [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(e) Additionally, if Denali or its affiliates enters into a transaction with a third party in accordance with the ROFN provisions above (following the expiration of the applicable time periods set forth Section 4.2.1(b) (Failure to Enter into ROFN Exercise Agreement)) that includes the grant by Denali or its affiliates of an option or other contingent right to acquire the right to market and sell a ROFN Program (or one or more products within such ROFN Program) (each such option or right being referred to as a "**Contingent Right**"), then the third party's exercise of such Contingent Right shall not be subject to the ROFN. Denali and its affiliates are not obligated under the ROFN to provide to Biogen any particular information other than as expressly stated in this Section 4.4 (Additional ROFN Details) and Denali may require a separate confidentiality agreement between Denali and Biogen as a condition to any disclosure of information relating to a particular ROFN Program(s) in connection with the ROFN.

4.3 Financials. In consideration of the rights granted to Biogen under the Options and the ROFNs, the Definitive ROFN and Option Agreement will provide that Biogen will pay to Denali the amounts set forth in Schedule 4.3 (ROFN and Option Financials).

4.4 Other ROFN and Option Terms.

4.4.1 The only obligations of Biogen and Denali and their respective affiliates with respect to the ROFN and Options described above are as expressly stated therein, there are no further implied obligations relating to the matters contemplated therein and [***].

4.4.2 It is further acknowledged and agreed that neither the ROFN or Options shall apply to, nor otherwise restrict, a transaction by which a third party acquires all or substantially all of the business or assets of Denali and its affiliates (whether in a merger, sale of stock, sale of assets or any other transaction), [***]. Further in no event shall the terms of the ROFN apply to any program of any third party acquirer of Denali (or any of such acquiror's affiliates) that is not such a ROFN Program.

4.4.3 [***]

ARTICLE 5
MISCELLANEOUS

5.1 Term and Termination of this Provisional Collaboration and License Agreement.

5.1.1 Term. The term of this Provisional Collaboration and License Agreement shall commence on the Execution Date and continue thereafter unless (i) the Stock Purchase Agreement is validly terminated pursuant to Section 9.4 (Termination) of the Stock Purchase Agreement prior to Closing (as defined in the Stock Purchase Agreement) occurring thereunder, in which case this Provisional Collaboration and License Agreement shall terminate concurrently with termination of the Stock Purchase Agreement, or (ii) either Party terminates this Provisional Collaboration and License Agreement in accordance with Section 5.1.2 (Termination). In addition:

(a) The terms of Article 3 (LRRK2 Program) (and all Schedules referenced therein) will expire (but not be considered terminated) upon execution of the Definitive LRRK2 Collaboration and License Agreement, and upon such execution, the Definitive LRRK2 Collaboration and License Agreement will automatically supersede and replace Article 3 (LRRK2 Program);

(b) The terms of Article 4 (Option Programs and ROFN Programs) (and all Schedules referenced therein) will expire (but not be considered terminated) upon execution of the Definitive ROFN and Option Agreement, and upon such execution, the Definitive ROFN and Option Agreement will automatically supersede and replace Article 4 (Option Programs and ROFN Programs); and

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(c) Except as otherwise set forth herein, all terms of this Provisional Collaboration and License Agreement will expire (but not be considered terminated) upon execution of both the Definitive LRRK2 Collaboration and License Agreement and the Definitive ROFN and Option Agreement.

5.1.2 Termination.

(a) **Termination for Material Breach**. Either Party (the "**Non-Breaching Party**") shall have the right to terminate this Provisional Collaboration and License Agreement in the case of a material breach of this Provisional Collaboration and License Agreement (including the Schedules referenced in Article 2 (LRRK2 Program)) by the other Party (the "**Breaching Party**") if such material breach remains uncured after [***] (or if applicable, the cure period specified in this Section 5.1.2(a) below) following delivery by the Non-Breaching Party of written notice of such material breach to the Breaching Party (a "**Breach Notice**"), *provided* that if such material breach is with respect to the LRRK2 Program only or the ROFN and Option only (or the compounds related to either of the foregoing), then such Non-Breaching Party shall have the right to terminate this Provisional Collaboration and License Agreement solely with respect to the LRRK2 Program or the ROFN and Option, as the case may be. The Breaching Party shall have [***] from its receipt of such Breach Notice to cure such material breach (subject to the dispute resolution procedures set forth in Section 5.1.2(b) (Disputes Regarding Material Breach) below). Notwithstanding any provision in this Provisional Collaboration and License Agreement to the contrary, [***].

(b) **Disputes Regarding Material Breach**. Notwithstanding anything in this Provisional Collaboration and License Agreement to the contrary, during the [***] cure period described in Section 5.1.2(a) (Termination for Material Breach) above, the Breaching Party may dispute that it has committed such material breach. If the Breaching Party disputes the applicable material breach notice within such cure period, then such cure period shall be tolled until the dispute is resolved pursuant to the dispute resolution procedures set forth in Schedule 5.5.2 (Disputes), and this Provisional Collaboration and License Agreement will remain in full force and effect during the pendency of any such dispute. If, as a result of the application of such dispute resolution procedures, the Breaching Party is determined by the Panel to be in material breach of this Provisional Collaboration and License Agreement (as it may be superseded by the applicable Definitive Agreement) (an "**Adverse Ruling**") and the Breaching Party fails to complete the actions specified by the Adverse Ruling to cure such material breach within the applicable remainder of such cure period after such ruling is issued (or such longer period as the Panel may determine appropriate), then the Non-Breaching Party may terminate this Provisional Collaboration and License Agreement in its entirety, with respect to the LRRK2 Program or with respect to the ROFN and Option, as the case may be and as described in Section 5.1.2(a) (Termination for Material Breach) above, upon written notice to the Breaching Party.

5.1.3 Termination for Insolvency. To the extent permitted by applicable law, either Party may terminate this Provisional Collaboration and License Agreement upon the filing or institution of bankruptcy, reorganization, liquidation, or receivership proceedings, upon the appointment of a receiver or trustee over all or substantially all property, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; *provided*, *however*, that in the case of any involuntary bankruptcy proceeding such right to terminate will only become effective if the Party consents to the involuntary bankruptcy or such proceeding is not dismissed within [***] after the filing thereof. In the event of any termination pursuant to this Section 5.1.3 (Termination for Insolvency):

(a) All rights and licenses now or hereafter granted by one Party to the other Party under or pursuant to this Provisional Collaboration and License Agreement are, for all purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined in the U.S. Bankruptcy Code. Upon the filing or institution of bankruptcy, reorganization, liquidation, or receivership proceedings, upon the appointment of a receiver or trustee over all or substantially all property, or upon an assignment of a substantial portion of the assets for the benefit of creditors by a Party, such Party agrees that the other Party, as licensee of such rights under this Provisional Collaboration and License Agreement, will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. Each Party will, during the term of this Provisional Collaboration and License Agreement, create and maintain current copies or, if not amenable to copying, other appropriate embodiments, to the extent feasible, of all intellectual property rights licensed under this Provisional Collaboration and License Agreement. Each Party acknowledges and agrees that "embodiments" of intellectual property rights within the meaning of Section 365(n) include laboratory notebooks, cell lines, product samples, and inventory, research studies and data, all Regulatory Approvals (and all applications for Regulatory Approval) and rights of reference therein, in each case, to the extent licensed by a Party to the other Party hereunder, as well as the Denali IP and the Biogen IP (as the case may be), and all information related to the Denali IP and the Biogen IP (as the case may be). If (i) a case under the U.S. Bankruptcy Code is commenced by or against the debtor Party, (ii) this Provisional Collaboration and License Agreement is rejected as provided in the U.S. Bankruptcy Code, and (iii) the non-debtor Party elects to retain its rights hereunder as provided in Section 365(n) of the U.S. Bankruptcy Code, then the debtor Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) will:

(i) provide the non-debtor Party with all such intellectual property rights (including all embodiments thereof) licensed hereunder and held by the debtor Party and such successors and assigns, or otherwise available to them, immediately upon the non-debtor Party's written request. Whenever the debtor Party or any of its successors or assigns provides to the non-debtor Party any of the intellectual property rights licensed hereunder (or any embodiment thereof) pursuant to this Section 5.1.3 (Termination for Insolvency), the non-debtor Party will have the right to perform the debtor Party's obligations hereunder with respect to such intellectual property rights, but neither such provision nor such performance by the non-debtor Party will release the debtor Party's from liability resulting from rejection of the license or the failure to perform such obligations; and

(ii) not interfere with the non-debtor Party's rights under this Provisional Collaboration and License Agreement, or any agreement supplemental hereto, with respect to such intellectual property rights (including such embodiments), including any right to obtain such intellectual property rights (or such embodiments) from another entity, to the extent provided in Section 365(n) of the U.S. Bankruptcy Code.

(b) All rights, powers, and remedies of the non-debtor Party provided in this Section 5.1.3 (Termination for Insolvency) are in addition to and not in substitution for any other rights, powers, and remedies now or hereafter existing at law or in equity (including the U.S. Bankruptcy Code) in the event of the commencement of a case under the U.S. Bankruptcy Code with respect to the debtor Party. The Parties intend the following rights to extend to the maximum extent permitted by applicable law, and to be enforceable under U.S. Bankruptcy Code Section 365(n):

(i) the right of access to any intellectual property rights (and all embodiments thereof) of the debtor Party licensed hereunder, or any third party with whom the debtor Party contracts to perform any obligation of the debtor Party under this Provisional Collaboration and License Agreement, and, in the case of any such third party, that is necessary for the Exploitation of Products and licensed hereunder; and

(ii) the right to contract directly with any third party to complete the contracted work.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

5.1.4 Effects of Termination. Termination or expiration of this Provisional Collaboration and License Agreement (either in its entirety or with respect to the LRRK2 Program or the ROFN and Option) for any reason shall not relieve a Party from any obligations that accrued prior to such termination or expiration. All rights and obligations of the Parties under this Provisional Collaboration and License Agreement shall terminate on any expiration or termination of this Provisional Collaboration and License Agreement in its entirety, except as provided in Section 3.11 (Effects of Termination) and those described in the following provisions (in each case, other than for expiration or termination of this Provisional Collaboration and License Agreement as a result of execution of the Definitive Agreements): [***].

5.2 Indemnification and Limitation of Liability.

5.2.1 Indemnification. Each Party (the "**Indemnifying Party**") shall indemnify the other Party, its affiliates and its and their respective directors, officers, employees, and agents ("**Indemnitees**") and defend and hold each of them harmless, from and against any and all losses, damages, liabilities, penalties, costs, and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Indemnified Losses**") in connection with any and all suits, investigations, claims, or demands of third parties (collectively, **Third Party Claims**") incurred by or rendered against the Indemnitees arising from or occurring as a result of: (a) subject to Section 5.2.3 below, the Development of LRRK2 Licensed Compounds or LRRK2 Licensed Products by or under the authority of the Indemnifying Party (other than by the Indemnitee (and its related Indemnitees)), including by or under the authority of Denali prior to the Execution Date or after termination of this Provisional Collaboration and License Agreement (or the Definitive Collaboration and License Agreement); (b) the gross negligence, reckless conduct or willful misconduct on the part of the Indemnifying Party or its affiliates or their respective directors, officers, employees, or agents in performing its or their obligations under this Provisional Collaboration and License Agreement; or (c) a breach by the Indemnifying Party of this Provisional Collaboration and License Agreement, including any breach of a representation, warranty or covenant by the Indemnifying Party in this Provisional Collaboration and License Agreement; except in the case of clauses (a) through (c), for those Indemnified Losses for which a Party has an obligation to indemnify the other Party, as to which Indemnified Losses each Party shall indemnify the other to the extent of their respective liability for such Indemnified Losses.

5.2.2 Indemnification Procedure. All indemnification claims in respect of a Party, its affiliates, or their respective directors, officers, employees and agents shall be made solely by such Party to this Provisional Collaboration and License Agreement ("**Indemnified Party**"). The Indemnified Party shall give the Indemnifying Party prompt written notice (an "**Indemnification Claim Notice**") of any Indemnified Losses or discovery of facts upon which such Indemnified Party intends to base a request for indemnification hereunder, but in no event shall the Indemnifying Party be liable for any Indemnified Losses to the extent such Indemnified Losses arise from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Indemnified Loss (to the extent that the nature and amount of such Indemnified Loss is known or reasonably able to be assessed at such time). The Indemnified Party shall furnish promptly to the Indemnifying Party copies of all papers and official documents received in respect of any Indemnified Losses and Third Party Claims.

5.2.3 Certain Indemnified Losses and out-of-pocket costs incurred in connection with the foregoing indemnification obligations, including to the extent pertaining [***], shall be shared costs pursuant to the Parties' cost sharing arrangements outlined in Schedule 3.8 and subject to procedures to be agreed and set forth in the Definitive LRRK2 Collaboration and License Agreement.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

5.2.4 Limitations of Liability. EXCEPT (A) [***], NEITHER PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE FOR INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR CONSEQUENTIAL DAMAGES, INCLUDING LOSS OF PROFITS OR BUSINESS INTERRUPTION (TO THE EXTENT THE SAME ARE CONSEQUENTIAL DAMAGES), HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE IN CONNECTION WITH OR ARISING IN ANY WAY OUT OF THE TERMS OF THIS PROVISIONAL COLLABORATION AND LICENSE AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THE USE OF A LRRK2 LICENSED COMPOUND OR LRRK2 LICENSED PRODUCT, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

5.3 Representations, Warranties and Covenants.

5.3.1 Mutual Representations and Warranties. Denali and Biogen each represents and warrants to the other Party, as of the Execution Date, as follows:

(a) **Organization**. It is duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform its obligations under this Provisional Collaboration and License Agreement.

(b) **Authorization**. The execution and delivery of this Provisional Collaboration and License Agreement and the performance by it of its obligations hereunder have been duly authorized by all necessary corporate action, and do not violate: (i) such Party's charter documents, bylaws or other organizational documents; (ii) in any material respect, any agreement, instrument or contractual obligation to which such Party is bound; (iii) any requirement of any applicable law existing as of the Execution Date and applicable to such Party; or (iv) any order, writ, judgment, injunction, decree, determination or award of any court or governmental agency in effect as of the Execution Date and applicable to such Party.

(c) **Binding Agreement**. This Provisional Collaboration and License Agreement is a legal, valid and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity).

(d) **No Inconsistent Obligation**. It is not under any obligation, contractual or otherwise, to any person that conflicts with or is inconsistent in any material respect with the terms of this Provisional Collaboration and License Agreement.

(e) **No Consents**. Except for any filings that may be required to comply with Antitrust Law (as defined in the Stock Purchase Agreement), no governmental authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any applicable laws currently in effect, is or will be necessary for, on in connection with, the transaction contemplated by this Provisional Collaboration and License Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of its obligations under this Provisional Collaboration and License Agreement and such other agreements.

(f) **Debarment**. Neither it nor any of its employees nor to its knowledge, any of the agents performing hereunder, has ever been, is currently, or is the subject of a proceeding that could lead to it or such employees or agents becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual. For purposes of this provision, the following definitions shall apply:

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(i) A "**Debarred Individual**" is an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from providing services in any capacity to a person that has an approved or pending drug or biological product application.

(ii) A "**Debarred Entity**" is a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of a Debarred Entity.

(iii) An "**Excluded Individual**" or "**Excluded Entity**" is (A) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services, or (B) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA).

(iv) A "**Convicted Individual**" or "**Convicted Entity**" is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §335a (a) or 42 U.S.C. §1320a - 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

5.3.2 Additional Representations and Warranties of Denali. Denali further represents and warrants to Biogen, as of [***] as follows:

(a) It has the full right, power and authority to grant all of the licenses and rights granted to Biogen under this Provisional Collaboration and License Agreement and each Definitive Agreement;

(b) No claim, suit, proceeding, settlement, arbitration, citation, summons, or subpoena of any nature, civil, criminal, regulatory or otherwise, in law or in equity, has been brought or obtained against Denali or any of its affiliates relating to the LRRK2 IP, ROFN IP or Option IP (collectively, the "**Denali IP**"). No claim, suit, proceeding, arbitration, citation, summons, or subpoena of any nature, civil, criminal, regulatory or otherwise, in law or in equity, to Denali's knowledge, has been threatened in writing by any person: [***].

(c) To Denali's knowledge: [***].

(d) (i) [***] that are owned or Controlled by Denali or any of its affiliates that are [***] to Develop, Manufacture, Commercialize or otherwise Exploit any LRRK2 Licensed Compound or LRRK2 Licensed Product, (ii) [***]; and (iii) [***].

(e) [***];

(f) To Denali's knowledge, the Denali Patents with respect to which Denali controls prosecution and maintenance activities are being prosecuted in the respective patent offices in the Territory in accordance with applicable law.

(g) To Denali's knowledge, all fees required to be paid by Denali in any jurisdiction where a Denali Patent with respect to which Denali controls prosecution and maintenance activities has issued in order to maintain such Denali Patent in such jurisdiction have been timely paid and to Denali's knowledge, the Denali Patents that have issued are subsisting, valid and enforceable.

(h) [***];

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(i) Denali has not previously assigned, transferred, conveyed or granted any license or other rights under the Denali IP that would conflict with or limit the scope of any of the rights or licenses granted to Biogen hereunder;

(j) To Denali's knowledge, no person is infringing or threatening to infringe or misappropriating or threatening to misappropriate or otherwise violating or threatening to violate the Denali IP.

(k) Denali's rights, title and interests to all Denali IP are free of any lien or security interest

(l) No written claim has been filed, or to Denali's knowledge, threatened in writing, against it by any third party alleging that the conception, development, or reduction to practice of the Denali IP owned by Denali involve the misappropriation of trade secrets or other violation of the rights or property of any person.

(m) Denali has conducted, and to Denali's knowledge, its contractors and consultants have conducted, all Development and Manufacturing of the LRRK2 Licensed Compounds, and Compounds within the Option Programs in accordance with applicable law.

(n) Denali has obtained, or caused its affiliates, as applicable, to obtain, assignments from the inventors of any Denali IP who were employees of Denali or its affiliates at the time of the invention, of all inventorship rights to such Denali IP, and, to Denali's knowledge, all such assignments are valid and enforceable.

(o) except for Existing LRRK2 Agreements and Existing Option Program Agreements, there are no third party agreements pursuant to which Denali is granted an exclusive license under any patents or know-how included in the Denali IP, and no third party has any rights, title or interests in or to, or any license under, any such Denali IP that would conflict with the rights and licenses granted to Biogen hereunder.

(p) Denali has provided Biogen with a redacted copy of each Existing LRRK2 Agreements and Existing Option Program Agreements, and each such agreement is in full force and effect, and no written notice of default or termination has been received or given under any such agreement, and, to Denali's knowledge, there is no act or omission by Denali or its affiliates that would provide a right to terminate any such agreement.

(q) Denali and its affiliates have taken commercially reasonable measures consistent with industry practices to protect the secrecy, confidentiality and value of all LRRK2 Know-How, ROFN Know-How and Option Know-How (collectively, "**Denali Know-How**") that constitutes trade secrets under applicable law (including requiring all employees, consultants and independent contractors to execute binding and enforceable agreements requiring all such employees, consultants, and independent contractors to maintain the confidentiality of such Denali Know-How) and, to Denali's knowledge, such Denali Know-How has not been used or disclosed to any third party except pursuant to such confidentiality agreements, and to Denali's knowledge, there has not been a material breach by any party to such confidentiality agreements.

(r) To Denali's knowledge, [***].

5.3.3 Covenants of Denali. Denali hereby covenants to Biogen as follows:

(a) [***]

(b) [***]

(c) [***]; and

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(d) [***]

5.3.4 Additional Representations and Warranties of Biogen. Biogen further represents and warrants to Denali, as of the Execution Date and as of the Effective Date as follows:

(a) [***]; and

(b) [***].

5.3.5 DISCLAIMER. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

5.4 Confidentiality and Non-Disclosure. The Definitive LRRK2 Collaboration and License Agreement and Definitive ROFN and Option Agreement will provide for confidentiality and use restrictions in respect of information disclosed by each Party to the other Party that are customary for such arrangements and similar to the terms set forth herein.

5.4.1 Confidentiality Obligations. At all times during the term of this Provisional Collaboration and License Agreement and for a period of [***] following termination or earlier expiration of this Provisional Collaboration and License Agreement, each Party shall, and shall cause its affiliates and its and their respective officers, directors, employees and agents to, keep confidential and not publish or otherwise disclose to a third party and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Provisional Collaboration and License Agreement and is reasonably necessary for the performance of such Party's obligations, or the exercise of rights expressly granted to such Party under, this Provisional Collaboration and License Agreement. As used herein, "**Confidential Information**" means any proprietary information or data provided orally, visually, in writing or other form by or on behalf of one (1) Party (or an affiliate or representative of such Party or such Party's affiliate) to the other Party (or to an affiliate or representative of such Party or such Party's affiliate) in connection with this Provisional Collaboration and License Agreement, whether prior to, on, or after the Execution Date. The terms, but not the mere existence, of this Provisional Collaboration and License Agreement will also be considered Confidential Information for which each Party is a receiving Party for purposes of this Section 5.4 (Confidentiality and Non-Disclosure). Notwithstanding the foregoing, the information will not be Confidential Information that is subject to the confidentiality and non-use obligations under this Section 5.4.1 (Confidentiality Obligations) if the receiving Party can demonstrate by documentation or other competent proof:

(a) has been published by a third party or otherwise is or becomes part of the public domain by public use, publication, general knowledge or the like through no wrongful act, fault or negligence on the part of the receiving Party;

(b) is in the receiving Party's possession prior to disclosure by the disclosing Party, to the extent the receiving Party has the right to use and disclose such information;

(c) is subsequently lawfully received by the receiving Party from a third party, to the extent the receiving Party has the right to use and disclose such information without breach of any agreement between such third party and the disclosing Party;

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(d) is published or otherwise generally made available to third parties by the disclosing Party without restriction on disclosure; or

(e) is independently developed by or for the receiving Party without reference to, or use or disclosure of, the disclosing Party's Confidential Information.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the receiving Party unless the combination is in the public domain or in the possession of the receiving Party.

5.4.2 Permitted Disclosures. Each Party may disclose Confidential Information to the extent that such disclosure is:

(a) in the reasonable opinion of the receiving Party's legal counsel, required to be disclosed pursuant to law, regulation or a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial and local governmental body of competent jurisdiction, (including by reason of filing with securities regulators, but subject to Section 5.4.4 (Public Announcements)); *provided* that the receiving Party shall, unless otherwise prohibited, first have given advanced written notice (and to the extent possible, at least [***] notice) to the disclosing Party and (other than with regard to disclosures to securities regulators or to comply with applicable securities law, which disclosures are covered in Section 5.4.4 (Public Announcements)) give the disclosing Party a reasonable opportunity to take whatever action it deems necessary to protect its Confidential Information. In the event that no such protective order or other remedy is obtained, or the disclosing Party waives compliance with the terms of this Provisional Collaboration and License Agreement, the receiving Party shall furnish only that portion of Confidential Information which the receiving Party is advised by counsel is legally required to be disclosed;

(b) made by or on behalf of the receiving Party to regulatory authorities in connection with any filing, application or request for Regulatory Approval in accordance with the terms of this Provisional Collaboration and License Agreement; *provided* that reasonable measures shall be taken to assure confidential treatment of such Confidential Information to the extent practicable and consistent with applicable law;

(c) made to its or its affiliates' strategic, financial or legal advisors who have a need to know such disclosing Party's Confidential Information and are either under professional codes of conduct giving rise to expectations of confidentiality and non-use or under written agreements of confidentiality and non-use, in each case, substantially similar to the obligations of confidentiality and non-use of the receiving Party pursuant to this Section 5.4 (Confidentiality and Non-Disclosure);

(d) [***];

(e) [***];

(f) [***]; or

(g) a disclosure of the terms of this Provisional Collaboration and License Agreement, that is made only on a need-to-know basis, to persons who are subject to enforceable obligations of confidentiality and non-use substantially similar to the obligations of confidentiality and non-use in this Section 5.4 (Confidentiality and Non-Disclosure).

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

For any disclosures made by the receiving Party pursuant to Sections 5.4.2(c)–5.4.2(g), the receiving Party shall remain responsible for any failure of the relevant person to treat such Confidential Information as required under this Section 5.4 (Confidentiality and Non-Disclosure). For clarity, in any case where the foregoing disclosure must be subject to obligations of confidentiality and non-use substantially similar to those under the provisions of this Section 5.4 (Confidentiality and Non-Disclosure), it is understood that the duration of such confidentiality and non-use obligations shall be no less than [***] from the date of disclosure.

5.4.3 Use of Name. Except as expressly provided in this Provisional Collaboration and License Agreement, neither Party shall mention or otherwise use the name, logo or trademark of the other Party or any of its affiliates (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material, website or other form of publicity, without the prior written approval of such other Party. Notwithstanding the foregoing, the restrictions imposed by this Section 5.4.3 (Use of Name) shall not prohibit either Party from using the name, logo or trademark of the other Party or any of its affiliates (or any abbreviation or adaptation thereof) in any disclosure: (a) identifying the other Party that, in the opinion of the disclosing Party's counsel, is required by applicable law (including stock exchange rules); *provided* that such Party shall submit the proposed disclosure identifying the other Party in writing to the other Party as far in advance as reasonably practicable (and in no event less than [***] prior to the anticipated date of disclosure unless such proposed disclosure is required under applicable law, or the rules of an applicable securities exchange, in each case to be made in [***] or less) so as to provide a reasonable opportunity to comment thereon; (b) in connection with a disclosure permitted pursuant to Section 5.4.2 (Permitted Disclosures) or (c) following a press release or other announcement issued pursuant to Section 5.4.4 (Public Announcements), using such name, logo or trademark included in such press release or other announcement in connection with a general description of the arrangement between the Parties or any other subsequent announcement specified as not requiring the other Party's approval under Section 5.4.4 (Public Announcements).

5.4.4 Public Announcements. The Parties have agreed upon the content of a joint press release to announce the collaboration, which shall be issued substantially in the form attached hereto as Schedule 5.4.4 (Joint Press Release) upon execution of this Provisional Collaboration and License Agreement. Each Party may each disclose to third parties the information contained in such press release or any other announcement previously approved by the other Party without the need for further approval by the other Party. Neither Party shall issue any other public announcement, press release or other public disclosure regarding this Provisional Collaboration and License Agreement or the Parties' activities hereunder without the other Party's prior written consent (which shall not be unreasonably withheld, delayed or conditioned), except for any such disclosure regarding [***] or any other disclosure that is, in the opinion of the disclosing Party's counsel, required by applicable law or the rules of a stock exchange on which the securities of the disclosing Party are listed, or is otherwise expressly permitted in accordance with the provisions of this Section 5.4 (Confidentiality and Non-Disclosure). In the event a Party desires to make a public announcement regarding the [***] or that is, in the opinion of its counsel, required by applicable law or the rules of a stock exchange on which its securities are listed, such Party shall submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable (and in no event less than [***] prior to the anticipated date of disclosure, unless such proposed disclosure is required under applicable law, or the rules of an applicable securities exchange, in each case, to be made in [***] or less) so as to provide a reasonable opportunity to comment thereon.

5.4.5 Prior Confidentiality. Any information disclosed by a Party or its affiliate to the other Party or its affiliate prior to the Execution Date under that certain Confidentiality Agreement between the Parties or their respective affiliates dated [***], as amended ("**Prior CDA**") shall be deemed to have been disclosed under this Provisional Collaboration and License Agreement and subject to the provisions of this Section 5.4 (Confidentiality and Non-Disclosure).

5.4.6 [***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

5.5 Governing Law; Dispute Resolution.

5.5.1 Governing Law. This Provisional Collaboration and License Agreement, the Definitive LRRK2 Collaboration and License Agreement and the Definitive ROFN and Option Agreement will be construed and governed in accordance with the laws of [***].

5.5.2 Dispute Resolution. Except (a) as otherwise expressly provided herein with respect to particular disputes arising in connection with this Provisional Collaboration and License Agreement (including a Definitive Agreement Terms Dispute, any dispute contemplated by the Definitive Agreement Terms section or any dispute contemplated under Section 6.1.3 (Disputes) of Schedule 3.8 (LRRK2 Financials)), [***], (b) with respect to any suit, action or other proceeding arising out of or based upon the SPA, which shall be subject to resolution in accordance with Section 9.13 of the SPA and (c) any with respect to any suit, action or other proceeding arising out of or based upon the Standstill and Stock Restriction Agreement between Denali and BIMA dated as of the date hereof ("**Standstill Agreement**"), which shall be subject to resolution in accordance with Section 7(d) of the Standstill Agreement, any dispute, claim or controversy arising out of, or in connection with, or relating to this Provisional Collaboration and License Agreement or the breach, termination, enforcement, interpretation or validity thereof (including the arbitrability of any such disputes, but excluding in all cases any Consent Matters), shall be finally resolved pursuant to Section 1.1 set forth in Schedule 5.5.2 (Disputes). The Parties agree that the Definitive LRRK2 Collaboration and License Agreement, and the Definitive ROFN and Option Agreement, each when executed, shall include dispute resolution procedures equivalent to those procedures set forth in this Section 5.5.2 (Dispute Resolution) and Schedule 5.5.2 (Disputes).

5.6 Definitive Agreement Terms.

5.6.1 Immediately following the Execution Date, Denali and Biogen shall commence negotiations with the intent to enter into the Definitive LRRK2 Collaboration and License Agreement and the Definitive ROFN and Option Agreement (each, a "**Definitive Agreement**"). Denali and Biogen shall use their respective best efforts to negotiate diligently and in good faith and agree upon final terms for both Definitive Agreements as promptly as practicable following the Execution Date and in no event later than [***] after the Execution Date (or such longer period as Denali and Biogen may mutually agree in writing) (the "**Negotiation Period**"). Without limitation, in addition to the terms contemplated by this Provisional Collaboration and License Agreement, the Definitive LRRK2 Collaboration and License Agreement will include terms providing additional detail regarding the following topics, which shall in all cases be consistent with the agreed principles and terms set forth in this Provisional Collaboration and License Agreement: defined terms, governance, Development activities, regulatory interactions, Commercialization, Medical Affairs, intellectual property, information reporting and audits, and taxes.

5.6.2 If the Parties are unable to reach agreement on the final terms of one or more of the Definitive Agreements within the Negotiation Period (an "**Definitive Agreement Terms Dispute**"), then the Parties agree that any dispute regarding the final terms of such Definitive Agreement(s) shall be finally resolved by [***].

5.6.3 The Parties further agree that during the pendency of a Definitive Agreement Terms Dispute, any dispute regarding the interpretation of any term of this Provisional Collaboration and License Agreement and its implementation in the Definitive LRRK2 Collaboration and License Agreement or the Definitive ROFN and Option Agreement shall also be finally resolved in accordance with Schedule 5.5.2 (Disputes) and shall be consolidated into any [***]. The Parties further agree that it is intended that the [***].

5.6.4 [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

5.7 Antitrust Matters.

5.7.1 Subject to the terms and conditions of this Provisional Collaboration and License Agreement, each of the Parties will use its reasonable best efforts to take, or cause to be taken, all actions and to do, or cause to be done, all things necessary, proper or advisable under applicable law to consummate the transactions contemplated hereunder and under the Stock Purchase Agreement as soon as practicable after the date hereof, including taking all steps as may be necessary, subject to the limitations in this Section 5.7 (Antitrust Matters), to obtain all applicable waiting period expirations or terminations, consents, clearances, waivers, licenses, registrations, permits, authorizations, orders and approvals. In furtherance and not in limitation of the foregoing, each of the Parties agrees to (i) file or cause to be filed with (A) the FTC and the DOJ any notifications required to be filed under the HSR Act no later than [***] after the date of this Agreement, (B) the U.K. Competition and Markets Authority under the U.K. Enterprise Act 2002, as amended by the Enterprise and Regulatory Reform Act of 2013, and the rules and regulations promulgated thereunder as soon as practicable and advisable and (C) any other regulatory body any notifications or other filings required to be filed under any other Antitrust Law as soon as practicable and advisable (any filings required pursuant to clause (A) or (B) or (C), the "**Required Filings**"), and (ii) use reasonable best efforts to obtain as promptly as practicable approvals, clearances, consents, decisions not to assume jurisdiction, or the termination or expiration of any waiting period as applicable under the HSR Act or other applicable Antitrust Law, including by filing as soon as practicable and advisable any supplemental or additional information which may reasonably be requested by the FTC or the DOJ or any other governmental authority in connection with applicable Antitrust Law. Each party hereto shall be responsible for its own costs in connection with the Required Filings, [***].

5.7.2 Each of the Parties shall use reasonable best efforts to provide or cause to be provided promptly all assistance and cooperation to allow the Parties to prepare and submit any Required Filings, including providing to either Party, as applicable, any information that it may require for the purpose of any filing, notification, application or request for further information made in respect of any such filing.

5.7.3 Each of the Parties shall, in connection with the transactions contemplated hereby, and the obtaining of all waiting period expirations or terminations, consents, clearances, waivers, licenses, orders, registrations, approvals, permits and authorizations under the HSR Act or any other Antitrust Law, with respect to actions taken on or after the date of this Provisional Collaboration and License Agreement, without limitation: (i) promptly notify the other of, and if in writing, furnish the other with copies of (or, in the case of oral communications, advise the other of) any material communications from or with any governmental authority, including the FTC and the DOJ, with respect to this Provisional Collaboration and License Agreement or the Stock Purchase Agreement, (ii) cooperate in all respects and consult with each other in connection with any filing or submission and in connection with any investigation or other inquiry, (iii) permit the other to review and discuss in advance, and consider in good faith the view of the other in connection with, any proposed written or oral communication with any governmental authority, (iv) not participate in any substantive meeting or have any substantive communication with any governmental authority unless it has given the other party a reasonable opportunity to consult with it in advance and, to the extent permitted by such governmental authority, gives the other the opportunity to attend and participate therein, (v) furnish the other party's outside legal counsel with copies of all supplemental filings and substantive communications between it and any such governmental authority with respect to this Provisional Collaboration and License Agreement or the Stock Purchase Agreement; *provided* that any materials subject to this Section 5.7 (Antitrust Matters) may be restricted to outside counsel and may be redacted or withheld as necessary (A) to comply with contractual arrangements, (B) to address good faith legal privilege or confidentiality concerns and (C) to comply with applicable law, (vi) furnish the other party's outside legal counsel with such necessary information and reasonable assistance as the other party's outside legal counsel may reasonably request in connection with its preparation of necessary submissions of information to any such governmental authority, and (vii) use reasonable best efforts to respond as soon as practicable to reasonable requests from the other party hereto.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

5.7.4 Notwithstanding anything herein to the contrary, nothing in this Provisional Collaboration and License Agreement will require either Party to (i) sell, hold separate, license or otherwise dispose of any assets or conduct its business in a specified manner, (ii) agree or proffer to sell, hold separate, license or otherwise dispose of any assets or conduct their business in a specified manner or (iii) permit or agree to the sale, holding separate, licensing or other disposition of, any assets of such party, whether as a condition to obtaining any approval from, or to avoid potential litigation or administrative action by, a governmental authority or any other person or for any other reason.

5.7.5 Notwithstanding anything to the contrary, each of the Parties shall coordinate their activities under this Section 5.7 (Antitrust Matters) with those activities undertaken under Section 9.3 of the Stock Purchase Agreement, and nothing in this Section 5.7 (Antitrust Matters) or Section 9.3 of the Stock Purchase Agreement shall be interpreted to require either Party to perform duplicative actions with respect to the matters and actions contemplated under such sections.

5.8 Assignment. Without the prior written consent of the other Party, neither Party shall sell, transfer, assign, delegate (except as expressly permitted under this Provisional Collaboration and License Agreement or a Definitive Agreement, when executed), pledge, or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Provisional Collaboration and License Agreement or such Definitive Agreement nor any of its rights or duties hereunder or thereunder; *provided* that (a) either Party may make such an assignment without the other Party's consent to: (i) [***]; or (ii) [***] Any attempted assignment or delegation in violation of this Section 5.8 (Assignment) shall be void and of no effect. All validly assigned and delegated rights and obligations of a Party hereunder shall be binding upon and inure to the benefit of and be enforceable by and against the successors and permitted assigns of such Party. The permitted assignee or transferee shall assume all obligations of its assignor or transferor under this Provisional Collaboration and License Agreement or, when executed, the applicable Definitive Agreement, as the case may be. Without limiting the foregoing, the grant of rights set forth in this Provisional Collaboration and License Agreement and, when executed, the applicable Definitive Agreement, shall be binding upon any successor or permitted assignee of a Party, and the obligations of the other Party, including the payment obligations, shall run in favor of any such successor or permitted assignee of such Party's benefits under this Provisional Collaboration and License Agreement or, when executed, the applicable Definitive Agreement, as the case may be.

5.9 Force Majeure. Neither Party will be held liable to the other Party nor be deemed to have defaulted under or breached this Provisional Collaboration and License Agreement for failure or delay performing any obligation under this Provisional Collaboration and License Agreement (other than a breach of Section 5.6 (Definitive Agreement Terms) or [***] to the extent that such failure or delay is caused by or results from acts of God, embargoes, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotions, strikes, lockouts, or other labor disturbances (other than strikes, lockouts, or labor disturbances involving a Party's own employees), government actions, fire, earthquakes, floods, [***] ("**Force Majeure**") beyond such Party's reasonable control, and renders the performance impossible or illegal. [***] The affected Party will notify the other Party in writing of any Force Majeure circumstances that may so affect its performance under this Provisional Collaboration and License Agreement as soon as reasonably practical, will provide a good faith estimate of the period for which its failure or delay in performance under this Provisional Collaboration and License Agreement is expected to continue based on currently available information, and will undertake reasonable efforts necessary to mitigate and overcome such Force Majeure circumstances and resume normal performance of its obligations hereunder as soon a reasonably practicable under the circumstances. If the Force Majeure circumstance continues, then the affected Party will update such notice to the other Party on a weekly basis to provide updated summaries of its mitigation efforts and its estimates of when normal performance under the Provisional Collaboration and License Agreement will be able to resume.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

5.10 Counterparts; Electronic Signatures. This Provisional Collaboration and License Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. This Provisional Collaboration and License Agreement may be executed by facsimile or electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

5.11 Severability. If any provision of this Provisional Collaboration and License Agreement is held to be illegal, invalid, or unenforceable under any present or future law, and if the rights or obligations of either Party under this Provisional Collaboration and License Agreement will not be materially and adversely affected thereby: (a) such provision shall be fully severable; (b) this Provisional Collaboration and License Agreement shall be construed and enforced as if such illegal, invalid, or unenforceable provision had never comprised a part hereof; (c) the remaining provisions of this Provisional Collaboration and License Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid, or unenforceable provision or by its severance herefrom; and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Provisional Collaboration and License Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties. In the event a Party seeks to avoid a provision of this Provisional Collaboration and License Agreement or a Definitive Agreement, when executed, by asserting that such provision is invalid, illegal or otherwise unenforceable, the other Party shall have the right to terminate the applicable agreement upon [***] prior written notice, unless such assertion is eliminated and its effect is cured within such [***] period. Any such termination by such other Party in accordance with this provision with respect to such an assertion by a Party shall be deemed a termination by such other Party on the basis of a material breach by such asserting Party. To the fullest extent permitted by applicable law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid, or unenforceable in any respect.

5.12 Entire Agreement; Amendments. This Provisional Collaboration and License Agreement, together with the Schedules attached hereto, and the Stock Purchase Agreement sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises, and representations, whether written or oral, with respect thereto are superseded hereby (including that certain Prior CDA). Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Provisional Collaboration and License Agreement. No amendment, modification, release, or discharge shall be binding upon the Parties, unless in writing and duly executed by authorized representatives of both Parties.

5.13 Notices. All notices that are required or permitted hereunder will be in writing and sufficient if delivered by internationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, and in each case, addressed as follows (with a courtesy copy sent by email, which will not constitute notice):

If to Denali:

Denali Therapeutics Inc.
161 Oyster Point Blvd
South San Francisco, CA 94080
[***]

With a copy (which shall not constitute notice) to:

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Wilson Sonsini Goodrich and Rosati P.C.
12235 El Camino Real, Suite 200
San Diego, CA 92130
[***]

If to Biogen:

Biogen MA Inc.
225 Binney Street
Cambridge, MA 02142
[***]

With a copy to:

Ropes & Gray LLP
Prudential Tower
800 Boylston Street
Boston, MA 02199-3600
[***]

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been given: (a) on the [***] after dispatch if sent by internationally-recognized overnight courier; or (b) on the [***] after dispatch if sent by registered or certified mail, postage prepaid, return receipt requested.

5.14 Performance by BIMA and BIG. [***]

5.15 Coordination between BIMA and BIG. [***]

5.16 Retained Rights.

5.16.1 Except as expressly provided herein, Denali grants no other right or license, including any rights or licenses to the LRRK2 IP, Option IP, TV Platform IP, or any other patent, know-how or intellectual property or proprietary rights not otherwise expressly granted herein, whether by implication, estoppel or otherwise. Notwithstanding anything to the contrary in this Provisional Collaboration and License Agreement, [***].

5.16.2 Except as expressly provided herein, Biogen grants no other right or license, including any rights or licenses to the Biogen IP, or any other patent, know-how or intellectual property or proprietary rights not otherwise expressly granted herein, whether by implication, estoppel or otherwise. Notwithstanding anything to the contrary in this Provisional Collaboration and License Agreement, [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

5.17 Interpretation. Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (b) the words "include", "includes" and "including" will be deemed to be followed by the phrase "without limitation," (c) the word "will" will be construed to have the same meaning and effect as the word "shall," (d) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person or entity will be construed to include the person's or entity's successors and assigns, (f) the words "herein," "hereof," and "hereunder", and words of similar import, will be construed to refer to this Provisional Collaboration and License Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections or Schedules will be construed to refer to Sections or Schedules of this Provisional Collaboration and License Agreement, and references to this Provisional Collaboration and License Agreement include all Schedules hereto, (h) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Provisional Collaboration and License Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent," or "approve" or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule or regulation, or article, section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, (k) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or," and (l) references to any Sections include Sections and subsections that are part of the related Section (*e.g.*, a section numbered "Section 2.2" would be part of "Section 2", and references to "Section 2.2" would also refer to material contained in the subsection described as "Section 2.2(a)").

5.18 Injunctive Relief. Notwithstanding any provision to the contrary set forth in this Provisional LRRK2 Collaboration and License Agreement, other than those matters to be resolved in accordance with the dispute resolution procedures set forth in [***], in the event of an actual or threatened breach or other default or non-performance hereunder, the aggrieved Party may seek equitable relief (including restraining orders, specific performance or other injunctive relief) in any court or other forum, without first submitting to the dispute resolution procedures set forth in Section 5.5.2 (Dispute Resolution).

5.19 No Benefit to Third Parties. Except as provided in Section 5.2 (Indemnification and Limitations of Liability), covenants and agreements set forth in this Provisional Collaboration and License Agreement are for the sole benefit of the Parties hereto and successors and permitted assigns of the Parties, and shall not be construed as conferring any rights on any other persons.

5.20 Other Terms. The Definitive LRRK2 Collaboration and License Agreement and the Definitive ROFN and Option Agreement would will include such other terms and conditions, to be negotiated by the Parties that are reasonable and customary in transactions of the type contemplated herein with respect to such agreement.

[Signature Page Follows]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

This Provisional Collaboration and License Agreement is executed by the authorized representatives of the Parties as of the Execution Date.

Denali Therapeutics Inc.

By: /s/ Ryan J. Watts
Name: Ryan Watts, Ph.D.
Title: President and CEO

Biogen MA, Inc.

By: /s/ Alfred W. Sandrock, Jr.
Name: Alfred W. Sandrock, Jr.
Title: EVP, R&D

Biogen International GmbH

By: /s/ Frederick Lawson
Name: Frederick Lawson
Title: Senior Director

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Schedule 2.28

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Schedule 2.32

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Schedule 3.8

LRRK2 Financials

1. **Upfront Payment**. Biogen shall pay Denali US$400M within [***] following the execution of the Definitive LRRK2 Collaboration and License Agreement.

2. **Milestones**.

2.1 PD Milestones.

2.1.1 PD Milestone Payments. Biogen will make the following [***] milestone payments to Denali with respect to the [***] of the corresponding milestone event for Parkinson's Disease ("**PD**"):

PD Development Milestone Event	***PD Development Milestone Payment (US$)***
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
PD Commercial Milestone Event	***PD Commercial Milestone Payment (US$)***
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

2.1.2 PD Milestone Details. If any PD development milestone event in the table in Section 2.1 (PD Milestones) is skipped for a particular indication, then the payment due upon achievement of such skipped milestone will become due and payable upon achievement of the next development milestone for the same indication. If, at the time of achievement of a commercial milestone for First Commercial Sale for a particular PD indication, any development milestone payment for such PD indication has not been paid, then the corresponding development milestone event shall be deemed to have been achieved for such PD indication and such PD development milestone payment shall become due and payable. In addition, if a particular development milestone event is [***] by a LRRK2 Licensed Product [***], [***]and, accordingly, the corresponding payments for such development milestone event with respect to [***] will be due and payable. Further, if a particular commercial milestone event for First Commercial Sale is [***] by a LRRK2 Licensed Product [***], then [***]. Conversely, if a particular commercial milestone event for First Commercial Sale is [***] by a LRRK2 Licensed Product [***], then [***]. For the avoidance of doubt, milestones are in addition to, and excluded from, Denali's portion of the Profit Share.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

2.2 Non-PD Milestones.

2.2.1 Non-PD Milestone Payments. If a LRRK2 Licensed Compound is developed by or on behalf of the Parties for an indication other than an indication included in PD (any such indication, a "**Non-PD Indication**"), then [***], Biogen shall pay to Denali the corresponding milestone payment amount:

Non-PD Development Milestone Event	Milestone Payment [***] ($US)	Milestone Payment [***] (US$)
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
Non-PD Commercial Milestone Event		
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

2.2.2 Non-PD Milestone Details. Notwithstanding the foregoing, (a) [***]; (b) [***] and (c) if a particular Non-PD development milestone event or Non-PD commercial milestone event is achieved with respect to [***] or [***], then the amount payable upon achievement of the relevant Non-PD development milestone event or Non-PD commercial milestone event with respect to the [***] or the [***], as the case may be, shall be equal to [***] of the corresponding milestone payment due upon the achievement of such Non-PD milestone event set forth in the table in Section 2.2.1 (Non-PD Milestone Payments) above. [***] In addition, if the [***] is skipped for a particular indication, then the payment due upon achievement of such skipped [***] will become due and payable upon achievement of the next non-PD commercial milestone event that is achieved by or on behalf of Biogen. [***].

2.3 Sales Milestones. Biogen will make the following [***]sales milestone payments to Denali with respect to the [***] of the corresponding sales milestone event:

Sales Milestone Event	*Sales Milestone Payment (US$)*
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

3. Royalties.

3.1 Royalty Rates. Subject to the adjustments below, Biogen will make royalty payments to Denali on annual Net Sales of each LRRK2 Licensed Product, on a LRRK2 Licensed Product-by-LRRK2 Licensed Product and country-by-country basis, in all countries other than the U.S. and China as follows:

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Portion of Annual Net Sales of a LRRK2 Licensed Product in all Countries other than the U.S. and China	*Royalty Rate*
[***]	[***]
[***]	[***]
[***]	[***]

3.2 Opt-Out Royalty Rates.

3.2.1 Opt-Out Prior to First Commercial Sale. If Denali opts-out of [***] of the Provisional Collaboration and License Agreement) cost-sharing with respect to a LRRK2 Licensed Product in a given country in the Co-Commercialization Territory prior to the First Commercial Sale of any LRRK2 Licensed Product in such country in accordance with Section 3.3.4 (Denali Opt-Out), then in lieu of the profit share provide in Section 4 (Profit Share) below, Biogen will make royalty payments to Denali on annual aggregate Net Sales of each Opt-Out Product in the applicable Opt-Out Country, on an Opt-Out Product-by-Opt-Out Product and Opt-Out Country-by-Opt-Out Country basis, [***], as follows:

Portion of Annual Aggregate Net Sales of LRRK2 Licensed Products in China	*Royalty Rate*		
	[***]	**[***]**	**[***]**
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

Portion of Annual Aggregate Net Sales of LRRK2 Licensed Products in the U.S.	*Royalty Rate*		
	[***]	**[***]**	**[***]**
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

3.2.2 Opt-Out After Commercial Sale. If Denali opts-out of [***] of the Provisional Collaboration and License Agreement) cost-sharing with respect to a given country in the Co-Commercialization Territory after the First Commercial Sale of any LRRK2 Licensed Product in such country, then in lieu of the profit share provide in Section 4 (Profit Share) below, Biogen will make royalty payments to Denali on annual Net Sales of each Opt-Out Product in the applicable Opt-Out Country, on an Opt-Out Product-by Opt-Out Product and Opt-Out Country-by-Opt-Out Country basis, as follows:

Portion of Annual Net Sales of an Opt-Out Product in China	*Royalty Rate*
[***]	[***]
[***]	[***]
[***]	[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Portion of Annual Net Sales of an Opt-Out Product in the U.S.	*Royalty Rate*
[***]	[***]
[***]	[***]
[***]	[***]

3.3 Generic Competition. On a LRRK2 Licensed Product-by-LRRK2 Licensed Product and country-by-country basis, in the event [***], [***]. Where used in this Section 3.3 (Generic Competition), "**Generic Product**" means, with respect to a given LRRK2 Licensed Product in a given country outside of the Co-Commercialization Territory, a pharmaceutical product that is (a) not marketed or sold by or under the authority of Biogen, its affiliates or Sublicensees and (b)(i) contains the same LRRK2 Inhibitor as such LRRK2 Licensed Product or [***] and (ii) is determined by the applicable Regulatory Authority in such country as [***] to such LRRK2 Licensed Product (A) in the United States through an ANDA filing under 505(j) of the FFDCA or (B) under equivalent procedures outside of the United States [***] with such LRRK2 Licensed Product.

3. Royalty Term. On a country-by-country and LRRK2 Licensed Product-by-LRRK2 Licensed Product basis, for countries outside the Co-Commercialization Territory (including the Opt-Out Countries), Biogen will make royalty payments for each LRRK2 Licensed Product during the period commencing upon the First Commercial Sale of such LRRK2 Licensed Product in such country and continuing until the latest of: [***] (the "**Royalty Term**"), [***].

4. Development Cost Share. So long as Denali has not opted-out of cost-sharing with respect to a LRRK2 Licensed Product and corresponding co-Commercialization country, Biogen and Denali will share the costs and expenses incurred in the performance of Development activities for LRRK2 Licensed Compounds and LRRK2 Licensed Products to the extent in accordance with the Global Development Plan/Budget (*plus* Allowable Overruns), including all Manufacturing Costs (to be defined in the Definitive LRRK2 Collaboration and License Agreement) of LRRK2 Licensed Compounds and LRRK2 Licensed Products required to perform such Development activities, at a ratio of 1.5:1 (Biogen 60% / Denali 40%). The Definitive LRRK2 Collaboration and License Agreement will contain a mechanism pursuant to which the Parties would report and true-up these costs on a quarterly basis.

5. Profit Share. So long as Denali has not opted-out of cost-sharing with respect to a LRRK2 Licensed Product and corresponding co-Commercialization country, Biogen and Denali will share the profits (or losses) with respect to the LRRK2 Licensed Products (including Net Sales and Other Income) calculated as follows: the Parties will share the costs and expenses incurred in the performance of Commercialization and Medical Affairs activities for the LRRK2 Licensed Products in the Co-Commercialization Territory to the extent in accordance with the Co-Commercialization Plan/Budget (*plus* Allowable Overruns) (including all Manufacturing Costs (to be defined in the Definitive LRRK2 Collaboration and License Agreement) of LRRK2 Licensed Compounds and LRRK2 Licensed Products required to perform such Commercialization and Medical Affairs activities), and profits (or losses) with respect to the Commercialization of LRRK2 Licensed Products in the Co-Commercialization Territory (but accounting separately for the U.S. and China markets, and on a LRRK2 Licensed Product-by-LRRK2 Licensed Product basis as follows (the "**Profit Share**"): (a) in the United States, at a ratio of 1:1 (Biogen 50% / Denali 50%) and (b) in China, at a ratio of 1.5:1 (Biogen 60% / Denali 40%), in each case, (a) and (b), for as long as the LRRK2 Licensed Products are sold in such country. The Definitive LRRK2 Collaboration and License Agreement will contain a mechanism pursuant to which the Parties would report and true-up these costs, revenue and profits (or losses) on a quarterly basis.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

6. Additional Royalty and Cost-Sharing Details.

6.1 New Third Party Technology.

6.1.1 New Technology. The Parties will share, as further described in this Section 6.1 (New Third Party Technology), all amounts payable for third party patent rights (or patent rights together with know-how) that are acquired or in-licensed after the Effective Date ("**New Technology**") and that (a) [***], (b) [***], (c) [***] or (d) [***].

6.1.2 Allocation of New Technology Costs. To the extent applicable to (a) [***] or (b) [***], the Parties shall [***], as applicable. Outside the Co-Commercialization Territory and subject to Section 6.4 (Cumulative Royalty Floor) below, Biogen may reduce the royalties otherwise payable to Denali under this Provisional Collaboration and License Agreement (and when executed, the Definitive LRRK2 Collaboration and License Agreement) with respect to a particular LRRK2 Licensed Product in a given country by [***] of any amounts paid to such third party with respect to New Technology that are attributable to the Commercialization of such LRRK2 Licensed Product in such country outside of the Co-Commercialization Territory. For clarity, Biogen shall not have the right under this Section 6.1 (New Third Party Technology) (or when executed, the Definitive LRRK2 Collaboration and License Agreement) to offset any amounts paid by Biogen that are shared by the Parties as Development costs or Commercialization costs and expenses, as described above.

6.1.3 Disputes. If a Party disputes whether certain third party patent rights (or patent rights together with know-how) are necessary to Develop, Manufacture, or, in the Co-Commercialization Territory, Commercialize a LRRK2 Licensed Product, then each Party may refer the matter to the Chief IP Counsel of Biogen and the Senior Director, IP Legal of Denali or their designees (the "**IP Counsels**"). The IP Counsels will meet promptly to discuss and resolve the matter within [***] after referral of such matter to such IP Counsels. If the IP Counsels cannot agree on a resolution to the matter within such [***] period, then either Party may refer such matter for resolution to an independent third party expert agreed upon by the Parties within [***] after the IP Counsels have failed to resolve such matter. Such independent third party expert will be an attorney who has practiced United States patent law for at least [***] (or who has such other similar credentials as agreed by the Parties), and unless otherwise agreed in writing by the Parties, must not be a current or former employee, contractor, agent, or consultant of either Party or its affiliates. The Party bringing a dispute pursuant to this Section 6.1.3 (Disputes) will promptly engage such expert and the Parties will share the out-of-pocket costs incurred in connection with the engagement of such expert [***]. Within [***] of the engagement of such expert by the disputing Party, such expert will deliver its written decision to the Parties (including a detailed report as to such expert's rationale for such decision), and such decision will be binding on the Parties. [***]

6.2 Pre-Existing Financial Obligations. [***].

6.3 [***]

6.4 Cumulative Royalty Floor. In no event will the aggregate amount of royalties due to Denali for a particular LRRK2 Licensed Product in a given calendar quarter during the Royalty Term for such LRRK2 Licensed Product be reduced by more than [***] of the amount that would otherwise be payable to Denali in such calendar quarter for such LRRK2 Licensed Product pursuant to [***].

6.5 Payment Allocations.

6.5.1 Unless otherwise stipulated above, payments under the Provisional Collaboration and License Agreement, the Definitive LRRK2 Collaboration and License Agreement and the Definitive ROFN and Option Agreement shall be paid by BIMA and BIG separately [***]; *provided* that [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

6.5.2 With respect to the upfront payment, BIG will pay a portion of such amount in consideration of the rights granted outside of the U.S. and BIMA will pay a portion of such amount in consideration of the rights granted in the U.S.

6.5.3 With respect to the PD development milestone payments in Section 2.1 (PD Milestones) and the non-PD development milestone payments in Section 2.2 (Non-PD Milestones), BIG will pay a percentage of each such amount in consideration of the rights granted outside of the U.S. and BIMA will pay a percentage each such amount in consideration to the rights granted in the U.S., such percentages, in each case, to be determined by Biogen at the time at which such amounts are due.

6.5.4 BIG will pay the milestone payments for PD commercial milestone events and Non-PD commercial milestone events that are achieved outside of the U.S. when such amounts become due and payable in accordance with Sections 2.1.1 (PD Milestone Payments) and 2.2.1 (Non-PD Milestone Payments). BIMA will pay the milestone payments for PD Commercial Milestone Events and Non-PD Commercial Milestone Events that are achieved in the U.S. when such amounts become due and payable in accordance with Sections 2.1.1 (PD Milestone Payments) and 2.2.1 (Non-PD Milestone Payments).

6.5.5 BIMA will pay the portion of the milestone payments for sales milestone events and royalties based on the pro rata allocation of the calendar year Net Sales attributable to sales of the applicable Product in the U.S., and BIG will pay the portion of the milestone payments for sales milestone events and royalties based on the pro rata allocation of the calendar year Net Sales attributable to sales of the applicable Product outside of the U.S.

6.5.6 With respect to all milestone payments set forth in this Schedule 3.8 (LRRK2 Financials) that are not described in Sections 6.5.2 through 6.5.5 above, BIG will pay a percentage of each such amount in consideration of the rights granted outside of the U.S. and BIMA will pay a percentage each such amount in consideration to the rights granted in the U.S., such percentages, in each case, to be determined by Biogen at the time in which such amounts are due.

6.5.7 For clarity, nothing in this Section 5.6 (Payment Allocations) is intended to limit Section 5.15 (Coordination between BIMA and BIG) of the Provisional Collaboration and License Agreement.

6.6 Taxes.

6.6.1 Each Party will be responsible for all Taxes imposed on such Party's net income, or on net income allocated to such Party under applicable law. To the extent one Party pays Taxes imposed on net income of the other Party, the other Party shall reimburse the paying Party for any such Taxes paid. The amounts payable pursuant to the Provisional Collaboration and License Agreement, the Definitive LRRK2 Collaboration and License Agreement and the Definitive ROFN and Option Agreement ("**Payments**") shall not be reduced on account of any Taxes unless required by applicable law. A payor Party shall deduct and withhold from the Payments any Taxes that it is required by applicable law to deduct or withhold including from subsequent Payments. Notwithstanding the foregoing, if the recipient Party is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, or recovery of, applicable withholding tax, it may deliver to the payor Party or the appropriate governmental authority the prescribed forms necessary to reduce the applicable rate of withholding or to relieve the payor Party of its obligation to withhold tax. In such case the payor Party shall apply the reduced rate of withholding, or not withhold, as the case may be, provided that the payor Party is in receipt of evidence, in a form reasonably satisfactory to the payor Party of the recipient Party's entitlement to a reduced or no withholding rate. If, in accordance with the foregoing, a payor Party withholds any amount, it shall pay to the recipient Party the balance when due, make timely payment to the proper taxing authority of the withheld amount, and send the recipient Party proof of such payment within [***] following that payment. The Parties shall use reasonable efforts to reduce any withholding required under applicable law. The

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Parties hereto agree that as of the date hereof, no U.S. or Swiss withholding taxes are required on the upfront payment described in Section 1 (Upfront Payment) under applicable law [***].

6.6.2 If a Party that owes a Payment assigns its rights and obligations to any person as permitted in accordance with Section 5.7 (Assignment) of the Provisional Collaboration and License Agreement (or any successor provision) and if, solely as a result of such assignment, the withholding of taxes required by applicable law with respect to the Payments is increased, then any Payments shall be increased to take into account such withheld taxes so that, after making all required withholding tax (including withholding tax on amounts payable pursuant to Section 5.6.1), the recipient Party receives an amount equal to the sum it would have received had no such assignment been made.

6.6.3 All payments or amounts due under the Provisional Collaboration and License Agreement, the Definitive LRRK2 Collaboration and License Agreement and the Definitive ROFN and Option Agreement, whether monetary or non-monetary are exclusive of VAT. Any Party receiving a supply under this Provisional Collaboration and License Agreement or the Definitive LRRK2 Collaboration and License Agreement, hereby covenants that it will pay any such VAT correctly charged in addition to any amounts due under this Provisional Collaboration and License Agreement or the Definitive LRRK2 Collaboration and License Agreement. Where the prevailing legislation requires a VAT reverse charge, then the receiving Party covenants that it shall correctly account for VAT in respect of the services received. The supplying Party agrees that it will raise a tax invoice (or equivalent document) to support the charge to VAT.

6.6.4 For the purposes of VAT, the services, rights and licenses provided by Denali under the Provisional Collaboration and License Agreement, the Definitive LRRK2 Collaboration and License Agreement and the Definitive ROFN and Option Agreement shall be considered to be taxed under by Art 44 of Council Directive 2006/112/EC or any equivalent provision in the country of performance if performed outside the European Union and as such will be considered to be taxed for VAT purposes in the country of the recipient. For the purposes of this clause, BIG warrants that it is established in Switzerland for the purposes of receiving any such services, rights or licenses.

6.6.5 Any supply of goods under the Provisional Collaboration and License Agreement, the Definitive LRRK2 Collaboration and License Agreement and the Definitive ROFN and Option Agreement shall be taxed in accordance with the prevailing VAT legislation. All Parties agree that they will reasonably cooperate to ensure the use of any VAT exemptions, zero-ratings, reduced-ratings, suspensions or other reliefs.

6.6.6 In the event that the local competent tax authority determines that VAT is chargeable, Denali in the first instance shall undertake all reasonable steps to refute any such assertions by the local tax authority. Only once this process is completed should Denali raise valid tax invoices for the additional VAT liability.

6.6.7 The Parties shall take all reasonable steps to recover any additional VAT liability from the same local tax authorities by submitting regular claims and shall use commercially reasonable efforts to provide necessary assistance to facilitate the recovery of VAT. If the VAT cannot be recovered, then the supplying Party shall be entitled to invoice the receiving Party directly for these amounts.

6.6.8 Each Party shall be responsible for any penalties or interest accruing due to incorrect VAT treatment of the supplies of goods or services made by that Party or any failure to correctly account for VAT on any receipt of a supply of goods or services under this Provisional Collaboration and License Agreement or the Definitive LRRK2 Collaboration and License Agreement except where those penalties or interest arise as a result of the actions of the other Party, in which case that Party shall be liable to reimburse the value of the penalties and interest.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

6.6.9 Each Party shall be responsible for reporting its own transactions to the local tax authorities if required for VAT purposes. There shall be no shared, mutual or otherwise collective VAT filings that may suggest that the parties are anything other than separately operational entities for VAT purposes.

6.7 Orphan Credit. Denali shall cooperate with Biogen in seeking any tax exemption or credits that may be available to Biogen with respect to any Compound, including the tax credit available under section 45C of the Internal Revenue Code by reason of Biogen's research and development expenditures contributing to the any compound under the Provisional Collaboration and License Agreement, the Definitive LRRK2 Collaboration and License Agreement and the Definitive ROFN and Option Agreement being granted Orphan Drug status by the FDA.

6.8 [***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Schedule 3.9.1

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Schedule 4.1.1(f)

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Schedule 4.3

ROFN and Option Financials

Biogen shall pay Denali $160M within [***] after the execution of the Definitive ROFN and Option Agreement.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Schedule 5.4.4

Joint Press Release

[See attached]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Schedule 5.5.2

Disputes

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Exhibit 10.3

Final Form

DENALI THERAPEUTICS INC.

STANDSTILL AND STOCK RESTRICTION AGREEMENT

This Standstill and Stock Restriction Agreement (this "**Agreement**") is made as of September 22, 2020 ("**Effective Date**") by and among Denali Therapeutics Inc., a Delaware corporation (the "**Company**") and Biogen MA Inc., a Massachusetts corporation (the "**Investor**").

WHEREAS, the Investor has agreed to purchase shares of the Company's Common Stock (the "**Purchased Shares**") pursuant to that certain Common Stock Purchase Agreement of even date herewith, by and between the Company and the Investor (the "**Purchase Agreement**").

WHEREAS, it is a condition to the Closing (as defined in the Purchase Agreement) of the sale of the Purchased Shares that the Company and Investor execute and deliver this Agreement.

NOW, THEREFORE, in consideration of the mutual promises and covenants herein contained, and other consideration, the receipt and adequacy of which is hereby acknowledged, the parties hereto agree as follows:

1. Standstill. Until terminated pursuant to Section 5(a), Investor hereby agrees that, without the prior approval of the Board (as defined in the Purchase Agreement), Investor shall not and shall not permit or cause any Affiliate (as defined in the Purchase Agreement) or Representative (as defined below) of Investor to:

(a) acting alone or with others, acquire, offer to acquire, or agree to acquire, directly or indirectly, by purchase, merger, business combination or in any other manner, any voting securities or direct or indirect rights to acquire any securities of the Company or any subsidiary thereof, or of any successor to or person in control of the Company if after such acquisition Investor, together with its Affiliates, would own 10% or more of the outstanding capital stock of the Company or voting power of the Company, or any assets of the Company or any subsidiary or division thereof or of any such successor or controlling person; *provided* that any investment by Investor or an Affiliate of Investor in third-party mutual funds or other similar passive investment vehicles that hold interests in securities of the Company or any of its Affiliates shall not be taken into account for the purpose of this subparagraph (a);

(b) enter into any voting agreements, trusts or similar arrangements with respect to voting securities of the Company other than as set forth herein;

(c) make, or in any way participate, directly or indirectly, in any "solicitation" of "proxies" to vote (as such terms are used in the rules promulgated by the Securities and Exchange Commission (the "**Commission**")), or seek to advise or influence any person or entity with respect to the voting by any third party of any voting securities of the Company;

(d) make any public announcement, directly or indirectly, with respect to, or submit a proposal for, or offer of (with or without conditions) any extraordinary transaction involving the Company or any of its securities or assets;

(e) form, join or in any way participate in a "group" as defined in Section 13(d)(3) (a "**13D Group**") of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), in connection with any of the foregoing;

(f) act, alone or in concert with others, to seek to control, advise, change or influence the management, Board, governing instruments, policies or affairs of the Company;

(g) disclose any intention, plan or arrangement inconsistent with the foregoing;

(h) have any discussions or enter into any arrangement with, or advise, assist or encourage any other person in connection with any of the foregoing events;

(i) take any action that could reasonably be expected to require the Company to make a public announcement regarding the possibility of any of the events described in clauses (a) through (h) above; or

(j) request the Company or any of its agents or Representatives, directly or indirectly, in any public manner, to amend or waive any of the foregoing provisions.

For the purposes of this Agreement, "**Representatives**" means as to any person, its directors, officers, employees, agents and advisors (including, without limitation, financial advisors, attorneys and accountants) and debt and/or equity financing sources and their advisors.

Notwithstanding the foregoing, it is understood and agreed that Investor shall not be prohibited from entering into an agreement and having discussions with legal, accounting or financial advisors for the limited purposes of evaluating any of the transactions contemplated by this Section 1, and Investor and/or its Affiliates may initiate private discussions with the Company that Investor and/or its Affiliates would be interested in engaging in discussions with the Company that could result in a negotiated transaction otherwise prohibited by this Section 1; *provided, however*, that any such discussions shall be expressly conditioned on approval of such proposal by the Board and will not reasonably be expected to require public disclosure.

2. Transfer Restrictions.

(a) Notwithstanding anything to the contrary in the Purchase Agreement, during the period from the date of the Closing (as defined in the Purchase Agreement) until the earliest to occur of (x) eighteen (18) months after the date of the Closing and (y) a Change of Control (as defined below) (such period, the "**Restricted Period**"), Investor shall not, directly or indirectly, sell, transfer, pledge, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, transfer the economic risk of ownership of, or otherwise dispose of (each, a "**Transfer**") any securities of the Company except:

(i) to the Company;

(ii) in response to a bona fide public tender offer or exchange offer subject to Regulation 14D or Rule 13e-3 of the rules promulgated under the Exchange Act by the Commission, for cash or other consideration which is made by or on behalf of the Company;

(iii) in connection with a Change of Control; or

(iv) to an Affiliate of Investor in one or more transactions, so long as prior to or concurrent with any such Transfer such Affiliate agrees in writing to be bound by the terms of this Agreement.

(b) Upon termination of the Restricted Period, Investor shall be permitted to Transfer the Purchased Shares in an amount not to exceed, on any trading day, ten percent (10%) of the average daily trading volume of the Common Stock on Nasdaq over the five (5) trading day period ending on the trading day immediately prior to such trading day; *provided, however*, that if over any consecutive three week period Investor Transfers Purchased Shares in an amount that exceeds five percent (5%) of the trading volume of the Common Stock on Nasdaq over such three week period, the Investor shall not be permitted to Transfer any Purchased Shares for the following five (5) trading days (the "**Volume Limitation**"). Notwithstanding the foregoing, this Section 2(b) will not preclude, and the Volume Limitation shall not apply to, sales of Purchased Shares by Investor pursuant to circumstances described in Section 2(a)(i)-(iv).

3. Voting Agreement.

(a) *Voting of Securities*. Until terminated pursuant to Section 5(b), in any vote or action by written consent of the stockholders of the Company, including, without limitation, with respect to the election of directors, but excluding any Extraordinary Matter (as defined below), the Investor shall, and shall cause its controlled Affiliates to, vote or execute a written consent with respect to all of the voting securities of the Company as to which it and its controlled Affiliates are entitled to vote or execute a written consent in the same manner and proportion as the votes cast by the holders of the voting securities other than Investor or any of its controlled Affiliates. Notwithstanding anything in this Agreement to the contrary, the Investor and its controlled Affiliates may vote or execute a written consent with respect to, any or all of the voting securities of the Company as to which they are entitled to vote or execute a written consent, as determined in their sole discretion, with respect to the following matters, if presented to the Company's stockholders for approval (each such matter being an ***"*Extraordinary Matter*"***):

(i) any issuance of the Company's Common Stock that represents more than 20% of the then outstanding Common Stock of the Company; or

(ii) a Change of Control, solely in the event that the Investor or one of its Affiliates has made and not withdrawn a good faith, bona fide proposal to be a counterparty to a Change of Control in compliance with the terms of Section 1. In such event, Investor agrees that it will not exercise any applicable dissenters or appraisal rights with respect to any Change of Control.

(b) *Irrevocable Proxy*. In furtherance of Section 3(a), the Investor hereby irrevocably appoints the Company and its designees, and each of them, as attorneys, agents and proxies, with full power of substitution, for the Investor, and in the name, place and stead of the Investor, to vote (or cause to be voted) in such manner as set forth in Section 3(a) with respect to all of the voting securities of the Company as to which the Investor is or may be entitled to vote at any meeting of the Company held after the date hereof, whether annual or special and whether or not an adjourned meeting (the "**Irrevocable Proxy**"). The Irrevocable Proxy is coupled with an interest, shall be irrevocable and binding on any successor in interest of the Investor and shall not be terminated by operation of law upon the occurrence of any event. The Irrevocable Proxy shall operate to revoke and render void any prior proxy as to any securities of the Company heretofore granted by the Investor that is inconsistent herewith. Notwithstanding the foregoing, the Irrevocable Proxy shall be effective only during the Restricted Period and if (and only if), at any annual or special meeting of the stockholders of the Company and at any adjournments or postponements of any such meetings, the Investor (A) fails to appear or otherwise fails to cause any securities of the Company to be counted as present for purposes of calculating a quorum or (B) fails to vote such securities of the Company in accordance with Section 3(a), in each case at least five (5) business days prior to the date of such stockholders' meeting. The Irrevocable Proxy shall terminate upon the earlier of the expiration or termination pursuant to Section 5(b) of the voting agreement set forth in Section 3(a).

4. Registration Rights

(a) *Rule 144 Reporting*. With a view to making available to the Investor the benefits of certain rules and regulations of the Commission which may permit the sale of the Purchased Shares to the public without registration, the Company agrees to use commercially reasonable efforts to:

(i) make and keep public information available, as those terms are understood and defined in Rule 144 promulgated under the Securities Act of 1933, as amended (the "Securities Act");

(ii) file with the Commission in a timely manner all reports and other documents required of the Company under the Exchange Act; and

(iii) furnish the Investor forthwith upon request (A) a written statement by the Company as to its compliance with the public information requirements of said Rule 144, (B) a copy of the most

recent annual or quarterly report of the Company, and (C) such other reports and documents as may be reasonably requested in availing the Investor of any rule or regulation of the Commission permitting the sale of any such securities without registration.

(b) *Registration*.

(i) If, following the termination of the Restricted Period, the Purchased Shares cannot be sold without restriction pursuant to Rule 144 promulgated under the Securities Act, then upon Investor's written request, the Company will use commercially reasonable efforts to promptly register all or a portion of the Purchased Shares for resale under the Securities Act on a Registration Statement on Form S-3 (the "**Registration Statement**"), and will use commercially reasonable efforts to have such Registration Statement promptly declared effective by the Commission.

(ii) The Company will use commercially reasonable efforts to keep the Registration Statement continuously effective under the Securities Act for one hundred eighty (180) days following the initial effectiveness of such Registration Statement or, if earlier, until the date all of the Purchased Shares covered by such Registration Statement have been sold or can be sold publicly without restriction or limitation under Rule 144.

(iii) The Investor shall furnish to the Company such information regarding the Investor, and the distribution proposed by the Investor, as the Company may reasonably request in writing and as shall be required in connection with the Registration Statement.

(iv) In the event Investor intends to dispose of the Purchased Shares registered on the Registration Statement through an underwritten public offering (an "**Underwritten Offering**"), (a) the Company shall select the underwriter(s) of the Underwritten Offering, subject to the approval of the Investor (such approval not to be unreasonably withheld, conditioned or delayed), (b) each of the Company and the Investor shall enter into and perform its obligations under an underwriting agreement, in usual and customary form, with the managing underwriter(s) of such offering; provided, that (1) the representations and warranties by, and the other agreements on the part of, the Company to and for the benefit of the underwriter(s) shall also be made to and for the benefit of the Investor, (2) the Investor shall not be required to make any representations and warranties to, or agreements with, any underwriter in a registration other than customary representations, warranties and agreements, (c) the Company will reasonably cooperate with the Investor and the underwriter(s) to effect the Underwritten Offering, including by using its commercially reasonable efforts to furnish (1) an opinion of the counsel representing the Company, in form and substance as is customarily given to underwriters in an underwritten public offering, addressed to the underwriter(s), (2) a letter from the independent certified public accountants of the Company, in form and substance as is customarily given by independent certified public accountants to underwriters in an underwritten public offering addressed to the underwriter(s); and (3) customary closing certificates and other such other documentation in form and substance as is customarily delivered by a company in a underwritten public offering.

(v) Notwithstanding the foregoing obligations, if the Company furnishes to Investor a certificate signed by the Company's chief executive officer stating that in the good faith judgment of the Board it would be materially detrimental to the Company and its stockholders for such registration statement to either become effective or remain effective for as long as such registration statement otherwise would be required to remain effective, because such action would (a) materially interfere with a significant acquisition, corporate reorganization, or other similar transaction involving the Company; (b) require premature disclosure of material information that the Company has a bona fide business purpose for preserving as confidential; or (c) render the Company unable to comply with requirements under the Securities Act or Exchange Act, then the Company shall have the right to defer taking action with respect to such filing, and any time periods with respect to filing or effectiveness thereof shall be tolled correspondingly, for a period of not more than sixty (60) days

after the request of Investor is given; *provided*, *however*, that the Company may not invoke this right more than once in any twelve (12) month period; and provided further that the Company shall not register any securities for its own account or that of any other stockholder during such sixty (60) day period (other than (1) a registration relating to the sale of securities to employees of the Company or a subsidiary pursuant to a stock option, stock purchase, or similar plan; (2) a registration relating to an SEC Rule 145 transaction; or (3) a registration in which the only Common Stock being registered is Common Stock issuable upon conversion of debt securities that are also being registered).

(vi) The Company shall not be obligated to effect, or to take any action to effect, any registration or Underwritten Offering pursuant to this Section 4(b) (x) during the period that is thirty (30) days before the Company's good faith estimate of the date of filing of, and ending on a date that is ninety (90) days after the effective date of, a Company-initiated registration, *provided* that the Company is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective; or (y) if the Company has previously effected one registration pursuant to this Section 4(b).

(vii) The Company shall pay all Registration Expenses (as defined below) incident to the performance of or compliance with this Section 4(b) by the Company. "**Registration Expenses**" means all expenses incurred by the Company in performing or complying with this Section 4(b), including, without limitation, all registration and filing fees, printing expenses, fees and disbursements of the Company's counsel, blue sky fees, and the expense of any audits, comfort letters or consents incident to or required by any registration, and the fully-burdened full time equivalent rate of the Company's employees who conduct activities related to any registration or offering of Purchased Shares under this Agreement. The Investor will bear the expenses of its own counsel and any Selling Expenses (as defined below) based upon the sale of Purchased Shares. "**Selling Expenses**" means all underwriting discounts and selling commissions applicable to an offering involving Purchased Shares registered pursuant to this Section 4(b).

5. Termination.

(a) *Termination of Standstill*. The restrictions set forth in Section 1 shall terminate upon the earliest to occur of the following:

(i) merger, consolidation or other business combination or transaction to which the Company is a party if the stockholders of the Company immediately prior to the effective date of such merger, consolidation or other business combination or transaction, as a result of such share ownership, have beneficial ownership of voting securities of the Company representing less than 50% of the total number of votes which may be cast in the election of members of the Board if all securities entitled to vote in the election of such directors are present and voted ("**Total Voting Power**") of the surviving entity following such merger, consolidation or other business combination or transaction; (ii) an acquisition by any person, entity or 13D Group (other than a 13D Group of which Investor or any of its Affiliates is a member) of direct or indirect beneficial ownership of voting securities of the Company representing 50% or more of the Total Voting Power; (iii) a sale of all or substantially all of the assets of the Company; or (iv) a liquidation or dissolution of the Company (collectively, a "**Change of Control**"); provided, however, that a Change of Control shall not include transactions for which the primary purpose is raising capital;

(ii) the date following the Closing on which Investor and its controlled Affiliates (or any 13D Group of which Investor or any of its Affiliates is a party) together beneficially own less than five percent (5%) of Company's outstanding stock; or

(iii) eighteen (18) months after the date of the Closing.

(b) *Termination Voting Agreement*. The restrictions set forth in Section 3 shall terminate upon the earliest to occur of the following:

(i) a Change of Control; or

(ii) eighteen (18) months after the date of the Closing.

(c) *Termination of Registration Rights*. The rights under Section 4 shall terminate upon the earliest to occur of the following:

(i) a Change of Control; or

(ii) three (3) years after the date the Restricted Period ends.

(d) The restrictions set forth in Section 1 and the restrictions set forth in Section 2 shall be suspended and shall not apply to or otherwise restrict the Investor's actions in respect of the Company's securities for so long as a Significant Event has occurred and is continuing. For purposes of this Section 5(d), a "**Significant Event**" shall mean any of the following not involving a violation of Section 1: (i) the public announcement of a proposal to acquire, or the acquisition, by any person or 13D Group of beneficial ownership of voting securities of the Company representing 15% or more of the then outstanding voting securities of the Company, or all or substantially all of the assets of the Company; (ii) the commencement, by any person or 13D Group of a tender or exchange offer, to acquire voting securities of the Company which, if successful, would result in such person or 13D Group owning, when combined with any other voting securities of the Company owned by such person or 13D Group, 15% or more of the then outstanding voting securities of the Company; or (iii) the entry into by the Company, or the public announcement by the Company of a determination to enter into or commence or continue any discussions relating to, any merger, sale or other business combination transaction, or an agreement therefor, pursuant to which the outstanding shares of capital stock of the Company would be converted into cash, other consideration or securities of another person or 13D Group or 50% or more of the then outstanding shares of capital stock of the Company would be owned by persons other than the then current holders of shares of capital stock of the Company, or which would result in all or a substantial portion of the Company's assets being sold to any person or 13D Group.

6. Indemnification. If the Purchased Shares are included in a registration statement pursuant to Section 4, then, subject to the provisions of this Section 6, the Company will indemnify and hold the Investor and its directors, officers, shareholders, members, partners, employees and agents, including underwriters, and each person or entity who controls the Investor (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act) and the directors, officers, shareholders, agents, members, partners or employees of such controlling persons (each, an "**Indemnified Person**") harmless from any and all Indemnified Losses (as defined below), *provided* that the Company shall not be liable for any Indemnified Losses to the extent that they arise out of or are based upon actions or omissions made in reliance upon and in conformity with written information furnished by or on behalf of any Investor, controlling person, or other aforementioned person expressly for use in connection with a registration of securities. Promptly after receipt by any Indemnified Person of notice of any demand or claim from any person or entity that would or might give rise to a claim or the commencement of any action, proceeding or investigation in respect of which indemnification may be sought pursuant to this Section 6 (a "**Third Party Claim**"), such Indemnified Person shall promptly notify the Company in writing, and in reasonable detail, of such Third Party Claim, but in no event shall the Company be liable for any Indemnified Losses to the extent such Indemnified Losses arose from any delay in the Indemnified Person providing notice the Company. Thereafter, the Indemnified Person will deliver to the Company, within five (5) business days after the Indemnified Person's receipt thereof, copies of all notices and documents (including court papers) received by the Indemnified Person relating to the Third Party Claim. If notice of a Third Party Claim is delivered to the Company, the Company will be entitled, if it so chooses, to assume the defense thereof (subject to a reservation of rights) with counsel selected by the Company by giving the Indemnified Person written notice within twenty (20) days of the Company's receipt of notice of the Third Party Claim pursuant to this Section 6. If the Company does

not give such notice to the Indemnified Person of the Company's intent to assume the defense of the Third Party Claim, the Indemnified Person shall be entitled to assume the defense thereof. Should the Company so elect to assume the defense of a Third Party Claim, the Company will not be liable to the Indemnified Person for legal expenses subsequently incurred by the Indemnified Person in connection with the defense thereof. If the Company assumes such defense, the Indemnified Person will have the right to participate in the defense thereof and to employ counsel, at its own expense, separate from the counsel employed by the Company, it being understood, however, that the Company will control such defense, except to the extent that (i) the employment thereof has been specifically authorized by the Company in writing, (ii) the Company has failed after a reasonable period of time to assume such defense and to employ counsel or (iii) in such action there is a material conflict on any material issue between the position of the Company and the position of such Indemnified Person, in which case the Company shall be responsible for the reasonable fees and expenses of no more than one such separate counsel for all Indemnified Persons entitled to indemnification hereunder. If the Company chooses to defend any Third Party Claim, then all the Parties will cooperate in the defense or prosecution of such Third Party Claim. The Indemnified Person will not admit any liability with respect to, or settle, compromise or discharge, any Third Party Claim without the prior written consent of the Company. Notwithstanding any other provision of this Agreement, the Company shall not enter into settlement of any Third Party Claim without the prior written consent of the Indemnified Person (which consent shall not be unreasonably withheld), unless such settlement requires only the payment of money that the Company is obligated to pay. For purposes of this Section 6, "**Indemnified Losses**" means any loss, damage, claim or liability (joint or several) to which an Indemnified Person hereto may become subject under the Securities Act, the Exchange Act, or other federal or state law, insofar as such loss, damage, claim or liability (or any action in respect thereof) arises out of or is based upon: (i) any untrue statement or alleged untrue statement of a material fact contained in any registration statement of the Company, including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto; (ii) an omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading; or (iii) any violation or alleged violation by the Company (or any of its agents or Affiliates) of the Securities Act, the Exchange Act, any state securities law, or any rule or regulation promulgated under the Securities Act, the Exchange Act, or any state securities law.

7. Miscellaneous Provisions.

(a) *Amendments and Waivers*. Any term of this Agreement may be amended, terminated or waived only with the written consent of the Company and the Investor. Any amendment or waiver effected in accordance with this Section 7(a) shall be binding upon the Investor and each transferee of the Purchased Shares, each future holder of all such securities, and the Company.

(b) *Notices*. All notices and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effectively given upon the earlier of actual receipt, or (i) personal delivery to the party to be notified, (ii) when sent, if sent by electronic mail during normal business hours of the recipient, and if not sent during normal business hours, then on the recipient's next business day, (iii) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (iv) one (1) business day after deposit with a nationally recognized overnight courier, freight prepaid, specifying next business day delivery, with written verification of receipt. All communications shall be sent to the respective parties at their address as set forth on the signature page or otherwise furnished to the Company at Closing, or to such e-mail address or address as subsequently modified by written notice given in accordance with this Section 7(b). If notice is given to the Company, a copy shall also be sent to Wilson Sonsini Goodrich and Rosati, P.C., 650 Page Mill Road, Palo Alto, CA 94304, Attn: Tony Jeffries, Esq., tjeffries@wsgr.com, and if notice is given to the Investor, a copy shall also be given to Ropes & Gray LLP, Prudential Tower, 800 Boylston Street, Boston, MA 02199, Attn: Zachary Blume, zachary.blume@ropesgray.com.

(c) *Governing Law*. This Agreement shall be governed by the internal law of the State of Delaware without regard to principles of conflicts of law.

(d) *Dispute Resolution*: The parties (i) hereby irrevocably and unconditionally submit to the jurisdiction of the state courts of the state of Delaware and to the jurisdiction of the United States District Court for the District of Delaware for the purpose of any suit, action or other proceeding arising out of or based upon this Agreement, (ii) agree not to commence any suit, action or other proceeding arising out of or based upon this Agreement except in the state courts of the state of Delaware or the United States District Court for the District of Delaware, and (iii) hereby waive, and agree not to assert, by way of motion, as a defense, or otherwise, in any such suit, action or proceeding, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper or that this Agreement or the subject matter hereof may not be enforced in or by such court.

WAIVER OF JURY TRIAL: EACH PARTY HEREBY WAIVES ITS RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT, THE PURCHASE AGREEMENT AND THE SECURITIES ISSUED THEREUNDER, OR THE SUBJECT MATTER HEREOF OR THEREOF. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL-ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT AND THAT RELATE TO THE SUBJECT MATTER OF THIS AGREEMENT, INCLUDING, WITHOUT LIMITATION, CONTRACT CLAIMS, TORT CLAIMS (INCLUDING NEGLIGENCE), BREACH OF DUTY CLAIMS, AND ALL OTHER COMMON LAW AND STATUTORY CLAIMS. THIS SECTION HAS BEEN FULLY DISCUSSED BY EACH OF THE PARTIES HERETO AND THESE PROVISIONS WILL NOT BE SUBJECT TO ANY EXCEPTIONS. EACH PARTY HERETO HEREBY FURTHER WARRANTS AND REPRESENTS THAT SUCH PARTY HAS REVIEWED THIS WAIVER WITH ITS LEGAL COUNSEL, AND THAT SUCH PARTY KNOWINGLY AND VOLUNTARILY WAIVES ITS JURY TRIAL RIGHTS FOLLOWING CONSULTATION WITH LEGAL COUNSEL.

(e) *Successors and Assigns*. Except as otherwise provided herein, the provisions of this Agreement shall inure to the benefit of, and be binding upon, the successors, assigns, heirs, executors and administrators of the parties hereto.

(f) *Entire Agreement*. This Agreement and the Purchase Agreement constitute the full and entire understanding and agreement between the parties with respect to the subject matter hereof, and any other written or oral agreement relating to the subject matter hereof existing between the parties are expressly canceled.

(g) *Delays or Omissions*. Except as expressly provided herein, no delay or omission to exercise any right, power or remedy accruing to any party to this Agreement upon any breach or default of any other party under this Agreement shall impair any such right, power or remedy of such non-breaching or non-defaulting party, nor shall it be construed to be a waiver of any such breach or default, or an acquiescence therein, or of or in any similar breach or default thereafter occurring, nor shall any waiver of any single breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. Any waiver, permit, consent or approval of any kind or character on the part of any party of any breach or default under this Agreement, or any waiver on the part of any party of any provisions or conditions of this Agreement, must be in writing and shall be effective only to the extent specifically set forth in such writing. All remedies, either under this Agreement or by law or otherwise afforded to any party to this Agreement, shall be cumulative and not alternative.

(h) *Severability*. The invalidity or unenforceability of any provision hereof shall in no way affect the validity or enforceability of any other provision.

(i) *Counterparts*. This Agreement may be executed in any number of counterparts, each of which shall be enforceable against the parties that execute such counterparts, and all of which together shall constitute one instrument. Counterparts may be delivered electronic mail (including .pdf or any electronic signature) or other transmission method and any counterpart so delivered shall be deemed an original.

(j) *Further Assurances*. Each party hereto agrees to execute and deliver, by the proper exercise of its corporate, limited liability company, partnership or other powers, all such other and additional instruments and documents and do all such other acts and things as may be necessary to more fully effectuate this Agreement.

(k) *Stop Transfer Instructions*. The Company may issue appropriate “stop transfer” instructions to enforce the covenants set forth in this Agreement.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the parties have executed this Standstill and Stock Restriction Agreement as of the Effective Date.

COMPANY:

DENALI THERAPEUTICS INC.
a Delaware corporation

By: /s/ Ryan J. Watts
Name: Ryan Watts, Ph.D.
Title: President and CEO

Address:
161 Oyster Point Boulevard
South San Francisco, CA 94080

E-mail:

IN WITNESS WHEREOF, the parties have executed this Standstill and Stock Restriction Agreement as of the Effective Date.

INVESTOR:
BIOGEN MA INC.

By: /s/ Alfred W. Sandrock, Jr.
Name: Alfred W. Sandrock, Jr.
Title: EVP, R&D

Address:
225 Binney Street
Cambridge, MA 02142

E-mail:

Definitive LRRK2 Collaboration and License Agreement

Between

Denali Therapeutics Inc.,

Biogen MA, Inc.

and

Biogen International GmbH

Dated October 4, 2020

DEFINITIVE LRRK2 COLLABORATION AND LICENSE AGREEMENT

This Definitive LRRK2 Collaboration and License Agreement ("**Definitive LRRK2 Agreement**") is entered into as of October 4, 2020 (the "**Effective Date**") by and between Denali Therapeutics Inc., a Delaware corporation with its principal place of business located at 161 Oyster Point Blvd., South San Francisco, California 94080 ("**Denali**"), Biogen MA, Inc., a corporation organized under the laws of the Commonwealth of Massachusetts having an office at 225 Binney Street, Cambridge, MA 02142 ("**BIMA**"), and Biogen International GmbH, a Gesellschaft mit beschränkter Haftung organized under the laws of Switzerland, whose registered office is at Neuhofstrasse 30, 6340 Baar, Switzerland ("**BIG**", together with BIMA, collectively, "**Biogen**"). Biogen and Denali are each individually referred to as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Denali has developed certain Licensed Compounds and Licensed Products and controls certain intellectual property and other rights with respect to such Licensed Compounds and Licensed Products in the Territory;

WHEREAS, BIMA and Denali entered into a Stock Purchase Agreement as of the Execution Date (the "**Stock Purchase Agreement**"), under which BIMA has purchased certain voting shares of Denali;

WHEREAS, the Parties have entered into a binding Provisional Collaboration and License Agreement as of the Execution Date ("**Provisional Collaboration and License Agreement**"), under which the Parties agreed, among other things, to collaborate in the development, manufacture and commercialization of Licensed Compounds and Licensed Products in accordance with the terms and conditions set forth therein;

WHEREAS, as contemplated under the Stock Purchase Agreement and the Provisional Collaboration and License Agreement, the Parties desire to agree to a more detailed set of terms as set forth in this Definitive LRRK2 Agreement that would govern the collaboration established under the Provisional Collaboration and License Agreement with respect to Licensed Compounds; and

WHEREAS, the terms set forth in this Definitive LRRK2 Agreement supersede those terms forth in the Provisional Collaboration and License Agreement pertaining to the Licensed Compounds and Licensed Products;

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

ARTICLE 1
DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

1.1 "**Accounting Standards**" means, with respect to a Party, its Affiliates or any other Selling Party, the United States Generally Accepted Accounting Principles ("**GAAP**") or International Financial Reporting Standards, as such Person uses for its financial reporting obligations, consistently applied.

1.2 "**Acquisition**" means, with respect to a Party, an acquisition by such Party of a Third Party (whether by merger or acquisition of all or substantially all of the stock or of all or substantially all of the assets of a Third Party or of any operating or business division of a Third Party or similar transaction), other than a Change of Control of the Party.

1.3 "**Affiliate**" means, with respect to a Person, any other Person that, directly or indirectly, through one (1) or more intermediaries, controls, is controlled by or is under common control with such Person. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" means (a) the possession, directly or indirectly, of the power to direct the management or policies of a Person, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise or (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of a Person (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity). The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that, in such case, such lower percentage shall be substituted in the preceding sentence, *provided* that such foreign investor has the power to direct the management or policies of such entity.

1.4 "**Allowable Expenses**" means, on a Cost-Profit Sharing Product-by-Cost-Profit Sharing Product and Cost-Profit Sharing Country-by-Cost-Profit Sharing Country basis, Eligible Commercialization Expenses, Eligible Medical Affairs Expenses, Other Operating Expenses, Sales and Marketing Costs and Sales Force Expenses for such Cost-Profit Sharing Product in such Cost-Profit Sharing Country.

1.5 "**Allowable Overruns**" means, with respect to any Eligible Development Expenses or Allowable Expenses, any amounts incurred by or on behalf of a Party in the performance of activities allocated to such Party under the Global Development Plan/Budget or Co-Commercialization Plan/Budget in a given Calendar Year that (a) are not [***] any breach of this Definitive LRRK2 Agreement, and (b) are in excess of the aggregate amount budgeted in the Global Development Plan/Budget or Co-Commercialization Plan/Budget (as applicable) for such Party in such Calendar Year (i) by an amount not to exceed [***] of the total amount budgeted under the then-current Global Development Plan/Budget or Co-Commercialization Plan/Budget, as applicable, to be incurred by such Party in such Calendar Year in the aggregate or (ii) that are otherwise approved by a unanimous decision of the JSC or the Finance Working Group.

1.6 "**Annual Net Sales**" means the total Net Sales of all Licensed Products in the Territory in a given Calendar Year.

1.7 "**Applicable Law**" means federal, state, local, national and supra-national laws, statutes, rules, and regulations, including any rules, regulations, regulatory guidelines, or other requirements of the Regulatory Authorities, major national securities exchanges or major securities listing organizations, that may be in effect from time to time during the Term and applicable to a particular activity or country or other jurisdiction hereunder.

1.8 "**Approved CMO**" means (a) those certain contract manufacturing organizations with which Denali has an agreement for the manufacture of Licensed Compounds or Licensed Products as of the Effective Date and (b) any other contract manufacturing organization approved in writing by Biogen, which approval shall not be unreasonably withheld, conditioned or delayed.

1.9 "**Biogen Development Activities**" means any Development activities for Licensed Compounds or Licensed Products to be conducted by Biogen pursuant to the Global Development Plan/Budget.

1.10 "**Biogen IP**" means Biogen Know-How and Biogen Patents.

1.11 "**Biogen Know-How**" means any and all Information: (a) Controlled by Biogen or its Affiliates as of the Execution Date or during the Term; (b) [***] for the Development of Licensed Compounds or Licensed Products in the Territory or, in the Co-Commercialization Territory, the sale or offer for sale or other Commercialization of Licensed Products[***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.12 "**Biogen Patents**" means: (a) all Patents that (i) are Controlled by Biogen or its Affiliates as of the Execution Date or during the Term, and (ii) claim any Biogen Know-How; and (b) all Biogen Program Patents or other Patents Controlled by Biogen or its Affiliates, in each case, that are [***] for the Development of Licensed Compounds or Licensed Products in the Territory or, in the Co-Commercialization Territory, the sale or offer for sale or other Commercialization of Licensed Products, in each case, in accordance with the Global Development Plan/Budget or Co-Commercialization Plan/Budget, as applicable or to conduct activities with respect to an Independent Study in accordance with Section 3.1.4 (Independent Study) or perform Denali's other obligations under this Definitive LRRK2 Agreement.

1.13 "**Biogen Program Patent**" means [***].

1.14 [***].

1.15 "**Business Day**" means a day, other than a Saturday or Sunday, on which banking institutions in Boston, Massachusetts, U.S.A. and San Francisco, California, U.S.A. are open for business.

1.16 "**Calendar Quarter**" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter shall end on the last day of the Term.

1.17 "**Calendar Year**" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

1.18 "**Centralized Approval Procedure**" means the procedure through which an MAA filed with the EMA results in a single marketing authorization valid throughout the European Union (or at least all Major Markets that are within the European Union or otherwise subject to such marketing authorization procedure, such as the United Kingdom if and as applicable).

1.19 "**Change of Control**" with respect to a Party, means any transaction or a series of related transactions in which such Party: (a) sells, conveys or otherwise disposes of all or substantially all, whether directly or indirectly, of its assets or business to any Person (other than to an Affiliate of such Party, provided that such Person was an Affiliate of such Party prior to the Execution Date); or (b) (i) merges, consolidates with, or is acquired by any other Person (other than an Affiliate of such Party, provided that such Person was an Affiliate of such Party prior to the Execution Date); or (ii) effects any other transaction or series of related transactions; in each case of subsection (i) or (ii), such that the stockholders of such Party immediately prior thereto, in the aggregate, no longer own, directly or indirectly, beneficially or legally, more than fifty percent (50%) of the outstanding voting securities, capital stock or other ownership interest of the surviving Person following the closing of such merger, consolidation, other transaction or series of related transactions. Notwithstanding the foregoing, a bona fide financing transaction (including any public offering of a Party's capital stock) shall not be deemed a Change of Control.

1.20 "**Clinical Data**" means the original source patient data and case report forms (CRFs) collected or generated by, on behalf of, or under the authority of a Party with respect to Clinical Studies of any Licensed Compound or Licensed Product, together with all analysis, reports, and results with respect thereto.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.21 "**Clinical Study**" or "**Clinical Studies**" means any Phase I Trial, Phase II Trial, Phase III Trial, [***] or any such other test or study in human subjects.

1.22 "**CNS Penetrant**" or "**CNS Penetrance**" means, with respect to a small molecule compound: (a) [***]; and (b) [***]. Notwithstanding any provision to the contrary set forth in this Definitive LRRK2 Agreement, the small molecule compounds known as [***] "DNL151" [***] each shall be deemed to be a CNS Penetrant, and the small molecule compounds known as [***] each shall be deemed not to be CNS Penetrant.

1.23 "**Co-Commercialization Budget**" means a rolling [***] Calendar Year budget setting forth the total budgeted amounts estimated to be incurred in the performance of those Commercialization and other activities included in the Co-Commercialization Plan/Budget pertaining to each Cost-Profit Sharing Country in the first Calendar Year (or part thereof) of such budget and next [***] thereafter, including a reasonably detailed budget for FTE Costs and Out-of-Pocket Costs, broken down by Calendar Quarter for the first Calendar Year (or part thereof) and a then current estimate of such FTE Costs and Out-of-Pocket Costs for the next [***], and, as determined by the JCC, a further breakout of costs by functional area or category.

1.24 "**Co-Commercialization Plan/Budget**" means a plan for the Commercialization of Cost-Profit Sharing Products in each Cost-Profit Sharing Country, as described in Section 5.2.2 (Co-Commercialization Plan/Budget), including the Co-Commercialization Budget.

1.25 "**Co-Commercialization Territory**" means U.S. and China.

1.26 "**Combination Product**" means a Licensed Product that is (a) sold in the form of a combination that contains or comprises a Licensed Compound together with one or more other therapeutically active pharmaceutical agents (whether coformulated or copackaged or otherwise sold together as a single unit) ("**Other Component**"), and (b) sold for a single invoice price. For purposes of the foregoing, none of the following shall be deemed to be an Other Component [***].

1.27 "**Commercialization**" means with respect to any product, any and all activities directed to: the marketing, advertising, promotion, distribution, import, export, offering for sale, and sale of such product, product samples, pre-launch activities to prepare a market for potential sales; modeling and pharmaco-economic studies, epidemiological studies, expanded access programs and associated registries and activities required to fulfill ongoing regulatory obligations; government affairs, and public policy activities; patient services, patient advocacy engagement, and adverse event reporting; the preparation and submission of Regulatory Documentation and interacting with Regulatory Authorities regarding any of the foregoing; and pricing and reimbursement activities, including seeking and maintaining any required Pricing and Reimbursement Approvals; but excluding, in each case, any activities directed to Manufacturing, Development, or Medical Affairs. "**Commercialize**," "**Commercializing**," and "**Commercialized**" will be construed accordingly.

1.28 "**Commercialization Plans**" means each Co-Commercialization Plan/Budget and Global Commercialization Plan.

1.29 "**Commercially Reasonable Efforts**" means, [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.30 "**Confidential Information**" means any proprietary Information or data provided orally, visually, in writing or other form by or on behalf of one (1) Party (or an Affiliate or representative of such Party or such Party's Affiliate) to the other Party (or to an Affiliate or representative of such Party or such Party's Affiliate) in connection with this Definitive LRRK2 Agreement, whether prior to, on, or after the Execution Date, including Information pertaining to the terms of the Provisional Collaboration and License Agreement (to the extent pertaining Licensed Compounds or Licensed Products) or this Definitive LRRK2 Agreement, a Licensed Compound or any Licensed Product (including relevant Regulatory Documentation and Regulatory Data), any Exploitation of a Licensed Compound or Licensed Product, any Information with respect thereto developed by or on behalf of the disclosing Party or its Affiliates (including Biogen Know-How and Denali Know-How), or the scientific, regulatory or business affairs or other activities of either Party. Notwithstanding the foregoing, Joint Program Know-How and all Regulatory Documentation generated after the Execution Date and owned by a Party pursuant to this Definitive LRRK2 Agreement shall be deemed to be the Confidential Information of both Parties, and the restrictions on use and disclosure in Section 10.1 (Confidentiality Obligations) and Section 10.2 (Permitted Disclosures) shall be deemed to apply to each Party as a receiving Party, regardless of which Party initially generated or disclosed the relevant Joint Program Know-How or Regulatory Documentation, as applicable, to the other Party in connection with this Definitive LRRK2 Agreement.

1.31 "**Control**" or "**Controlled**" means the possession by a Party or its Affiliate (whether by ownership, license or otherwise other than pursuant to this Definitive LRRK2 Agreement) of (a) with respect to any tangible Information, the legal authority or right to physical possession of such tangible Information, with the right to provide such tangible Information to the other Party on the terms set forth herein, or (b) with respect to Patents, Regulatory Approvals, regulatory submissions, intangible Information or other intellectual property or subject matter, the legal authority or right to grant a license, sublicense, access, or right to use (as applicable) to the other Party under such Patents, Regulatory Approvals, regulatory submissions, intangible Information or other intellectual property or subject matter on the terms set forth herein, in each case ((a) and (b)), without breaching or otherwise violating the terms of any arrangement or agreement with a Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such access, right to use, licenses or sublicense, and (c) with respect to any product, the possession by a Party of the ability (whether by sole or joint ownership, license or otherwise, other than pursuant to the license grants under this Definitive LRRK2 Agreement) to grant a license or sublicense on the terms set forth herein of Patents within clause (b) above that claim such product or proprietary Information within clause (a) or (b) above that is used in connection with the exploitation of such product. Notwithstanding any provision to the contrary set forth in this Definitive LRRK2 Agreement, a Party and its Affiliates will not be deemed to "Control" any Patents, Regulatory Approvals, regulatory submissions, Information or other intellectual property or subject matter that is [***]

1.32 "**Corporate Names**" means the Trademarks and logos identified on Schedule 1.32 (Corporate Names of Denali and Biogen) (as the same may be updated from time to time) and such other names and logos, in each case, as Denali or Biogen may designate in writing from time to time.

1.33 "**Cover**," "**Covering**" or "**Covered**" means, with respect to a product, technology, process, method or mode of administration that, in the absence of ownership of or a license granted under a particular Valid Claim, the manufacture, use, offer for sale, sale or importation of such product or the practice of such technology, process, method or mode of administration would infringe such Valid Claim or, in the case of a claim that has not yet issued, would infringe such claim if it were to issue and become a Valid Claim.

1.34 "**Denali Development Activities**" means any Development activities for Licensed Compounds or Licensed Products to be conducted by Denali pursuant to the Global Development Plan/Budget.

1.35 "**Denali IP**" means Denali Know-How, Denali Patents and Denali's interest in Joint Program Patents.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.36 "**Denali Know-How**" means any and all Information that is: (a) Controlled by Denali or its Affiliates as of the Execution Date or during the Term; and (b) [***] for the Development, Manufacture or use of Licensed Compounds or Licensed Products or the Commercialization of Licensed Products [***].

1.37 "**Denali Patents**" means all Patents (excluding Denali's interest in any Joint Program Patents) that are: (a) Controlled by Denali or its Affiliates as of the Execution Date or during the Term; and (b) [***] for the Development, Manufacture or use of Licensed Compounds or Licensed Products or the Commercialization of Licensed Products [***]. Such Patents existing as of the Execution Date are set forth in Schedule 1.37 (Denali Patents as of the Execution Date).

1.38 "**Detail**" means a face-to-face meeting, between a sales representative of the applicable Party, and a health care professional, during which a presentation of a Licensed Product's attributes is presented in a manner consistent with Applicable Law and industry standards and with the quality of similar presentations made by a Party's sales representatives for such Party's other products, if applicable. A Detail does not include a sample drop made by a sales representative. The Parties may agree in the Co-Commercialization Plan/Budget to include real-time, electronic Detailing by means of information technology (*e.g.*, videoconferencing). "**Detailing**" shall mean the act of presenting a Detail.

1.39 "**Development**" means, with respect to any product, any and all internal and external research or development activities regarding such product, including (a) research, non-clinical testing and activities, IND-enabling pre-clinical studies and other pre-clinical activities, and Clinical Studies [***], (b) test method development and stability testing, process development and formulation development and toxicology, and (c) preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct Clinical Studies or to obtain Regulatory Approval of such product (excluding any activities reasonably necessary for obtaining Pricing and Reimbursement Approval, but not for other elements of the Regulatory Approval) and interacting with Regulatory Authorities regarding any of the foregoing; but excluding, in each case, any activities directed to Manufacturing, Medical Affairs, or Commercialization. "**Develop**," "**Developing**," and "**Developed**" will be construed accordingly.

1.40 "**Development Lead**" means the Party specified as the "Development Lead" pursuant to the terms of Section 3.1.3(e) (Designation of Development Lead) or Section 3.1.4(d)(ii).

1.41 "**Divestiture**" means (a) the divestiture of a LRRK2 Alternative Product through (i) an outright sale or assignment of all rights in such LRRK2 Alternative Product to a Third Party or (ii) an exclusive out-license to a Third Party of all Development and Commercialization rights with respect to such LRRK2 Alternative Product, in each case, with no further role, influence or authority of the applicable Party, directly or indirectly, with respect to such LRRK2 Alternative Product or (b) the complete cessation of all Development and Commercialization activities with respect to such LRRK2 Alternative Product; *provided* that [***]. When used as a verb, "**Divest**" and "**Divested**" means to cause a Divestiture.

1.42 "**Dollars**" or "**$**" means United States Dollars.

1.43 "**Drug Approval Application**" means a New Drug Application as defined in the FFDCA ("**NDA**"), or any corresponding application for Regulatory Approval in the Territory, including, with respect to the European Union, a marketing authorization application (an "**MAA**") filed with the EMA pursuant to the Centralized Approval Procedure or an MAA filed with the PMDA, including, in each case, all supplements, amendments, variations, extensions and renewals thereof.

1.44 "**Eligible Commercialization Expenses**" means, on a Cost-Profit Sharing Product-by-Cost-Profit Sharing Product and Cost-Profit Sharing Country-by-Cost Profit Sharing Country basis, costs and expenses incurred by or on behalf of a Party or its Affiliates [***] such Cost-Profit Sharing Product and such Cost-Profit Sharing Country in accordance with the Co-Commercialization Plan/Budget with respect to the following:

(a) Manufacturing Costs for such Cost-Profit Sharing Products used for performance of Commercialization activities in such Cost-Profit Sharing Country (and not used in connection with Clinical Studies or other Development activities), or incurred in support of such Commercialization activities, all to the extent incurred [***];

(b) Sales and Marketing Costs for such Cost-Profit Sharing Products in such Cost-Profit Sharing Country;

(c) FTE Costs or Out-of-Pocket Costs pertaining to any obtaining or maintaining Pricing and Reimbursement Approvals or any filing and other Regulatory Authority fees associated therewith; and

(d) any other FTE Costs and Out-of-Pocket Costs agreed to be shared by the Parties as Eligible Commercialization Expenses under this Definitive LRRK2 Agreement.

Eligible Commercialization Expenses specifically exclude any FTE Costs, Out-of-Pocket Costs and other costs and expenses: (i) incurred by or on behalf of the performing Party or its Affiliates to the extent caused by such Party's or its Affiliates' action or omission that constitutes a breach under this Definitive LRRK2 Agreement by or on behalf of the performing Party; (ii) incurred after the Co-Funding End Date for a particular Cost-Profit Sharing Product and corresponding Cost-Profit Sharing Country to the extent a Denali Commercialization Opt-Out has occurred; or (iii) [***].

If any cost or expense [***] more than one Commercialization cost category set forth above, then such cost or expense will only be counted once (*i.e.*, as an Eligible Commercialization Expense with respect to only one such category). No cost or expense included as an Eligible Commercialization Expense will (x) also be included as an Eligible Development Expense or an Eligible Medical Affairs Expense, (y) be (or have been) included in the calculation of Net Sales as a deduction from the total amount billed or invoiced on sales of the applicable Cost-Profit Sharing Product, or (z) be an amount for which one Party or the other is solely responsible under this Definitive LRRK2 Agreement. Eligible Commercialization Expenses will be recognized and calculated in accordance with GAAP.

1.45 "**Eligible Development Expenses**" means, with respect to all Licensed Products that are Cost-Profit Sharing Products (and all Licensed Compounds included in such Licensed Products), costs and expenses incurred by or on behalf of a Party or its Affiliates [***] such Licensed Products in accordance with the Global Development Plan/Budget or otherwise provided in Section 12.3 (Certain Indemnified Losses), as applicable:

(a) Manufacturing Costs for such Licensed Products (and all Licensed Compounds included in such Licensed Products) used for performance of Development activities or incurred in support of Development activities for Licensed Products, as well as comparator and placebo reasonably necessary to conduct such Development activities, all to the extent incurred under and in accordance with the Global Development Plan/Budget;

(b) Payments made by a Party or its Affiliate to any Third Party with respect to New Technology to the extent such payments will be shared by the Parties as an Eligible Development Expense in accordance with Section 6.5.2(c) (Cost Sharing) and are not included in Other Operating Expenses for such Cost-Profit Sharing Product;

(c) all FTE Costs and Out-of-Pocket Costs with respect to Clinical Studies for such Licensed Product included in the Global Development Plan/Budget [***], including (i) the preparation for and conduct of such Clinical Studies and such other testing and studies, (ii) data collections and analysis and report writing, (iii) clinical trial participant and recruiting activities, (iv) clinical laboratory work, (v) regulatory activities conducted directly in connection with such Clinical Studies and such other testing and studies, including adverse event recordation and reporting and (vi) advisory meetings in connection with such Licensed Product (or a Licensed Compound included therein);

(d) all FTE Costs and Out-of-Pocket Costs with respect to pre-clinical and non-clinical activities, testing and studies for such Licensed Products (and all Licensed Compounds included in such Licensed Products), such as toxicology studies, formulation development, test method development, stability testing, quality assurance, quality control development and statistical analysis and other Development activities, in each case, conducted under and in accordance with the Global Development Plan/Budget;

(e) all FTE Costs and Out-of-Pocket Costs incurred in accordance with the Global Development Plan/Budget with respect to preparing, filing, obtaining and maintaining Regulatory Approval or other submissions to Regulatory Authorities (including associated filing and other Regulatory Authority fees, translation expenses and legal and other professional services fees), but excluding any FTE Costs or Out-of-Pocket Costs pertaining to any obtaining or maintaining Pricing and Reimbursement Approvals or any filing and other Regulatory Authority fees associated therewith;

(f) to the extent provided in Section 12.3 (Certain Indemnified Losses), Indemnified Losses from Third Party Claims arising from the Development (or Manufacture in support of Development) for the applicable Cost-Profit Sharing Product; and

(g) any other FTE Costs and Out-of-Pocket Costs agreed to be shared by the Parties as an Eligible Development Expense under this Definitive LRRK2 Agreement.

Eligible Development Expenses shall also include (i) those FTE Costs and Out-of-Pocket Costs incurred by or on behalf of Denali in performing activities for the Development of Licensed Compounds and Licensed Products from the Execution Date up to and including the Effective Date (such period, the "**Interim Development Period**") and (ii) Manufacturing Costs incurred by Denali prior to the Effective Date for quantities of Licensed Compounds and Licensed Products used in the performance of the activities described in the preceding clause (i); *provided* that such amounts shall not, in the aggregate, exceed [***] for each consecutive [***] period included in the Interim Development Period, or a *pro rata* portion of such amount for any period that is less than [***] included in the Interim Development Period (such amount, collectively, "**Pre-Definitive LRRK2 Agreement Eligible Development Expenses**"). In addition, Eligible Development Expenses specifically exclude any FTE Costs, Out-of-Pocket Costs and other costs and expenses (A) incurred by or on behalf of the performing Party or its Affiliates to the extent caused by such Party's or its Affiliates' action or omission that constitutes a breach under this Definitive LRRK2 Agreement by or on behalf of the performing Party or (B) incurred after the Co-Funding End Date for a particular Licensed Product to the extent a Denali Development Opt-Out has occurred.

If any cost or expense [***] more than one Development cost category above, then such cost or expense will only be counted once (*i.e.*, as an Eligible Development Expense with respect to only one such category). No cost or expense included as an Eligible Development Expense will: (x) also be included as an Eligible Commercialization Expense or an Eligible Medical Affairs Expense; or (y) be an amount for which one Party or the other is solely responsible under this Definitive LRRK2 Agreement. Eligible Development Expenses will be recognized and calculated in accordance with GAAP.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.46 "**Eligible Medical Affairs Expenses**" means, on a Cost-Profit Sharing Product-by-Cost-Profit Sharing Product and Cost-Profit Sharing Country-by-Cost Profit Sharing Country basis, all FTE Costs and Out-of-Pocket Costs incurred by or on behalf of a Party or its Affiliates [***] the Medical Affairs activities for such Cost-Profit Sharing Product and such Cost-Profit Sharing Country under and in accordance with the Co-Commercialization Plan/Budget. Eligible Medical Affairs Expenses specifically exclude any FTE Costs, Out-of-Pocket Costs and other costs and expense: (a) incurred by or on behalf of a Party or its Affiliates to the extent caused by such Party or its Affiliates' action or omission that constitutes a breach under this Definitive LRRK2 Agreement by or on behalf of such Party; (b) incurred after the Co-Funding End Date for a particular Cost-Profit Sharing Product and corresponding Cost-Profit Sharing Country to the extent a Denali Opt-Out has occurred; or (c) to the extent specifically identifiable to Medical Affairs activities for any Licensed Product for countries other than the corresponding Cost-Profit Sharing Countries. No expense included as an Eligible Medical Affairs Expense will (i) also be included as an Eligible Development Expense or Eligible Commercialization Expense or (ii) be an amount for which one Party or the other is solely responsible under this Definitive LRRK2 Agreement. Eligible Medical Affairs Expenses will be recognized and calculated in accordance with GAAP.

1.47 "**EMA**" means the European Medicines Agency and any successor agency(ies) or authority having substantially the same function.

1.48 "**European Union**" means the economic, scientific, and political organization of member states known as the European Union, as its membership may be altered from time to time, and any successor thereto.

1.49 "**Execution Date**" means August 5, 2020.

1.50 "**Exploit**" means to make, have made, use, import, export, offer to sell, sell, Develop, Manufacture, perform Medical Affairs activities, Commercialize or otherwise exploit. "**Exploitation**" will be construed accordingly.

1.51 "**FDA**" means the United States Food and Drug Administration and any successor agency(ies) or authority having substantially the same function.

1.52 "**FFDCA**" means the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.53 "**Field**" means any and all uses.

1.54 "**First Commercial Sale**" means, with respect to a particular Licensed Product in a particular country in the Territory, the first sale of such Licensed Product to a Third Party (other than a Sublicensee) for distribution, use or consumption in such country or region. First Commercial Sale excludes transfers of Licensed Product to Third Parties as *bona fide* samples, as donations, for the performance of Clinical Studies, or for similar purposes in accordance with Applicable Law pertaining to any expanded access program, any compassionate sales or use program (including named patient program or single patient program), or any indigent program.

1.55 "**FTE**" means the equivalent of the work of one (1) employee full time for one (1) Calendar Year (consisting of at least a total of [***] hours per Calendar Year). Each employee utilized by a Party in connection with its performance under this Definitive LRRK2 Agreement may be less than or greater than one FTE based on the hours actually worked by such employee performing Development, Medical Affairs, Commercialization or Manufacturing activities with respect to a Licensed Product (or Licensed Compounds included in a Licensed Product) and shall be treated as an FTE on a pro rata basis based upon the actual number of such hours worked divided by [***].

1.56 "**FTE Costs**" means, with respect to a Party for any period, the applicable FTE Rate multiplied by the applicable number of FTEs of such Party performing Development, Medical Affairs, Commercialization or Manufacturing activities during such period in accordance with the applicable Global Development Plan/Budget, Independent Study Proposal or Co-Commercialization Plan/Budget, as the case may be.

1.57 "**FTE Rate**" means the applicable rate specified on Schedule 1.57 (FTE Rates) for the relevant category of FTE's activities; *provided* that, commencing with Calendar Year [***] and for each subsequent Calendar Year thereafter, each of the rates specified on Schedule 1.57 (FTE Rates) (as updated pursuant to this Section 1.57 ("FTE Rate" definition)) shall be adjusted annually, effective January 1 of the applicable Calendar Year, to [***], unless the Parties otherwise agree.

1.58 "**Generic Product**" means, with respect to a given Licensed Product in a given country outside of the Co-Commercialization Territory, a pharmaceutical product that is (a) not marketed or sold by or under the authority of Biogen, its Affiliates or Sublicensees and (b) (i) contains the same LRRK2 Inhibitor as such Licensed Product or [***] and (ii) is determined by the applicable Regulatory Authority in such country as [***] to such Licensed Product (A) in the United States through an ANDA filing under 505(j) of the FFDCA or (B) under equivalent procedures outside of the United States [***] with such Licensed Product.

1.59 "**Global Commercialization Plan**" means the global commercialization plan for the Commercialization of Licensed Products in the Field in the Territory, as described in Section 5.2.1 (Global Commercialization Plan).

1.60 "**Global Development Plan/Budget**" means the plan for the Development of Licensed Compounds and Licensed Products, as described in Section 3.1.1 (Global Development Plan/Budget), including the Global Development Budget. The Global Development Plan/Budget as of the Effective Date is set forth in Schedule 1.60 (Initial Global Development Plan/Budget) ("**Initial Global Development Plan/Budget**").

1.61 "**Good Clinical Practices**," "**GCP**" or "**cGCP**" means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in the guidelines adopted by the International Conference on Harmonization ("**ICH**"), titled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," (or any successor document) including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the EMA, PMDA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time.

1.62 "**Good Laboratory Practices**," "**GLP**" or "**cGLP**" means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in 21 C.F.R. Part 58 (or any successor statute or regulation), including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the EMA, PMDA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time, including applicable guidelines promulgated under the ICH.

1.63 "**Good Manufacturing Practice**," "**GMP**" or "**cGMP**" means the then-current good manufacturing practices required by the FDA, as set forth in the FFDCA, as amended, and the regulations promulgated thereunder, for the manufacture and testing of pharmaceutical materials, and comparable Applicable Law related to the manufacture and testing of pharmaceutical materials in jurisdictions outside the U.S., including the quality guideline promulgated by the ICH designated ICH Q7A, titled "Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients" and the regulations promulgated thereunder, in each case as they may be updated from time to time.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.64 "**In-License Agreement**" means any agreement between a Party and a Third Party pursuant to which such Party obtains rights to any Third Party intellectual property (including Information) or materials that is [***] for the Exploitation of a Licensed Compound or Licensed Product pursuant to this Definitive LRRK2 Agreement. In-License Agreements include those certain agreements between Denali and a Third Party listed on Schedule 1.64 (Existing Denali Agreements and Provisions) (each, an "**Existing Denali Agreement**").

1.65 "**IND**" means an Investigational New Drug application as defined in 21 C.F.R. Part 312 or any comparable filings outside of the United States that are required to commence Clinical Studies in such country or region, and all supplements or amendments that may be filed with respect to the foregoing.

1.66 "**Independent Study Costs**" means those Out-of-Pocket Costs and FTE Costs incurred by the Proposing Party in performing the relevant Independent Study (prior to receipt of Regulatory Approval or inclusion under the Global Development Plan/Budget), which costs shall be determined using the same manner of calculating Eligible Development Expenses as if such Independent Study had been incorporated into the Global Development Plan/Budget.

1.67 "**Indication**" means a disease or pathological condition [***].

1.68 "**Information**" means all knowledge of a technical, scientific, business and other nature, including know-how, inventions, technology, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, Clinical Data, and other biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, materials, reagents (*e.g.*, plasmids, proteins, cell lines, assays and compounds) and biological methodology; in each case (whether or not confidential, proprietary, patented or patentable, or of commercial advantage) in written, electronic or any other form now known or hereafter developed.

1.69 "**Initiate**" or "**Initiation**" means, with respect to a Clinical Study of a Licensed Product, the [***] in such Clinical Study.

1.70 "**iPD**" means idiopathic Parkinson's Disease, [***]. Notwithstanding the foregoing, [***].

1.71 "**Joint Committee**" means the JSC, JDC, JCC, CMC Working Group, Finance Working Group or any other joint subcommittee or Working Group established by the Parties or the JSC, as applicable.

1.72 "**Joint Program Know-How**" means any proprietary Information that is generated jointly by or on behalf of each of Denali and Biogen, or their respective Affiliates, in the performance of activities under this Definitive LRRK2 Agreement.

1.73 "**Joint Program Patents**" means any Program Patents that claim any inventions included in the Joint Program Know-How.

1.74 "**Launch Window**" means, for a Licensed Product and a country, the time period [***] before the anticipated date of the First Commercial Sale for such Licensed Product in such country (as determined by the JCC and for which Denali has received written notice) and ending on the date of First Commercial Sale for such Licensed Product in such country.

175. "**Licensed Compound**" means the following small molecule compounds: (a) those compounds set forth in Schedule 1.75 (Licensed Compounds), including the compounds known internally at Denali as [***] "DNL151" [***]; (b) all other LRRK2 Inhibitors (i) [***]; and (c) [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.76 "**Licensed Product**" means any product containing a Licensed Compound, alone or in combination with one or more other active ingredients, and in any formulation, dosage strength or method of delivery.

1.77 "**LRRK2**" means a naturally occurring Leucine-rich repeat kinase 2 mRNA sequence or protein, [***].

1.78 "**LRRK2 Inhibitor**" means any small molecule compound: (a) [***] and (b) [***]

1.79 "**LRRK2-PD Patient**" means [***].

1.80 "**LRRK2-PD**" means Parkinson's Disease in LRRK2-PD Patients. [***]

1.81 "**Major European Market**" means France, Germany, Italy, Spain and United Kingdom.

1.82 "**Major Markets**" means the United States, each Major European Market, Japan and China.

1.83 "**Manufacture**," "**Manufacturing**" and "**Manufactured**" means with respect to any product, any and all activities directed to manufacturing, processing, packaging, labeling, filling, finishing, assembly, quality assurance, quality control, testing, and release, shipping, supply, or storage of such product (or any components or process steps involving such product or any companion diagnostic), placebo, or comparator agent, as the case may be, including qualification, validation activities (including validation batches), and scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, quality assurance technical support activities qualification and audit of clinical and commercial manufacturing facilities, and stability testing, but excluding any activities directed to Development, Medical Affairs or Commercialization. "**Manufacturing**" and "**Manufactured**" will be construed accordingly.

1.84 "**Manufacturing Costs**" means the [***] manufacturing cost incurred by a Party or its Affiliate for a Licensed Compound or Licensed Product and in accordance with GAAP (consistently applied by such Party and its Affiliates with respect to all small molecule compounds and products), which will be the sum of:

1.84.1 [***].

1.85 "**Material Adverse LRRK2 Program Effect**" means (a) [***], or (b) [***].

1.86 "**Medical Affairs**" means any and all activities conducted by or on behalf of a Party's or any of its Affiliates' personnel designated as medical science liaisons (or similar title) ("**MSLs**") as well as other personnel within their respective medical affairs departments interacting with physicians or other healthcare professionals who utilize or conduct research related to a drug or biological product, including communications with key opinion leaders, medical education, symposia, advisory boards (to the extent related to medical affairs or clinical guidance), and other medical programs and communications, including educational grants and fellowships, research grants (including conducting investigator-initiated studies following Regulatory Approval), charitable donations, medical resourcing and allocation, medical and scientific platform, content development, publications, and communications, KME and KOL engagement, congress planning, real-world evidence generation through registry [***], conducting advisory board meetings or other consultant programs, the purpose of which is to obtain advice and feedback related to the launch of a given product, post-approval investigator initiated trials or scientific research agreements, activities related to patient registries, physician and nurse services, education and support, in each case, to the extent related to medical affairs and not to activities that involve the promotion, marketing, sale, or other Commercialization of Licensed Products. Medical Affairs excludes any activities directed to Manufacturing, Development, or Commercialization.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.87 "**Net Revenues**" means, to the extent allocable to Cost-Profit Sharing Products in the Cost-Profit Sharing Country(ies) and, if applicable for one or more particular Cost-Profit Sharing Product(s), accrued prior to the applicable Co-Funding End Date following Denali's exercise of the Denali Opt-Out: (a) the total Net Sales of all Cost-Profit Sharing Products in the Cost-Profit Sharing Country(ies); *plus* (b) Other Income received in connection with Cost-Profit Sharing Products (and Licensed Compounds included in such Cost-Profit Sharing Products) in the corresponding Cost-Profit Sharing Country(ies). Net Revenues shall be accounted for in accordance with the applicable Party's standard accounting practices, as practiced in the relevant country in the Territory, but in any event in accordance with Accounting Standards, as consistently applied by such Party in such country in the Territory.

1.88 "**Net Sales**" means with respect to a Licensed Product, the gross amount invoiced or received in a country by or on behalf of Biogen or its Affiliates, or, other than with respect to Cost-Profit Sharing Products for Cost-Profit Sharing Countries, its Sublicensees (each of the foregoing persons, a "**Selling Party**") for the sale or other disposition of such Licensed Product to Third Parties (including Third Party distributors, wholesalers and end-users) in *bona fide* arms' length transactions in the Territory, less the following deductions, in each case, pertaining specifically to such Licensed Product and actually allowed or taken by such Third Party and not otherwise received by or reimbursed to a Selling Party:

1.88.1 sales returns and allowances actually paid, granted or accrued on such Licensed Product, including reasonable and customary trade, quantity, prompt pay and cash discounts, and any adjustments granted on account of price adjustments or billing errors;

1.88.2 credits or allowances given or made for rejection, recall, return or wastage replacement of [***] such Licensed Product or for rebates or retroactive price reductions (including Medicare, Medicaid, copay assistance, managed care and similar types of rebates and chargebacks);

1.88.3 taxes, duties or other governmental charges levied on or measured by the billing amount for such Licensed Product, as adjusted for rebates and refunds, [***]

1.88.4 charges for freight, customs [***] specifically related to the distribution of such Licensed Product [***]; and

1.88.5 [***].

Such amounts will be determined consistent with a Selling Party's customary practices and in accordance with such Selling Party's Accounting Standards. It is understood that any accruals for individual items reflected in Net Sales are periodically (at least quarterly) trued up and adjusted by each Selling Party consistent with its customary practices and in accordance with its Accounting Standards.

Notwithstanding any provision to the contrary set forth in this Definitive LRRK2 Agreement, Net Sales will not be imputed to transfers of Licensed Product to Third Parties as *bona fide* samples, as donations, for the performance of Clinical Studies, or for similar purposes in accordance with Applicable Law pertaining to any expanded access program, any compassionate sales or use program (including named patient program or single patient program), or any indigent program.

Sale or transfer of Licensed Products between any of the Selling Parties will not result in any Net Sales, with Net Sales to be based only on any subsequent sales or dispositions to a non-Selling Party. To the extent that any Selling Party receives consideration other than or in addition to cash upon the sale or disposition of a Licensed Product to a non-Selling Party, Net Sales will be [***]. For clarity, Net Sales will not include [***].

In the case of any Combination Product sold in a given country and reporting period, Net Sales for the purpose of determining royalties and sales milestones of the Combination Product in such country will be calculated by [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

If, on a country-by-country basis in a particular reporting period, the Licensed Product is sold separately in the same indication in a country, but the Other Components in the Combination Product are not sold separately in the same indication in such country, then Net Sales for the purpose of determining royalties and sales milestones of the Combination Product for such country will be [***].

If, on a country-by-country basis in a particular reporting period, the Licensed Product in the Combination Product is not sold separately in the same indication in such country, but the Other Components included in the Licensed Product are sold separately in the same indication in such country, then Net Sales for the purpose of determining royalties and sales milestones of the Combination Product for such country will be [***].

If neither the Licensed Product nor the Other Components are sold separately in the same indication in a given country during a particular reporting period, then Net Sales will be [***].

[***]

1.89 "**Non-Development Lead**" means the Party that is not the Development Lead.

1.90 "**Non-Regulatory Lead**" means the Party that is not the Regulatory Lead.

1.91 "**Other Income**" means (a) any payment received by a Party or its Affiliate from a Sublicensee in consideration for the grant of rights (including an option to obtain rights) to Develop, Manufacture, perform Medical Affairs activities with respect to or Commercialize a Cost-Profit Sharing Product (or a Licensed Compound included in such Cost-Profit Sharing Product) in a Cost-Profit Sharing Country; and (b) to the extent not already described in clause (a), other payments (excluding Net Sales) when recognized as income or an offset to an expenses (other than any Eligible Commercialization Expenses) in accordance with GAAP by a Party or its Affiliate [***] a Cost-Profit Sharing Product (or a Licensed Compound included in a Cost-Profit Sharing Product) in Cost-Profit Sharing Country; *provided*, *however*, [***].

1.92 "**Other Operating Expenses**" means the following items, [***] activities for a Cost-Profit Sharing Product in a Cost-Profit Sharing Country during the applicable period of the Cost-Profit Share for such Cost-Profit Sharing Product (or a Licensed Compound included in such Cost-Profit Sharing Product):

(a) [***];

(b) Payments made by a Party or its Affiliate to any Third Party with respect to New Technology to the extent such payments will be shared by the Parties as an Allowable Expense in accordance with Section 6.5.2(c) (Cost Sharing) and are not included in Eligible Development Expenses for such Cost-Profit Sharing Product;

(c) [***]; and

(d) other FTE Costs and Out-of-Pocket Costs agreed to be shared by the Parties as an Other Operating Expense as set forth in this Definitive LRRK2 Agreement.

No expense included as an Other Operating Expense will (w) also be included as an Eligible Development Expense, an Eligible Commercialization Expense or an Eligible Medical Affairs Expense; (x) be an amount for which one Party or the other is solely responsible under this Definitive LRRK2 Agreement; (y) represent any FTE Costs, Out-of-Pocket Costs and other costs and expense incurred by or on behalf of a Party or its Affiliates to the extent caused by such Party or its Affiliates' action or omission that constitutes a breach under this Definitive LRRK2 Agreement by or on behalf of such Party; or (z) be [***] Development, Manufacturing or Commercialization activities occurring after the Co-Funding End Date for a particular Cost-Profit Sharing Product. Other Operating Expenses will be recognized and calculated in accordance with GAAP.

1.93 "**Out-of-Pocket Costs**" means amounts actually paid to Third Party vendors or contractors, for services or materials: (a) provided by such Person directly in the performance of activities under and in accordance with a Global Development Plan/Budget or Co-Commercialization Plan/Budget and in accordance with the associated Global Development Budget or Co-Commercialization Budget, as applicable; or (b) to the extent such services or materials apply directly to a Licensed Compound or a Licensed Product and for which this Definitive LRRK2 Agreement provides that such costs are (i) sharable or allocable between the Parties as an Eligible Development Expense, an Eligible Commercialization Expense, an Eligible Medical Affairs Expense or an Other Operating Expense or (ii) otherwise required to be paid or incurred by a Party in the performance of activities under this Definitive LRRK2 Agreement. For clarity, Out-of-Pocket Costs do not include payments for amounts otherwise included in the FTE Rate or as FTE Costs or Overhead Costs.

1.94 "**Overhead Costs**" means costs incurred by a Party or any of its Affiliates, or for such Person's account, [***] the performing Party's [***].

1.95 "**Parkinson's Disease**" means any Indication [***]

1.96 "**Patents**" means: (a) all national, regional and international patents and patent applications, including provisional patent applications; (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications; (c) any and all patents that have issued or in the future issue from the foregoing patent applications (*i.e.*, described in clauses (a) and (b) above), including utility models, petty patents and design patents and certificates of invention; (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications (*i.e.*, described clauses (a), (b), and (c) above); and (e) any similar rights, including so-called pipeline protection.

1.97 "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.98 "**Phase I Trial**" means a human clinical trial of a Licensed Product, the principal purpose of which is a preliminary determination of safety, tolerability or pharmacokinetics in healthy individuals or patients or similar clinical study prescribed by the Regulatory Authorities, including the trials referred to in 21 C.F.R. §312.21(a), as amended (and any equivalent Clinical Study in any jurisdiction outside the United States).

1.99 "**Phase II Trial**" means a human clinical trial of a Licensed Product, the principal purpose of which is to explore dose ranges, efficacy, pharmacodynamics, biomarkers, or biological activity in one (1) or more specified doses in the target patient population, or a similar clinical study recommended by the Regulatory Authorities, from time to time, pursuant to Applicable Law or otherwise, including the trials referred to in 21 C.F.R. §312.21(b), as amended (and any equivalent Clinical Study in any jurisdiction outside the United States).

1.100 "**Phase III Trial**" means [***].

1.101 [***]

1.102 [***]

1.103 "**PMDA**" means Japan's Pharmaceuticals and Medical Devices Agency and any successor agency(ies) or authority having substantially the same function.

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1.104 "**Post-Grant Proceedings**" means proceedings conducted with respect to a Patent before a patent office or other administrative agency that is not a court of law and that has jurisdiction to grant and review such Patent following the grant or issuance of such Patent and pursuant to which the validity, enforceability or scope of such Patent is challenged by a Third Party, including a post-grant opposition proceeding, *ex parte* re-examination (but only if such re-examination is requested by a Third Party), *inter partes* review and other post-grant review proceedings. An appeal, including to a court of law, from such Post-Grant Proceeding, shall be understood to be encompassed by the term Post-Grant Proceedings.

1.105 "**Pricing and Reimbursement Approval**" means, in a country in which Regulatory Authorities authorize reimbursement for, or approve or determine pricing for, pharmaceutical or biologic products to be marketed and sold or reimbursed in such country, receipt (or, if required to make such authorization, approval or determination effective, publication) of such reimbursement authorization or pricing approval or determination (as the case may be).

1.106 "**Product Labeling**" means, with respect to a Licensed Product in a country or other jurisdiction in the Territory: (a) the full prescribing information for such Licensed Product for such country or other jurisdiction, including any required patient information, approved by the applicable Regulatory Authority; and (b) all labels and other written, printed or graphic matter upon a container, wrapper or any package insert utilized with or for such Licensed Product in such country or other jurisdiction, including material labeling supplements.

1.107 "**Product Trademarks**" means the product specific Trademark(s) to be used by a Party or its Affiliates or its or their respective Sublicensees for the Development, performance of Medical Affairs activities or Commercialization of Licensed Products in the Territory and any registrations thereof or any pending applications relating thereto in the Territory (excluding, in any event, any trademarks, service marks, names or logos that include any corporate name or logo of the Parties or their Affiliates, including the Corporate Names of the Parties).

1.108 "**Program Patent**" means any [***].

1.109 "**Prosecution and Maintenance**" (including variations such as "**Prosecute and Maintain**") means, with respect to a Patent or Patents, the preparing, filing, prosecuting and maintenance, and strategy for each of the foregoing, of such Patent or Patents, including paying to the applicable patent office or other governmental agency all maintenance or governmental fees to maintain such Patent in force, and requests for patent term extensions, supplementary protection certificates, and the like with respect to such Patent or Patents, together with the conduct of interferences, Post-Grant Proceedings and other similar proceedings with respect to a Patent or Patents, but excluding any Post-Grant Proceedings arising in connection with prosecution of any Product Infringement.

1.110 "**Region**" means each of the following: [***].

1.111 "**Regulatory Approval**" means, with respect to a particular country or other regulatory jurisdiction, all approvals, licenses, registrations or authorizations of any Regulatory Authority necessary to market and sell a pharmaceutical product or biologic in such country or regulatory jurisdiction, excluding, in each case, Pricing and Reimbursement Approvals in such country.

1.112 "**Regulatory Authority**" means any applicable supra-national, federal, national, regional, state, provincial or local governmental or regulatory authority, agency, department, bureau, commission, council or other entities (*e.g.*, the FDA, EMA and PMDA) regulating or otherwise exercising authority with respect to the Development, Manufacture or Commercialization (including Pricing and Reimbursement Approval) of a pharmaceutical or biologic product in a particular country or other regulatory jurisdiction.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.113 "**Regulatory Documentation**" means all (a) applications (including all INDs and Drug Approval Applications and other Co-Commercialization Territory Regulatory Filings), registrations, licenses, authorizations and approvals (including Regulatory Approvals, Pricing and Reimbursement Approvals and Product Labeling) and designations (including designations of a product as an "orphan" drug or its equivalent outside of the United States), (b) correspondence, materials and reports submitted to or received from Regulatory Authorities (including meeting requests, pre-meeting submissions and minutes and official contact reports relating to any communications with any Regulatory Authority and reports issued by a Regulatory Authority in connection with any audit conducted by such Regulatory Authority) and all supporting documents with respect thereto, including all investigator brochures, regulatory drug lists, advertising and promotion documents, drug safety and signaling update reports, adverse event files, complaint files (including product technical complaints communications and handling) and other material regulatory submissions and (c) Clinical Data and data contained or relied upon in any of the foregoing, including core data sheets, in each case (*i.e.*, clauses (a), (b) and (c) above), to the extent pertaining to a Licensed Compound or Licensed Product.

1.114 "**Regulatory Exclusivity**" means any exclusive marketing rights or exclusivity rights or protection conferred by any Regulatory Authority with respect to a pharmaceutical or biologic product in a particular country or other regulatory jurisdiction, including any regulatory protection exclusivity such as orphan drug designation or pediatric exclusivity, but in all cases excluding patent rights and patent term extensions.

1.115 "**Regulatory Lead**" means the Party specified as the "Regulatory Lead" in Section 3.1.4(d)(iii) or Section 3.3.1 (Regulatory Lead).

1.116 "**Related Compound**" means [***].

1.117 [***].

1.118 "**Sales and Marketing Costs**" means, on a Cost-Profit Sharing Product-by-Cost-Profit Sharing Product and Cost-Profit Sharing Country-by-Cost Profit Sharing Country basis, the FTE Costs and Out-of-Pocket Costs incurred by or on behalf of a Party or its Affiliates [***] Commercialization activities for such Cost-Profit Sharing Product in such Cost-Profit Sharing Country under and in accordance with the Co-Commercialization Plan/Budget, including FTE Costs and Out-of-Pocket Costs [***] the following, to the extent incurred under and in accordance with the Co-Commercialization Plan/Budget: (a) sales, pricing and activities directed to the managed care market and marketing of such Cost-Profit Sharing Product in such Cost-Profit Sharing Country; (b) marketing (including telemarketing), promotion, advertising, professional education, symposia and opinion leader development, and Promotional Materials; (c) recalls, withdrawals or corrective actions, and returned product destruction with respect to such Cost-Profit Sharing Product or components therefor, all to the extent treated as Sales and Marketing Costs pursuant to Section 5.9 (Recalls, Market Withdrawals or Corrective Actions); (d) activities related to obtaining reimbursement from payers and costs and expenses of sales and marketing data for such Cost-Profit Sharing Product in such Cost-Profit Sharing Country; (e) market research and strategic planning activities specific to such Cost-Profit Sharing Product in such Cost-Profit Sharing Country; (f) the preparation of Regulatory Documentation as reasonably necessary to conduct Commercialization activities for such Cost-Profit Sharing Products in such Cost-Profit Sharing Country, including to the extent applicable any Regulatory Documentation with respect to Pricing and Reimbursement Approvals for such Cost-Profit Sharing Product and any filing fees incurred in connection therewith; (g) Sales Force Expenses, to the extent not otherwise included in Sales and Marketing Costs; and (h) Out-of-Pocket Costs to seek, maintain, defend or enforce any Product Trademark specific to such Cost-Profit Sharing Product in such Cost-Profit Sharing Country to the extent provided in Section 8.6.4 (Expenses).

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.119 "**Sales Force Expenses**" means, on a Cost-Profit Sharing Product-by-Cost-Profit Sharing Product and Cost-Profit Sharing Country-by-Cost Profit Sharing Country basis, the FTE Costs and Out-of-Pocket Costs incurred by or on behalf of a Party or its Affiliates [***] operation and management of sales personnel (including a field-based sales force and regional managers) to the extent such personnel are, or will be, assigned to selling such Cost-Profit Sharing Product in such Cost-Profit Sharing Country and to the extent incurred under and in accordance with the Co-Commercialization Plan/Budget, including FTE Costs and Out-of-Pocket Costs with respect to the following to the extent incurred under and in accordance with the Co-Commercialization Plan/Budget: [***].

1.120 "**Standstill Agreement**" has the meaning set forth in the Provisional Collaboration and License Agreement.

1.121 "**Subcontract Agreement**" means, with respect to a Subcontractor, a written agreement between a Party and such Subcontractor.

1.122 "**Subcontractor**" means a Third Party contractor (including contract research organizations or contract manufacturing organizations) engaged by a Party or its Affiliates on a fee-for-service to perform certain services or activities on behalf of and for the benefit of such Party or its Affiliates or exercise certain rights on behalf of such Party or its Affiliates, in each case, under this Definitive LRRK2 Agreement.

1.123 "**Sublicensee**" means a Third Party that is granted (directly or indirectly) a sublicense by a Party or its Affiliate under any of the rights granted in Section 6.1 (License Grants to Biogen) or Section 6.2 (License Grants to Denali), as applicable and as provided in Section 6.3 (Sublicenses) or other rights to Develop, perform Medical Affairs activities with respect to or Commercialize a Licensed Compound or Licensed Product, other than any Subcontractor that is granted any such sublicense or other rights solely for the purpose of performing specific limited services or activities solely on behalf of and for the benefit of a Party or its Affiliate.

1.124 "**Tax**" means all forms of taxation whether direct or indirect and whether levied by reference to income, profits, gains, net wealth, asset values, turnover, added value or other reference and statutory, governmental, state, provincial, local or foreign governmental or municipal impositions, duties (including but not limited to stamp duties), contributions, rates and levies (including social security contributions and any other payroll taxes), whenever and wherever imposed (whether imposed by way of a withholding or deduction for or on account of tax or otherwise) and in respect of any Person (including taxes imposed on another Person for which a Person is liable by reason of being a member of a consolidated, combined, unitary or similar tax group, as a transferee or successor, by contract or otherwise) and all penalties, charges, costs and interest relating thereto.

1.125 "**Territory**" means worldwide.

1.126 "**Third Party**" means any Person other than Denali, Biogen and their respective Affiliates.

1.127 "**Trademark**" means any word, name, symbol, color, designation or device or any combination thereof that functions as an identifier of the source or origin of goods or services, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo, business symbol or domain names, whether or not registered.

1.128 "**United States**" or "**U**.**S**." means the United States of America and its territories and possessions (including the District of Columbia and Puerto Rico).

1.129 "**Valid Claim**" means [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.130 "**VAT**" means (a) in relation to any jurisdiction within the European Union, the tax imposed by the EC Council Directive on the common system of value added tax (2006/112/EC) and any successor or equivalent legislation and any national legislation implementing that directive together with legislation supplemental thereto and the equivalent tax (if any) in that jurisdiction; and (b) in any other jurisdiction, any other value added, goods and services, consumption or similar tax chargeable on the supply or deemed supply of goods or services under applicable legislation or regulation.

1.131 **Additional Definitions**. In addition, each of the following terms shall have the meaning described in the corresponding Section of this Definitive LRRK2 Agreement identified below.

Term	**Section**	**Term**	**Section**
Acquired Party	6.8.4	Cost-Profit Share	7.7
Acquiring Party	6.8.3	Cost-Profit Sharing Country	7.7
Adverse Ruling	13.2.2	Cost-Profit Sharing Product	7.7
[***]	[***]	Debarred Entity	11.1.6(b)
[***]	[***]	Debarred Individual	11.1.6(a)
Alliance Manager	2.6	Declining Party	3.1.4(c)
[***]	[***]	Definitive LRRK2 Agreement	Preamble
BIG	Preamble	Denali	Preamble
BIMA	Preamble	[***]	[***]
Biogen	Preamble	Denali Commercialization Opt-Out	7.8.1(a)
Biogen Executive	2.4.5(c)	Denali Development Opt-Out	7.8.1(a)
[***]	[***]	Denali Indemnitees	12.1
Biogen Indemnitees	12.2	Denali Opt-Out	7.8.1(a)
[***]	[***]	Denali Opt-Out Notice	7.8.1(a)
[***]	[***]	Development Expense Report	7.7.2(a)
[***]	[***]	Dispute	14.6
Breach Notice	13.2.1	Effective Date	Preamble
Breaching Party	13.2.1	[***]	[***]
[***]	[***]	Excluded Entity	11.1.6(c)
Chief Executive Officers	14.6.1	Excluded Individual	11.1.6(c)
CMC Working Group	4.5	Existing Denali Agreement	1.64
CMO Supply Agreement	4.2	Final Royalty Report	7.6.7(b)
Co-Commercialization Activities	5.1.4(a)	Finance Working Group	7.7.6
Co-Commercialization Activities End Date	5.1.4(c)	Force Majeure	Article 14

Co-Commercialization Agreement	5.1.4(b)	GAAP	1.1
Co-Commercialization Territory Regulatory Filings	3.3.2(c)	[***]	[***]
[***]	[***]	[***]	[***]
Co-Funding End Date	7.8.1(a)	Global Development Budget	3.1.1(b)
Commercialization Wind-Down Period	13.7.2(b)	[***]	[***]
[***]	[***]	ICH	1.61
Consolidated Report	7.7.3	Indemnification Claim Notice	12.4
Convicted Entity	11.1.6(d)	Indemnified Losses	12.1
Convicted Individual	11.1.6(d)	Indemnified Party	12.4

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Independent Study	3.1.4	Opt-Out Country	7.8.1(a)
Independent Study Opt-In Notice	3.1.4(e)(i)	Opt-Out Product	7.8.1(a)
Independent Study Proposal	3.1.4(a)	Other Component	1.26
Independent Third Party Lab	14.6.4	Other LRRK2 Inhibitors	13.7.1(b)(i)
Initial Global Development Plan/Budget	1.6	[***]	[***]
Interim Development Period	1.45	[***]	[***]
IP Counsels	6.5.2(d)	[***]	[***]
JCC	2.3.1	[***]	[***]
JDC	2.2.1	[***]	[***]
JSC	2.1.1	Parties	Preamble
[***]	[***]	Party	Preamble
LRRK2 Alternative Product	6.8.1	Patient Samples	3.5
[***]	[***]	Payments	7.11.1
MAA	1.43	PD Commercial Milestone Event	7.2.2
[***]	[***]	PD Commercial Milestone Payment	7.2.2
Manufacturing Party	4.4	PD Development Milestone Event	7.2.1
Manufacturing Transfer	4.2	PD Development Milestone Payment	7.2.1
Manufacturing Transition Plan	4.2	PD Milestone	7.5
Maximum Commercial Milestone Amount	7.2.4(c)	[***]	[***]
Maximum Development Milestone Amount	7.2.4(c)	[***]	[***]
[***]	[***]	Pharmacovigilance Agreement	9.1
MSL	1.86	Phase II Notice	3.1.4(e)(i)
NDA	1.43	[***]	[***]
[***]	[***]	Phase III Update	3.1.4(e)(ii)
New Technology	6.5.2(b)	Pre-Definitive LRRK2 Agreement Eligible Development Expenses	1.45
New Technology Terms	6.5.2(b)	Prior CDA	10.6
Non-Breaching Party	13.2.1	[***]	[***]
[***]	[***]	[***]	[***]
Non-Manufacturing Party	4.4	Promotional Materials	5.4
Non-PD Commercial Milestone Event	7.3.2	Proposing Party	3.1.4(a)
Non-PD Commercial Milestone Payment	7.3.2	[***]	[***]
Non-PD Development Milestone Event	7.3.1	[***]	[***]
Non-PD Development Milestone Payment	7.3.1	Provisional Collaboration and License Agreement	Preamble
Non-PD Indication	7.3.1	Regulatory Approval Costs Update	3.1.4(e)(iii)
Non-PD Milestone	7.5	Regulatory Approval Update	3.1.4(e)(iii)
[***]	[***]	Regulatory Data	3.1.3(g)
Operating Profits or Losses	7.7.3	Reimbursable Development Expenses	7.7

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Reimbursable Expenses	7.7	[***]	[***]
Relevant Biogen Know-How	3.2.1	[***]	[***]
[***]	[***]	Supply and Quality Agreement	4.4
Royalty Term	7.6.2	Term	13.1
[***]	[***]	Terminated Compound	13.7
Sales Milestone	7.5	Terminated Product	13.7
Sales Milestone Event	7.4.1	Terminated Region	13.3
Sales Milestone Payment	7.4.1	Third Party Claims	12.1
Selling Party	1.88	[***]	[***]
Shared Expense Report	7.7.2(b)	Working Group	2.7
Stock Purchase Agreement	Preamble		

ARTICLE 2
COLLABORATION MANAGEMENT

2.1 **Joint Steering Committee**.

2.1.1 **Formation**. As soon as practical, but no later than [***] after the Effective Date, the Parties shall establish a joint steering committee (the "**JSC**"), which shall perform the functions set forth in Section 2.1.2 (Responsibilities) and oversee Development under the Global Development Plan/Budget in the Territory and Commercialization under the Co-Commercialization Plan/Budget in the Co-Commercialization Territory, in each case, of Licensed Compounds and Licensed Products, and for discussing and sharing information regarding the Parties' Development, Manufacturing, Medical Affairs and Commercialization activities in the Territory with respect to Licensed Compounds and Licensed Products. The JSC shall consist of an equal number of representatives from each of the Parties, unless otherwise agreed by the Parties in writing.

2.1.2 **Responsibilities**. The JSC shall manage the implementation of this Definitive LRRK2 Agreement, oversee and coordinate the Parties' respective activities pertaining to Licensed Compounds and Licensed Products in the Territory and, subject to Section 2.4.5 (Joint Committee Decision-Making) below, resolve certain matters that are not unanimously decided by the JDC or JCC. In particular, the JSC shall:

(a) facilitate communication of the Parties in connection with the Development, Manufacture, and in the Co-Commercialization Territory, performance of Medical Affairs and Commercialization of Licensed Compounds and Licensed Products;

(b) review and discuss the progress of activities in connection with the Development, Manufacture, and in the Co-Commercialization Territory, performance of Medical Affairs with respect to and Commercialization of Licensed Compounds and Licensed Products, including data and results generated in performance of such activities;

(c) coordinate and oversee the operation of the JDC, JCC and any Working Group established by the JSC, including resolving any disputed matter of the JDC, JCC and such Working Groups in accordance with Section 2.4.5 (Joint Committee Decision-Making), and promote effective member participation in each such Joint Committee's or Working Group's operations;

(d) review and determine whether to approve any amendment to the then-current Global Development Plan/Budget;

(e) review and determine whether to approve any Independent Study Proposal in accordance with Section 3.1.4 (Independent Study);

(f) review and determine whether to approve the initial Co-Commercialization Plan/Budget, and any amendments thereto;

(g) [***];

(h) coordinate and oversee the preparation and transfer of the Information, Regulatory Documentation and Development activities in accordance with Section 3.2 (Transfer for Development Purposes);

(i) form Working Groups as needed to fulfill the obligations of the JSC under this Definitive LRRK2 Agreement, including the Finance Working Group;

(j) resolve issues presented to the JSC in accordance with this Definitive LRRK2 Agreement; and

(k) perform such other functions as are set forth in this Definitive LRRK2 Agreement as the function of the JSC or as the Parties may otherwise mutually agree in writing.

2.2 **Joint Development Committee**.

2.2.1 **Formation**. As soon as practical, but no later than [***] after the Effective Date, the Parties shall establish a joint development committee (the "**JDC**"). The JDC shall consist of an equal number of representatives from each of the Parties, unless otherwise agreed by the Parties in writing.

2.2.2 **Responsibilities**. The JDC shall oversee the Development of Licensed Compounds and Licensed Products in the Territory. In particular, the JDC shall:

(a) review and finalize, for submission to the JSC, any amendment to a then-current Global Development Plan/Budget (at least [***] per Calendar Year);

(b) discuss, coordinate and monitor workflow for the activities being conducted by each Party under the Global Development Plan/Budget (including Manufacturing activities in support thereof), and the overall progress of activities being conducted under the Global Development Plan/Budget, including the data and results generated in performance of such activities;

(c) review and discuss the design of the Clinical Studies, including with respect to a biomarker/endpoint plan and patient recruitment, to be conducted under the Global Development Plan/Budget, and the selection of clinical trial sites, clinical research organizations and other key Third Party service providers for Clinical Studies under the Global Development Plan/Budget;

(d) prepare and determine whether to approve, the Parties' strategies related to funding for any investigator-initiated Clinical Study for the Territory, including Clinical Studies involving a safety issue or the head-to-head comparison of a Licensed Product with any other pharmaceutical agent;

(e) oversee and coordinate the preparation and transfer of the Information, Regulatory Documentation and Development activities in accordance with Section 3.2 (Transfer for Development Purposes);

(f) [***];

(g) review, discuss and finalize, for submission to the JSC, any Independent Study Proposal;

(h) form Working Groups as needed to fulfill the obligations of the JDC under this Definitive LRRK2 Agreement, including a CMC Working Group;

(i) coordinate and oversee the operation of each Working Group created by the JDC, including resolving any disputed matter within such Working Group; and

(j) perform such other functions as are set forth in this Definitive LRRK2 Agreement, or as the Parties may mutually agree in writing.

2.3 **Joint Commercialization Committee**.

2.3.1 **Formation**. No later than [***] after the Effective Date, the Parties shall establish a joint commercialization committee (the "**JCC**"). The JCC shall consist of an equal number of representatives from each of the Parties, unless otherwise agreed by the Parties in writing.

2.3.2 **Responsibilities**. The JCC shall oversee the Commercialization of Licensed Products in the Co-Commercialization Territory, and provide a forum for sharing information pertaining to the Commercialization of Licensed Products outside of the Co-Commercialization Territory. In particular, the JCC shall:

(a) review, and finalize for submission to the JSC, the Co-Commercialization Plan/Budget and any amendments thereto;

(b) discuss the Global Commercialization Plan and any material updates thereto;

(c) [***];

(d) [***];

(e) with respect to any Cost-Profit Sharing Product(s) and each Cost-Profit Sharing Country, [***];

(f) discuss, review and finalize and submit to the JSC for approval the Parties' strategies related to any [***], epidemiological studies, modeling and pharmaco-economic studies, investigator-initiated Clinical Studies or post-marketing surveillance studies with respect to Licensed Products;

(g) [***];

(h) [***];

(i) coordinate and oversee the operation of each Working Group created by the JCC, including resolving any disputed matter within such Working Group; and

(j) perform such other functions as are set forth in this Definitive LRRK2 Agreement as the function of the JCC or as the Parties may otherwise mutually agree in writing.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

2.4 **General Provisions Applicable to Joint Committees**.

2.4.1 **Meetings and Minutes**. The JSC shall meet at least semi-annually, or as otherwise agreed to by the JSC. The JDC shall meet at least once per Calendar Quarter, or as otherwise agreed to by the JDC. Beginning after formation of the JCC, the JCC shall meet at least once per Calendar Quarter, or as otherwise agreed to by the JCC. Meetings of each Joint Committee may be conducted by telephone, video-conference or in-person as determined by such Joint Committee. In-person meetings of each Joint Committee, unless otherwise agreed, shall alternate between Denali's offices and Biogen's offices. Regularly scheduled meetings of each Joint Committee may be called by either Party on no less than [***] notice, or such shorter time period as agreed by the Parties. Each Party shall make all proposals for agenda items for regularly scheduled meetings of a Joint Committee, including any decision to be made by such Joint Committee at such meeting, and shall provide all appropriate information with respect to such proposed items, to the applicable meeting managers at least [***] in advance of the applicable meeting, or such shorter time period as agreed by the Parties. Each Party may also call a special meeting of a Joint Committee to resolve particular matters requested by such Party, on no less than [***] notice (or such shorter time period as may be appropriate under the circumstances, but in no event less than [***] notice). In the case of a special meeting of a Joint Committee called by a Party, the proposed agenda items, including any decision to be made by such Joint Committee at such meeting, and appropriate information with respect to such proposed items shall be provided to the applicable meeting managers together with the notice calling for such special meeting to the other Party. Draft minutes of the meetings of any Joint Committee will be generated and circulated to its members within [***] following the meeting. The responsibility for generating and circulating such minutes will alternate between the Alliance Managers (or their designees). The Joint Committees will use reasonable diligence to review and finalize the minutes within [***] after their circulation and, in all circumstances, no later than the next meeting of the same Joint Committee.

2.4.2 **Chairpersons**. The Joint Committees shall each have co-chairpersons that each of Denali and Biogen select from their respective representatives. Each Party may change any of its designated chairpersons from time to time upon written notice to the other Party.

2.4.3 **Procedural Rules**. Each Joint Committee shall have the right to adopt such standing rules as shall be necessary to perform its responsibilities, to the extent that such rules are consistent with this Definitive LRRK2 Agreement; *provided* that such rules shall not be subject to a deciding vote of either Party having final decision-making authority for such Joint Committee. At least [***] representative from each Party on each Joint Committee shall have the requisite seniority to make decisions on behalf of the relevant Party with respect to the issues falling within the decision-making authority of the relevant Joint Committee. A quorum of the Joint Committee shall exist whenever there is present at a meeting at least [***] representative appointed by each Party with the requisite seniority to make decisions described in the second sentence of this Section 2.4.3 (Procedural Rules). From time to time, each Party may substitute one (1) (or more, if applicable) of its representatives to a particular Joint Committee on written notice to the other Party, *provided* that the criteria in the second sentence of this Section 2.4.3 (Procedural Rules) shall continue to be satisfied. Representatives of the Parties on a Joint Committee may attend a meeting either in person or by telephone, audio conference, video conference, or similar means through which each participant can hear what is said by, and be heard by, the other participants.

2.4.4 **Meeting Attendance**. Personnel of either Party (or a Party's Affiliate) that are not representatives of such Party on a Joint Committee may attend meetings of such Joint Committee; *provided* that the Party wishing such persons to participate in a meeting has provided reasonable advance notice to the other Party and non-employees may only attend meetings of a Joint Committee if such non-employee is bound by written obligations of confidentiality and non-disclosure substantially equivalent to those set forth in Article 10 (Confidentiality and Non-Disclosure) or is otherwise bound by professional ethical obligations.

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2.4.5 **Joint Committee Decision-Making**.

(a) **Voting.** Except as set forth in Section 2.4.5(b) (Joint Committee Escalation), the decisions of each Joint Committee shall be by unanimous agreement. Each Party shall have a single vote on a matter to be decided by the applicable Joint Committee irrespective of the number of representatives of such Party in attendance at the applicable Joint Committee meeting. Decisions of a Joint Committee will be documented in the relevant final approved meeting minutes, or should a decision be made outside of a meeting forum, such decision may also be made by a written resolution unanimously agreed by the Parties and signed by at least one representative of each Party appointed to the applicable Joint Committee; it being understood that such unanimous written agreement may be provided by email if the Parties so agree.

(b) **Joint Committee Escalation**. If the JDC or JCC does not reach unanimous agreement on an issue within the decision-making authority of the JDC or JCC within [***] after the meeting at which such issue was first presented for decision by the JDC or JCC, as the case may be, despite good faith efforts to do so, then, such matter shall be referred to the JSC for resolution. If the JSC reaches unanimous agreement on an issue within the decision-making authority of the JSC, then such decision shall become the decision of the applicable Joint Committee. If the JSC does not reach unanimous agreement on an issue within the decision-making authority of the JSC within [***] after the JSC meeting at which the applicable issue was first presented for decision, despite good faith efforts to do so, then, it shall be resolved in accordance with Section 2.4.5(c) (Dispute Escalation) below.

(c) **Dispute Escalation.** If the JSC has not reached unanimous agreement on any matter or dispute within the scope of JSC's decision-making authority following the [***] period described in the last sentence of Section 2.4.5(b) (Joint Committee Escalation), then, such matter shall be referred, by a joint written notice, to Denali's CEO and Biogen's CEO (or his/her executive-level designee) (the "**Biogen Executive**"), who shall confer in good faith on the resolution of the dispute. Any final decision mutually agreed to by Denali's CEO and the Biogen Executive shall be conclusive and binding on the Parties. If Denali's CEO and the Biogen Executive are not able to agree on the resolution of any such dispute within [***] (or such other period of time as agreed by Denali's CEO and the Biogen Executive) after the [***] period described in the last sentence of Section 2.4.5(b) (Joint Committee Escalation) (*i.e.*, a total of [***] after the JSC meeting at which the applicable issue was first presented for decision), then, to the extent the matter: (i) [***], the [***] shall be entitled to make the final determination with respect to such matter by notifying the JSC (and [***]) in writing and such final decision of [***] shall become the decision of the JSC on such matter, [***].

(d) [***].

(i) [***];

(ii) [***];

(iii) [***];

(iv) [***];

(v) [***];

(vi) [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

2.4.6 **Limitations on Authority**. Each Party shall retain the rights, powers and discretion granted to it under this Definitive LRRK2 Agreement and no such rights, powers or discretion shall be delegated to or vested in a Joint Committee unless such delegation or vesting of rights is expressly provided for in this Definitive LRRK2 Agreement or the Parties expressly so agree in writing. No Joint Committee shall have the power to, and no deciding vote of a Party on a matter referred to such Person shall, amend, modify or waive compliance with this Definitive LRRK2 Agreement, which compliance may only be amended or modified as provided in Section 14.8 (Entire Agreement; Amendments) or compliance with which may only be waived as provided in Section 14.11 (Waiver and Non-Exclusion of Remedies). No decision of any Joint Committee or by a Party in the exercise of its deciding vote in accordance with Section 2.4.5 (Joint Committee Decision-Making) or Section 2.5 (Discontinuation of Joint Committees) shall (a) finally determine any interpretation of this Definitive LRRK2 Agreement or the Parties' rights or obligations hereunder, (b) conflict with any terms and conditions of this Definitive LRRK2 Agreement or (c) be in contravention of Applicable Law in any material respect. For the avoidance of doubt, disputes arising between the Parties in connection with or relating to this Definitive LRRK2 Agreement, or any document or instrument delivered in connection herewith, in each case, that are outside of the decision-making authority of the Joint Committees and not within a Party's sole decision-making authority hereunder, shall be resolved pursuant to Section 14.6 (Dispute Resolution).

2.5 **Discontinuation of Joint Committees**. Each Joint Committee shall continue to exist until the first to occur of: (a) the date on which the Parties agree to disband the Joint Committee; and (b) the Co-Funding End Date corresponding to a Denali Opt-Out for all Cost-Profit Sharing Products in all countries. Notwithstanding any provision herein to the contrary, once one or more Joint Committees have been disbanded, such disbanded Joint Committee and all Working Groups appointed by such Joint Committee shall be terminated and thereafter (i) any requirement of a Party to provide Information or other materials to such Joint Committee shall be deemed a requirement to provide such Information or other materials to the other Party [***].

2.6 **Alliance Manager**. Each Party shall appoint an individual to act as a single point of contact between the Parties to facilitate the effective exchange of information between the Parties and discuss the performance of this Definitive LRRK2 Agreement (each, an "**Alliance Manager**"). Each Party may replace its Alliance Manager at any time by notice in writing to the other Party. The Alliance Managers (or their designees) will be responsible for coordinating the Joint Committees and any Working Groups by organizing their meetings, helping to develop the agendas for the meetings, and drafting and finalizing meeting minutes; *provided* that such responsibilities shall terminate upon the disbandment of the Joint Committees and Working Groups. Each Alliance Manager will be charged with creating and maintaining effective communication within and among the Parties. Each Alliance Manager may have additional responsibilities as agreed between the Parties. [***]

2.7 **Working Groups**. From time to time, a Joint Committee may establish and delegate duties to sub-committees or directed teams (each, a "**Working Group**") to oversee particular projects or activities (for example, the Finance Working Group and CMC Working Group), *provided* that in no event shall a Joint Committee have the right to, and no Joint Committee shall, delegate its respective decision-making authority to any such Working Group. Each such Working Group shall be constituted as the applicable Joint Committee determines and shall establish its own procedures, to the extent that such procedures are consistent with this Definitive LRRK2 Agreement. Members of a Working Group may also be members of a Joint Committee. Working Groups may be established as a standing subcommittee or on an *ad hoc* basis for purposes of a specific project or on such other basis as the applicable Joint Committee may determine. Each Working Group and its activities shall be subject to the oversight, review and approval of, and shall report to, the Joint Committee that established such Working Group. In no event shall the authority of a Working Group exceed the authority specified for the Joint Committee that established the Working Group pursuant to this Article 2 (Collaboration Management). All decisions of a Working Group shall be made by unanimous agreement. Any disagreement between the representatives of Biogen and Denali on a Working Group shall be referred to the Joint Committee that established the

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Working Group for resolution in accordance with Section 2.4.5 (Joint Committee Decision-Making). Personnel of either Party (or a Party's Affiliate) that are not representatives of such Party on a Working Group may attend meetings of such Working Group; *provided* that the Party wishing such persons to participate in a meeting has provided reasonable advance notice to the other Party and non-employees may only attend meetings of a Working Group if such non-employee is bound by written obligations of confidentiality and non-disclosure substantially equivalent to those set forth in Article 10 (Confidentiality and Non-Disclosure) or is otherwise bound by professional ethical obligations. Unless the Parties otherwise agree, draft minutes of the meetings of any Working Group will be generated and circulated to its members within [***] following the meeting. The responsibility for generating and circulating any such minutes will alternate between the Alliance Managers (or their designees). The Working Groups will use diligent efforts to review and finalize any such minutes within [***] after their circulation and, in all circumstances, no later than the next meeting of the same Working Group.

2.8 **Expenses**. Each Party shall be responsible for all travel and related costs and expenses for its representatives and, if applicable, its (or any of its Affiliate's) other personnel to prepare for, attend meetings of, and otherwise participate in, a Joint Committee or other Working Group.

ARTICLE 3
DEVELOPMENT AND REGULATORY ACTIVITIES

3.1 **Development Plan and Activities**. The Parties will jointly be responsible for all Development activities with respect to the Licensed Compounds and Licensed Products (as further described below) for the Territory, and such activities will be conducted in accordance with the Global Development Plan/Budget (as defined below).

3.1.1 **Global Development Plan/Budget**.

(a) **Initial Global Development Plan/Budget**. The Initial Global Development Plan/Budget are attached to this Definitive LRRK2 Agreement as Schedule 1.60 (Initial Global Development Plan/Budget).

(b) **Content of Global Development Plan/Budget**. The Global Development Plan/Budget shall outline: (i) the Denali Development Activities and Biogen Development Activities to be conducted in order to obtain Regulatory Approval of the Licensed Products in the Territory, including a description of any activities for the Development of [***] in each case for the applicable Licensed Products; (ii) overall regulatory strategies for obtaining such Regulatory Approvals for Licensed Products; (iii) a timeline for the Denali Development Activities and the Biogen Development Activities, including timelines for the performance of each clinical study for a Licensed Product to be initiated and other material Development activities for the Licensed Products; and (iv) budgeted amounts estimated to be incurred for conducting activities to be undertaken in accordance with such plan (the "**Global Development Budget**"). Unless otherwise agreed by the Parties, a Licensed Product containing DNL151 will be the subject of the initial Clinical Studies set forth in the Global Development Plan/Budget. The Global Development Plan/Budget will include a meaningful allocation of Development activities to each Party, *provided* that to the extent this Definitive LRRK2 Agreement or the Global Development Plan/Budget does not allocate responsibility for a Development activity set forth in the Global Development Plan/Budget to a Party, the JSC shall allocate such responsibility to a Party. The Global Development Budget shall be reasonably detailed with respect to such Development and Manufacturing activities and estimated FTE Costs and Out-of-Pocket Costs, broken down by Calendar Quarter, for the first Calendar Year (or part thereof) and shall also outline the then-current estimate of Development and Manufacturing activities (including estimated associated FTE Costs and Out-of-Pocket Costs) by Calendar Year for the next [***]. In the event of a Denali Opt-Out for all Licensed Products in all countries, then [***].

3.1.2 **Amendments and Updates**. The JDC shall review the Global Development Plan/Budget on a regular basis, and in no event less frequently than [***] each [***]. Either Party, through its representatives on the JDC, may propose amendments to, and comment upon, the Global Development Plan/Budget from time to time. In any event, an updated Global Development Plan/Budget shall be provided by the JDC to the JSC (and, with respect to each updated Global Development Plan/Budget, approved by the JSC as required) no later than September 1 of each Calendar Year, in accordance with the timing of Biogen's annual operating plan. If any such revised Global Development Plan/Budget is not approved by the JSC, then, until such time as the applicable updated Global Development Plan/Budget is approved by the JSC in accordance with Section 2.4.5 (Joint Committee Decision-Making): (a) the then-current Global Development Plan/Budget shall continue to govern the Parties' Development activities under this Definitive LRRK2 Agreement; and (b) each Party shall conduct Development activities allocated to such Party under such then-current Global Development Plan/Budget and shall be permitted to incur Eligible Development Expenses consistent with the then-current Global Development Budget, which Eligible Development Expenses shall be borne or shared by the Parties in accordance with Section 7.7 (Cost-Profit Sharing).

3.1.3 **Development Activities**.

(a) **Efforts**.

(i) **Global Development Plan/Budget**. Each Party shall use Commercially Reasonable Efforts to perform the Development activities allocated to it under the then-current Global Development Plan/Budget in accordance with the timelines set forth therein.

(ii) **Co-Commercialization Territory**. Each Party (and in the case of Denali, to the extent permitted under this Definitive LRRK2 Agreement) will use Commercially Reasonable Efforts to: (a) seek and obtain Regulatory Approval for at least [***], in each case ((i) and (ii)), [***].

(iii) **Ex-Co-Commercialization Territory**. Biogen will use Commercially Reasonable Efforts to: (a) seek and obtain Regulatory Approval for at least [***], in each case ((i) and (ii)), [***].

(b) **Compliance**. Each Party shall perform any and all of its Development activities under this Definitive LRRK2 Agreement in good scientific manner and in compliance with all Applicable Law, including applicable national and international (*e.g.*, ICH, GCP, GLP, and GMP guidelines), informed consent and institutional review board regulations, current standards for pharmacovigilance practice, and all applicable requirements relating to the protection of human subjects.

(c) **Allocation of Activities and Costs**. Denali shall be primarily responsible for the planning and conduct of the Denali Development Activities and Biogen shall be primarily responsible for the planning and conduct of the Biogen Development Activities, in each case, in a manner consistent with the then-current Global Development Plan/Budget. Otherwise, each Party shall be responsible for day-to-day implementation and operational management of those Development activities allocated to such Party under the Global Development Plan/Budget. All FTE Costs and Out-of-Pocket Costs that the Parties incur as Eligible Development Expenses in connection with the Development of Licensed Compounds and Licensed Products under the Global Development Plan/Budget shall be borne or shared in accordance with Section 7.7 (Cost-Profit Sharing). [***]

(d) **LRRK2 Inhibitor and CNS Penetrance Determinations**. [***] then the Parties shall [***] and in any event, [***].

(e) **Designation of Development Lead**. Denali shall be the Development Lead with respect to the Denali Development Activities and Biogen shall be the Development Lead with respect to the Biogen Development Activities [***]. In addition to any activities that the Parties agree the Non-Development Lead may conduct under the Global Development Plan/Budget, the Non-Development Lead shall have the right to have [***] or more of its employees attend, and participate in, all global advisory board meetings and other meetings with key opinion leaders regarding the Licensed Compounds or Licensed Products.

(f) **Transition of Development Lead**. With respect to any Development activities allocated to Biogen under the Global Development Plan/Budget that are not transferred to Biogen pursuant to Section 3.2 (Transfer for Development Purposes), the Parties will coordinate in good faith, through the JDC, the transfer of Development Lead from one Party to the other Party with respect such Development activity.

(g) **Development Reports**. Each Party shall report on the Development activities such Party has performed (or caused to be performed) under the Global Development Plan/Budget in accordance with the procedures established by the JDC and Section 2.2.2 (Responsibilities). Each Party shall provide the JDC with such other material Information pertaining to its Development activities under the Global Development Plan/Budget as may be reasonably requested by the other Party. The JDC shall establish a process pursuant to which each Party shall, on an on-going basis, provide to the other Party copies of or access to non-clinical data and Clinical Data, and other Information, results and analyses pertaining to any Development activities conducted under the Global Development Plan/Budget or with respect to any Independent Study [***] (collectively, "**Regulatory Data**").

3.1.4 **Independent Study**. Each Party shall be permitted to undertake Clinical Studies [***] (any such activities, an "**Independent Study**"); *provided* that such Party complies with the provisions of this Section 3.1.4 (Independent Study). [***].

(a) **Independent Study Proposals**. If a Party (such Party, the "**Proposing Party**") desires to undertake an Independent Study, then such Party shall submit to the JDC a proposal for the addition of such Independent Study to the Global Development Plan/Budget that includes a proposed work plan, timeline and budget for such Independent Study (an "**Independent Study Proposal**"). The Independent Study Proposal shall be prepared in a similar scope and format of the Global Development Plan/Budget. The Proposing Party shall provide the JDC with any additional Information related to the Independent Study Proposal reasonably requested by the JDC.

(b) **Inclusion of Independent Study in the Global Development Plan/Budget**. The JDC shall review and discuss such Independent Study Proposal, including considering in good faith any comments thereon from the non-Proposing Party, and within [***] after its receipt of such Independent Study Proposal shall decide whether to approve such Independent Study Proposal and submit the same to the JSC to review, discuss and determine whether to approve; *provided* that if the Proposing Party has not provided all available Information reasonably requested by the JDC during such [***] period, then such time shall be extended by the number of days it takes the Proposing Party to provide such Information. If the JSC approves an Independent Study Proposal, then the Global Development Plan/Budget shall be deemed to be amended to include the Independent Study and associated budget upon approval of such Independent Study Proposal by the JSC. For the sake of clarity, all Eligible Development Expenses incurred thereafter by the Parties in performing such Clinical Study (that was formerly the Independent Study) shall be shared as part of the Cost-Profit Share unless and until a Denali Opt-Out occurs with respect to the Licensed Product that is the subject of such Clinical Study and the Co-Funding End Date occurs. If the JSC does not approve the Independent Study Proposal, then the Independent Study will not be included within the Global Development Plan/Budget and shall not be deemed to be part of the Global Development Plan/Budget, and instead the provisions of Section 3.1.4(c) (Objection by the Other Party) through Section 3.1.4(e) (Opt-In for Independent Study) shall apply.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(c) **Objection by the Other Party**. If, at any time within [***] after receipt of the Independent Study Proposal by the JDC, the other Party (the "**Declining Party**") objects to the inclusion of the Independent Study Proposal under the Global Development Plan/Budget and also objects to the conduct of such Independent Study on the basis that such Independent Study would [***]

(d) **Performance of Independent Study**. If the JDC and JSC do not timely approve an Independent Study Proposal due to an objection by the Declining Party within the time periods set forth in Section 3.1.4(b) (Inclusion of Independent Study in the Global Development Plan/Budget) and the Declining Party does not timely provide written notice of a Material Adverse LRRK2 Program Effect as set forth in Section 3.1.4(c) (Objection by the Other Party) or if the Declining Party does timely provide such written notice, but a dispute regarding the existence of such Material Adverse LRRK2 Program Effect is resolved pursuant to Section 14.6 (Dispute Resolution) in favor of the Proposing Party, then the Proposing Party may, upon notice to the JSC, conduct the relevant Independent Study described in the Independent Study Proposal and the following shall apply until the Proposing Party's receipt of an Independent Study Opt-In Notice for such Independent Study:

(i) The Licensed Product that is the subject of Independent Study shall continue to be a Licensed Product for all purposes of this Definitive LRRK2 Agreement; *provided* that if any PD Development Milestone Event or Non-PD Development Milestone Event is first achieved as a result of a Clinical Study that is conducted by Denali as an Independent Study, then the corresponding PD Development Milestone Payment or Non-PD Development Milestone Payment, as the case may be, shall be deferred and shall not be payable unless and until Biogen issues an Independent Study Opt-In Notice or the occurrence of a Regulatory Approval Update, whichever is earlier, with respect to the applicable Independent Study, and in such case, each such PD Development Milestone Event or Non-PD Development Milestone Event shall be deemed achieved and the corresponding PD Development Milestone Payment or Non-PD Development Milestone Payment, as the case may be, shall be due and payable as of the date such Independent Study Opt-In Notice is provided.

(ii) The Proposing Party shall be the Development Lead with respect to such Independent Study until the Proposing Party's receipt of an Independent Study Opt-In Notice for such Independent Study, after which the provisions of Section 3.1.3 (Development Activities) shall apply.

(iii) Unless otherwise agreed by the Parties, [***]shall be the Regulatory Lead with respect to such Independent Study and, if [***] is the Proposing Party with respect to such Independent Study, then the Parties will cooperate in good faith with respect to all regulatory activities relating to such Independent Study. Notwithstanding the foregoing, [***]. To the extent Denali is the Regulatory Lead for any such Independent Study, then the provisions of Section 3.3.2(d) (Regulatory Authority Interactions) shall apply with respect thereto, *mutatis mutandis*, [***].

(iv) In the event the Proposing Party is not then-responsible for Manufacturing the applicable Licensed Compound or Licensed Product, then, subject to Section 4.4 (Supply Agreements), [***]

(v) The Proposing Party shall initially bear all costs and expenses associated with the Independent Study it undertakes and such costs and expenses shall not be taken into account as Eligible Development Expenses.

(vi) Except as expressly set forth in this Section 3.1.4(d) (Performance of Independent Study), the conduct of the Independent Study will be subject to all terms and conditions of this Definitive LRRK2 Agreement relating to Development of Licensed Products. The Declining Party shall have the right to use, at no additional cost, any data arising from the Independent Study in the performance of its obligations and the exercise of its rights under this Definitive LRRK2 Agreement in accordance with the licenses and rights granted under Article 6 (License Grants; Exclusivity).

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(vii) All Independent Studies undertaken by the Proposing Party shall be subject to the oversight of the JDC and the Declining Party shall have the right to provide comments thereon; [***]. At each meeting of the JDC, the Proposing Party shall report its progress with regard to the Independent Study in the same manner as the Parties provide reports to the JDC with respect to activities covered by the Global Development Plan/Budget, including providing formal written reports of the results related to the Independent Study, as well as the actual FTE Costs and Out-of-Pocket Costs incurred by the Proposing Party, along with estimated future budgets for such Independent Study.

(e) **Opt-In for Independent Study**.

(i) **Completion of Phase II Trial**. No less than [***], the Proposing Party shall furnish to the JDC and the Declining Party a written summary of the results of such Phase II Trial and of any preceding and related Phase I Trials and the Independent Study Costs incurred to date by the Proposing Party ("**Phase II Notice**"). The Proposing Party shall also provide the JDC with any other Information related to the Independent Study that is reasonably requested by the JDC and available to the Proposing Party. If, within [***] after the Declining Party's receipt of the Phase II Notice, the Declining Party notifies the JDC and the Proposing Party in writing that it desires to include the Independent Study into the Global Development Plan/Budget (such notice, whenever given in accordance with this Section 3.1.4(e) (Opt-In for Independent Study), an "**Independent Study Opt-In Notice**"), then (A) the Declining Party shall, subject to the review rights set forth in Section 7.7.2(c) (Expense Review) and to the extent applicable, pay to the Proposing Party an amount equal to that portion of the Independent Study Costs identified in the Phase II Notice that would have been borne by the Declining Party if such Independent Study had been included in the Global Development Plan/Budget [***] of such portion of Independent Study Costs, which amount shall be due within [***] of invoicing by the Proposing Party; and (B) the terms of Section 3.1.4(e)(iv) (Independent Study Opt-In Notice) shall apply.

(ii) **Completion of Phase III Trial**. In the event that the Declining Party does not submit the Independent Study Opt-In Notice in accordance with Section 3.1.4(e)(i) (Completion of Phase II Trial), then within [***], the Proposing Party shall furnish to the JDC and the Declining Party, a written report of the results of such Clinical Study and the Independent Study Costs incurred by the Proposing Party since the Phase II Notice (the "**Phase III Update**"). The Proposing Party shall also provide the JDC with the Clinical Data and any other Information related to the Independent Study that is reasonably requested by the JDC and available to the Proposing Party. If, within [***] of the Declining Party's receipt of the Phase III Update, the Declining Party submits an Independent Study Opt-In Notice to the JDC and Proposing Party: then (A) the Declining Party shall, subject the review rights set forth in to Section 7.7.2(c) (Expense Review), pay to the Proposing Party an amount equal to that portion of the Independent Study Costs identified in the Phase II Notice and Phase III Update that would have been borne by the Declining Party if such Independent Study Costs had been included in the Global Development Budget [***], which amount shall be due within [***] of invoicing by the Proposing Party and (B) the terms of Section 3.1.4(e)(iv) (Independent Study Opt-In Notice) shall apply.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(iii) **Regulatory Approval**. In the event that the Declining Party does not submit the Independent Study Opt-In Notice in accordance with Section 3.1.4(e)(i) (Completion of Phase II Trial) or Section 3.1.4(e)(ii) (Completion of Phase III Trial) and either Party receives Regulatory Approval in any country utilizing any data generated from such Independent Study, the Party receiving such Regulatory Approval shall promptly notify the other Party in writing of receipt of such Regulatory Approval (such receipt of Regulatory Approval, the "**Regulatory Approval Update**") and the Proposing Party shall promptly notify the Declining Party of the Independent Study Costs incurred by the Proposing Party since the Phase III Update (the "**Regulatory Approval Costs Update**"). Promptly after receipt of a Regulatory Approval Update, the Declining Party shall, subject to Section 3.1.4(e)(v) (Denali Opt-Out), promptly submit an Independent Study Opt-In Notice to the JDC and the Proposing Party and (A) the Declining Party shall, subject to the review rights set forth in to Section 7.7.2(c) (Expense Review), pay to the Proposing Party an amount equal to that portion of the Independent Study Costs identified in the Phase II Notice, Phase III Update and Regulatory Approval Costs Update that would have been borne by the Declining Party if such Independent Study Costs had been included in the Global Development Budget [***] which amount shall be due within [***] of invoicing by the Proposing Party and (B) the terms of Section 3.1.4(e)(iv) (Independent Study Opt-In Notice) shall apply.

(iv) **Independent Study Opt-In Notice**. Immediately upon the Proposing Party's receipt of the Independent Study Opt-In Notice: (A) the relevant Independent Study (if any) for such Licensed Product shall be deemed to be included in the Global Development Plan/Budget; (B) the then-current plan and budget for such Independent Study shall be deemed to be included within and part of the Global Development Plan/Budget and shall control with respect to such Independent Study unless and until an amendment to the Global Development Plan/Budget providing for a different or modified plan and budget is approved by the JSC in accordance with Section 3.1.2 (Amendments and Updates) and Section 2.4.5 (Joint Committee Decision-Making); (C) all FTE Costs and Out-of-Pocket Costs incurred thereafter in connection with such Independent Study shall be treated as Eligible Development Expenses and borne or shared by the Parties in accordance with Section 7.7 (Cost-Profit Sharing) unless and until a Denali Opt-Out occurs with respect to the Licensed Product that is the subject of the applicable Independent Study and the Co-Funding End Date occurs; and (D) to the extent the Co-Commercialization Plan/Budget or Global Commercialization Plan for such Licensed Product then-exists and the Phase III Update or Regulatory Approval Update has occurred, the JCC will update such Co-Commercialization Plan/Budget and Global Commercialization Plan in accordance with Section 5.2.4 (Amendments and Updates) to address Commercialization of such Licensed Product for the applicable Indication in any country for which Regulatory Approval is obtained.

(v) **Denali Opt-Out**. Notwithstanding the foregoing, if Denali provides a Denali Development Opt-Out Notice for a Denali Development Opt-Out with respect to a Licensed Compound or Licensed Product, then thereafter, Denali shall not be permitted to undertake any Independent Study pursuant to this Section 3.1.4 (Independent Study) with respect to such Licensed Compound or Licensed Product, nor be required to pay any amounts that may become due pursuant Section 3.1.4(e)(iii) (Regulatory Approval) with respect to such Licensed Compound or Licensed Product after the Co-Funding End Date, and Biogen shall have the right to conduct any Independent Study for such Licensed Compound or Licensed Product by amending the applicable Global Development Plan/Budget and this Section 3.1.4 (Independent Study) will not apply to such activities by Biogen after the Co-Funding End Date with respect to such Licensed Product.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

3.2 **Transfer for Development Purposes.**

3.2.1 **Transfer Procedure.** Denali shall (a) transfer to Biogen: (i) all Regulatory Documentation related to the Licensed Compounds and Licensed Products Controlled by Denali; and (ii) ongoing Development activities to the extent necessary for Biogen's commencement of the Biogen Development Activities and (b) disclose and make available to Biogen all Information that is: (i) Controlled by Denali or its Affiliates as of the Effective Date; and (ii) [***] for the continued Development (but not discovery), Manufacture or use of Licensed Compounds or Licensed Products or the Commercialization of Licensed Products [***] and such transfer or disclosure shall occur reasonably in advance of Biogen's need for such items in the performance of the applicable Biogen Development Activity. For the avoidance of doubt, if any such items described in clause (a) or (b) that are physical materials are necessary for Denali to perform any Denali Development Activities, then, unless such items can be duplicated, Denali shall not be obligated to transfer such items until completion of such Denali Development Activities and the Parties shall cooperate in good faith to provide Biogen with access to such items. The Parties shall cooperate and reasonably agree upon formats and procedures to facilitate the orderly and efficient exchanges of Regulatory Documentation and Information contemplated under this Section 3.2.1 (Transfer Procedure). The JDC (or the Parties prior to formation of the JDC) shall establish a process pursuant to which (A) Denali shall disclose and make available to Biogen on an ongoing basis any Regulatory Documentation or Denali Know-How (including any Joint Program Know-How), in each case, to the extent Controlled by Denali or any of its Affiliates and that are [***] for Biogen to Develop, Manufacture or use Licensed Compounds or Licensed Products or Commercialize Licensed Products in the Territory in accordance with the terms of this Definitive LRRK2 Agreement and (B) Biogen shall disclose and make available to Denali on an ongoing basis any Information Controlled by Biogen that is [***] for (I) Denali's performance of the Denali Development Activities in accordance with the Global Development Plan/Budget, (II) Denali's performance of the activities allocated to it under the Co-Commercialization Plan/Budget in accordance with such plan, or (III) Denali to have informed discussions at the Joint Committees regarding activities performed or to be performed under the Global Development Plan/Budget or the Co-Commercialization Plan/Budget, and making informed decisions at the Joint Committees with respect thereto (such Information Controlled by Biogen, "**Relevant Biogen Know-How**"), in each case ((A) and (B)) to the extent such items have not previously been provided to the other Party; and the Parties shall share such Regulatory Documentation, Denali Know-How, and Relevant Biogen Know-How in accordance with such process and otherwise in accordance with the terms and conditions of this Definitive LRRK2 Agreement.

3.2.2 **Cooperation**. Each Party shall, to the extent requested by the other Party, provide such other Party with all reasonable assistance required in order to transfer to the other Party the Regulatory Documentation, Denali Know-How, Relevant Biogen Know-How and Joint Program Know-How required to be provided pursuant to Section 3.2.1 (Transfer Procedure), in each case, in a timely manner; *provided* that such Party's requirement to provide the other Party any tangible items, including any documentation, shall be limited to those items then-existing and Controlled by such Party or any of its Affiliates at the time of such request by the other Party. Without limiting the foregoing, if visits of a Party's representatives to the other Party's facilities are reasonably requested by the other Party for purposes of transferring such Regulatory Documentation, Denali Know-How, Relevant Biogen Know-How or Joint Program Know-How Controlled by a Party to the other Party or for purposes of the other Party acquiring expertise on the practical application of such Information, then such Party shall [***].

3.2.3 **Transfer Costs**. Subject to Section 4.2 (Manufacturing Transfer), each Party shall be [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

3.3 **Regulatory Matters.**

3.3.1 **Regulatory Lead**. On a jurisdiction-by-jurisdiction basis for a Licensed Product: (a) Denali shall be the Regulatory Lead with respect to regulatory matters and interactions related to the Denali Development Activities with respect to such Licensed Product; and (b) Biogen shall be the Regulatory Lead with respect to regulatory matters and interactions related to the Biogen Development Activities [***] and all Commercialization activities for such Licensed Product, including filing, in its own name or the name of its designee, all MAAs for the Licensed Products throughout the Territory (subject to Section 3.1.4(d) (Performance of Independent Study)). [***]

3.3.2 **Regulatory Activities**.

(a) **Regulatory Responsibility**. Subject to Section 3.3.2(c) (Co-Commercialization Territory Involvement) below, the applicable Regulatory Lead shall have the lead role for the day-to-day implementation and operational management of the preparation, obtaining and maintenance of all Regulatory Documentation necessary to perform the applicable activities under the Global Development Plan/Budget or Co-Commercialization Plan/Budget for which it is the Regulatory Lead. The Non-Regulatory Lead shall support the Regulatory Lead, as may be reasonably necessary, in the preparation, obtaining and maintenance of such Regulatory Documentation, and in the activities in support thereof, including providing or facilitating access to necessary documents or other materials required by Applicable Law or required or requested by a Regulatory Authority to obtain such Regulatory Approvals, in each case, in accordance with the terms and conditions of this Definitive LRRK2 Agreement.

(b) **Regulatory Documentation.** Unless the Parties otherwise agree, Regulatory Documentation to the extent relating to a Licensed Compound or Licensed Product shall be owned by, and shall be the sole property and held in the name of the then-Regulatory Lead for the applicable activities (or its designee). In order to effect the transfer of Regulatory Documentation to [***]

(c) **Co-Commercialization Territory Involvement**. The Regulatory Lead in a Co-Commercialization Territory for the applicable Licensed Compounds and Licensed Products shall provide the Non-Regulatory Lead with an opportunity to review and comment on all Regulatory Documentation for the Co-Commercialization Territories (collectively, "**Co-Commercialization Territory Regulatory Filings**"). The Regulatory Lead shall consider in good faith the Non-Regulatory Lead's comments and use reasonable efforts to implement such comments. The Regulatory Lead shall provide access to interim drafts of such Co-Commercialization Territory Regulatory Filings to the Non-Regulatory Lead via the access methods (such as secure databases) established by the JDC, and the Non-Regulatory Lead shall provide its comments on the drafts of such Co-Commercialization Territory Regulatory Filings or of proposed material actions within [***] (or [***] period in the case of Drug Approval Applications), or such other period of time agreed to by the Parties. In the event that a Regulatory Authority in the Territory establishes a response deadline for any such Co-Commercialization Territory Regulatory Filing (or material action with respect thereto) shorter than such [***] period (or [***] period in the case of Drug Approval Applications), the Parties shall work cooperatively to ensure that, to the extent possible, the Non-Regulatory Lead has a reasonable opportunity for review and comment within such deadlines. The Regulatory Lead shall consider in good faith any such comments of the Non-Regulatory Lead.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(d) **Regulatory Authority Interactions**. The Regulatory Lead shall provide the Non-Regulatory Lead with prior written notice, to the extent the Regulatory Lead has advance knowledge, of any action taken by a Regulatory Authority pertaining to a Licensed Compound or Licensed Product or of any scheduled substantive meeting or discussion (including any advisory committee meeting) with a Regulatory Authority in the Major Markets relating to a Licensed Compound or Licensed Product, which notice shall be provided within [***] after the Regulatory Lead first receives notice of the scheduling of such substantive meeting or discussion (or within such shorter period as may be necessary in order to give the Non-Regulatory Lead a reasonable opportunity to attend such meeting or discussion). In addition to any other involvement of the Non-Regulatory Lead in regulatory interactions agreed to by the Parties, the Non-Regulatory Lead shall (i) have the right to have at least [***] of its employees participate in, all such substantive meetings and discussions for the [***], and (ii) with the Regulatory Lead's consent (not to be unreasonably withheld, delayed or conditioned), have at least [***] of its employees attend, as an observer, all such substantive meetings and discussions [***]. The Regulatory Lead will, at the request of the other Party, provide the other Party with a copy of any substantive correspondence from or to the Regulatory Authority, including any substantive reports, such as meeting minutes, or findings issued by the Regulatory Authority in connection with an audit by such Regulatory Authority or otherwise.

(e) **Cost-Profit Sharing**. All costs incurred with respect to regulatory activities relating to (i) the Global Development Plan/Budget or Co-Commercialization Plan/Budget shall be borne or shared by the Parties in accordance with Section 7.7 (Cost-Profit Sharing) or (ii) any other Development or Commercialization activities shall be borne by [***].

3.3.3 **Records**. Each Party shall maintain records in accordance with its standard practices, which in cases shall be consistent with standard practices in the pharmaceutical industry and in compliance with Applicable Law. Such records shall be retained by such Party for at least [***] after the Calendar Year to which such records relate, or for such longer period as may be required by Applicable Law. Upon request, such Party shall provide copies of the records it has maintained pursuant to this Section 3.3.3 (Records) to the other Party.

3.4 **Clinical Trial Register and Data Transparency**. The JDC will cooperate to establish timelines and procedures for reviewing any public disclosure of Clinical Data, which procedures will include review and approval by the JDC before any public disclosure. The applicable Development Lead will, in accordance with Applicable Law and its internal data transparency policies, publish the results or summaries of Clinical Studies relating to a Licensed Compound or Licensed Product on a Clinical Study register maintained by it and the protocols of Clinical Studies relating to such Licensed Compound or Licensed Product on www.ClinicalTrials.gov (or an equivalent register, or as otherwise required by Applicable Law or such Party's policies).

3.5 **Patient Samples**. All patient samples collected and retained in connection with Clinical Studies involving a Licensed Compound or Licensed Product that are performed under the Global Development Plan/Budget (together with compilations of Information comprising annotations regarding patient histories or correlating patient outcomes, with respect to such samples, "**Patient Samples**") shall be a shared resource of the Parties, to be used first for the conduct of activities under the Global Development Plan/Budget, and otherwise in accordance with this Section 3.5 (Patient Samples). Unless otherwise agreed by the Parties or otherwise set forth in this Section 3.5 (Patient Samples), any remaining Patient Samples in excess of those required to conduct the activities under the Global Development Plan/Budget shall be [***] between Biogen and Denali, and each Party may store its portion of such remaining Patient Samples, at its own cost, in such Party's (or its Affiliate's) facilities or with a Subcontractor and, to the extent permitted under Applicable Law and the applicable informed consents pursuant to which such Patient Samples were collected, each Party may use the Patient Samples that it stores for activities outside the scope of this Definitive LRRK2 Agreement. Each Party's use of Patient Samples shall be in accordance with Applicable Law, including any informed consent and institutional review board regulations and all applicable requirements relating to the protection of human subjects.

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3.6 **Regulatory Audits by a Party**. The Regulatory Lead may review the other Party's, including of its and, to the extent permitted, its Subcontractor's, Regulatory Documentation (including reports from an audit conducted by a Regulatory Authority and any material correspondence relating thereto) or other records, Manufacturing and premises from time to time upon reasonable advance notice and during regular business hours as reasonably deemed necessary or appropriate by the inspecting Party to ensure compliance with GCP, GLP, GMP, other good practice guidelines and regulations, Regulatory Approvals or other requirements of Regulatory Authorities applicable to the Licensed Compounds or Licensed Products. Each Party shall promptly notify the other Party of any audit conducted by a Regulatory Authority of such Party, or Affiliates of such Party, or Subcontractors of such Party or its Affiliates to the extent known by such Party, and, in each case, to the extent relating to a Licensed Compound or Licensed Product.

ARTICLE 4
MANUFACTURING

4.1 **Manufacturing Responsibility**. Denali shall be responsible for Manufacturing or having Manufactured Licensed Product for the first clinical study contemplated under the Global Development Plan/Budget to be initiated after the Effective Date and thereafter until transfer of Manufacturing responsibility to Biogen pursuant to Section 4.2 (Manufacturing Transfer). Following such transfer, Biogen shall be solely responsible for Manufacturing Licensed Compounds and Licensed Products, except that Denali shall retain the right to have Manufactured by an Approved CMO quantities of Licensed Compounds and Licensed Products for use in an Independent Study conducted by Denali, *provided* that, [***] In addition, following such transfer of Manufacturing responsibility to Biogen, upon agreement of the Parties, Denali shall have a right to provide up to [***] FTEs to support the Manufacture of Licensed Compounds and Licensed Products and responsibility for costs incurred by Denali with respect thereto shall be subject to the terms of Section 4.3 (Manufacturing Costs). Unless otherwise agreed by the Parties, Denali will not enter into any agreement for Commercial supply of Licensed Compounds or Licensed Products.

4.2 **Manufacturing Transfer**. [***], with the intent of minimizing interruptions to the Development of Licensed Products, but no later than [***] Denali will, no later than [***] after such request (or such other period as the Parties may agree), commence transfer of Manufacturing responsibilities of Licensed Compounds and Licensed Products to Biogen or its designee pursuant to a plan to be agreed by the Parties through the CMC Working Group (such plan, "**Manufacturing Transition Plan**," and such transfer, "**Manufacturing Transfer**"). Notwithstanding any provision to the contrary in this Definitive LRRK2 Agreement, the Manufacturing Transfer shall be subject to the terms and conditions of the agreements between Denali and its Approved CMOs (each agreement, a "**CMO Supply Agreement**"). A list of CMO Supply Agreements existing as of the Effective Date is set forth on Schedule 4.2 (Existing CMO Supply Agreements). Each Party will bear its respective FTE Costs incurred in connection with such Manufacturing Transfer and Out-of-Pocket Costs shall be shared by the Parties be an Eligible Development Expense. The Parties will cooperate to effect such transition of Manufacturing responsibilities in accordance with such Manufacturing Transition Plan.

4.3 **Manufacturing Costs**. All Manufacturing Costs for Licensed Compounds and Licensed Products incurred (a) for Cost-Profit Sharing Products in furtherance of the Global Development Plan/Budget, or Cost-Profit Sharing Products for a corresponding Cost-Profit Sharing Country in furtherance of the Co-Commercialization Plan/Budget, shall be borne or shared by the Parties in accordance with Section 7.7 (Cost-Profit Sharing) and (b) in furtherance of (i) any Independent Study or (ii) other Commercialization activities, shall be borne by [***]. Manufacturing Costs charged by either Party and shared by the Parties for all such Licensed Compounds and Licensed Products will be consistent with arms-length, commercial terms with a Third Party contract manufacturing organization.

4.4 **Supply Agreements**. If during the Term in a given country or region, a Party ("**Non-Manufacturing Party**") requires Licensed Compound or Licensed Product for the conduct of activities under the Global Development Plan/Budget or an Independent Study Proposal and at such time the other Party ("**Manufacturing Party**") is responsible for Manufacturing such Licensed Compound or Licensed Product, then, upon either Party's request, the Parties shall enter into separate supply and associated quality agreements (each, a "**Supply and Quality Agreement**") covering the terms of supply to such Party for such activities. The Supply and Quality Agreement will contain terms and conditions that are reasonable and customary for agreements of such nature. In addition, the Supply and Quality Agreement will provide that if Manufacturing Costs are incurred to provide Licensed Product to the Non-Manufacturing Party for Independent Studies conducted by the Non-Manufacturing Party, then the Non-Manufacturing Party shall reimburse the Manufacturing Party for such Manufacturing Costs. If the Parties are unable to reach agreement on such provisions of the Supply and Quality Agreement within [***] of a request by either Party to enter into the Supply and Quality Agreement (which [***] period may be extended upon the mutual agreement of the Parties), upon request by either Party, the same shall be determined pursuant to [***]. The terms of any such Supply and Quality Agreement, including the Manufacturing Party's and the Non-Manufacturing Party's respective rights and obligations under such Supply and Quality Agreement, shall be consistent with, and limited by, rights and obligations of the Manufacturing Party under any applicable CMO Supply Agreements.

4.5 **CMC Working Group**. The JDC shall establish a chemistry, manufacturing and controls Working Group ("**CMC Working Group**") to coordinate the Manufacturing Transfer activities by the Parties as set forth in Section 4.2 (Manufacturing Transfer) and to assist the JDC in its responsibility with respect to the review and resolution of Manufacturing matters. The CMC Working Group shall meet at least once per Calendar Quarter, or as otherwise agreed to by the CMC Working Group. Each Party may refer disagreements between the representatives of Biogen and Denali on the CMC Working Group with respect to substantial matters ([***]) to the JDC or JCC, as applicable, for resolution in accordance with Section 2.4.5 (Joint Committee Decision-Making), *provided* that, in any event, the Manufacturing Party shall lead day-to-day implementation and operational management of its performance of the Manufacturing activities under this Definitive LRRK2 Agreement. [***]

ARTICLE 5
COMMERCIALIZATION

5.1 **Commercialization Activities**.

5.1.1 **Efforts**. Biogen will use Commercially Reasonable Efforts to (a) [***], (b) [***], and (c) [***].

5.1.2 **Compliance.** Each Party shall perform any and all of its Medical Affairs and Commercialization activities under this Definitive LRRK2 Agreement, in compliance with all Applicable Law.

5.1.3 **Allocation of Activities and Costs**. The Parties will jointly be responsible for the Commercialization of the Licensed Products in the Co-Commercialization Territory, *provided* that Denali's obligation to perform Commercialization activities shall be limited to those activities allocated to Denali under the Co-Commercialization Plan/Budget and subject to Section 7.8 (Opt-Out and Consequences). Neither Party shall Commercialize a Licensed Compound or Licensed Product in the Co-Commercialization Territory other than pursuant to and in accordance with the then-current Co-Commercialization Plan/Budget. Biogen will [***] perform [***]the Commercialization of Licensed Products in all other countries outside of the Co-Commercialization Territory. Biogen shall be responsible for all costs for such Commercialization activities, except for costs to be shared by the Parties pursuant to Section 7.7 (Cost-Profit Sharing).

5.1.4 **Co-Commercialization of Cost-Profit Sharing Products**.

(a) **Co-Commercialization**. Denali shall provide up to [***] of the Detailing efforts for each Cost-Profit Sharing Product in each Cost-Profit Sharing Country, to be distributed throughout each such Cost-Profit Sharing Country, including equally throughout rural and key metropolitan areas, and such other Commercialization activities as the Parties agree, including patient advocacy engagement (such Detailing and other activities, the "**Co□Commercialization Activities**"), subject to Section 5.1.4(c) (Termination of Co-Commercialization). For purposes of the preceding sentence, any efforts with respect to electronic contacts by means of information technology (*e.g.*, videoconferencing) by or on behalf of either Party shall not be considered in determining the percentage of Detailing efforts.

(b) **Co-Commercialization Agreement**. Without limiting Biogen's obligations under Section 5.2.2 (Co-Commercialization Plan/Budget), the Parties, through the JCC and JSC, shall negotiate in good faith and agree to a Co-Commercialization Plan/Budget to be in place at least [***] before the anticipated date of First Commercial Sale for a Cost-Profit Sharing Product in a Cost-Profit Sharing Country, and, to the extent required by Applicable Law in a Cost-Profit Sharing Country, or if reasonably requested by a Party with respect to one or more Cost-Profit Sharing Countries, the Parties will negotiate in good faith to enter into a co-commercialization agreement based on the Co-Commercialization Plan/Budget as applicable to such country or countries pursuant to which the Parties will conduct the Co-Commercialization Activities for such Licensed Product in such Cost-Profit Sharing Country ("**Co-Commercialization Agreement**"). Until the Parties enter into the Co-Commercialization Agreement, the terms of this Definitive LRRK2 Agreement shall govern the Parties' Co-Commercialization Activities.

(c) **Termination of Co-Commercialization**. Following a Denali Opt-Out with respect to a Cost-Profit Sharing Product in a Cost-Profit Sharing Country, Denali's right and obligation to perform Co-Commercialization Activities for such Cost-Profit Sharing Product in such Cost-Profit Sharing Country shall terminate upon the Co-Commercialization Activities End Date for such Denali Opt-Out, and Denali's obligation to share in Allowable Expenses and Net Revenues for such Cost-Profit Sharing Country shall terminate upon the Co-Funding End Date for such Cost-Profit Sharing Product. Following Biogen's receipt of a Denali Opt-Out Notice (or Denali's receipt of a [***], as applicable), with respect to a Cost-Profit Sharing Country, the Parties, through the JCC, will make arrangements to transition Denali's Co-Commercialization Activities for the applicable Cost-Profit Sharing Products in the applicable Opt-Out Countries to Biogen over a [***] period after the date of the relevant Denali Opt-Out Notice (or [***], as applicable), or such other reasonable time period as may be determined by the Parties, unless [***], in which case, such [***] period (or such other reasonable time period agreed by the Parties) shall begin at the end of such Launch Window (the expiration of the time period for transition as determined in accordance with the foregoing by the Parties, the "**Co-Commercialization Activities End Date**"). If Biogen requests that Denali perform any Commercialization activities with respect to an Opt-Out Product following the Co-Funding End Date, then Biogen will reimburse Denali for the costs incurred by Denali for the conduct of such Commercialization activities with respect to an Opt-Out Product following the Co-Funding End Date to the extent in accordance with a budget for the performance of such activities agreed by the Parties; *provided* that, if the Parties fail to agree to a budget for the performance of any Commercialization activities with respect to an Opt-Out Product following the Co-Funding End Date, then Denali shall have no obligation to perform any such Commercialization activities following the Co-Funding End Date.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

5.1.5 **Commercialization outside of the Co-Commercialization Territory and for Opt-Out Products**. Biogen will share plans for, and information regarding activities with respect to, the Commercialization of Licensed Products outside the Co-Commercialization Territory and such Commercialization activities will be discussed by the Parties through the JCC and JSC, *provided* that, if Denali exercises a Denali Opt-Out with respect to all Cost-Profit Sharing Products in all countries within the Co-Commercialization Territory, then Biogen's obligations to share information regarding the Commercialization of the Licensed Products outside of the Co-Commercialization pursuant to this Section 5.1.5 (Commercialization outside of the Co-Commercialization Territory and for Opt-Out Products) will terminate, and without limiting Biogen's obligations under Sections 7.6.7 (Manner of Royalty Payment) and 7.7.2 (Eligible Development Expenses and Allowable Expenses) through 7.7.4 (Balancing Payment), Biogen shall provide information regarding its Commercialization of Licensed Products outside of the Co-Commercialization Territory in accordance with Section 7.8.3(c). [***]

5.1.6 **[***]**. At its election, Biogen will have the right, at its sole cost and expense, to conduct [***], and, [***], each Party will have the right, at its sole cost and expense, to conduct [***].

5.1.7 **Commercialization Reports**. Each Party shall report on the Commercialization activities such Party has performed (or caused to be performed) with respect to Licensed Compounds and Licensed Products in accordance with the procedures established by the JCC and in any case no less frequently than once every [***]. Each Party shall provide the JCC such other Information pertaining to its Commercialization activities for Licensed Compounds and Licensed Products as reasonably requested by the other Party.

5.2 **Commercialization Plans**.

5.2.1 **Global Commercialization Plan**. Reasonably in advance of the first Regulatory Approval for the first Cost-Profit Sharing Product, Biogen shall prepare for the JCC's review a Global Commercialization Plan for Cost-Profit Sharing Products. Such plan shall consist of: [***].

5.2.2 **Co-Commercialization Plan/Budget**. [***] prior to First Commercial Sale of a Cost-Profit Sharing Product in the Co-Commercialization Territory, Biogen shall prepare, in consultation with Denali and for discussion, review and approval by the JCC and JSC, a detailed Co-Commercialization Plan/Budget that includes a written plan and budget for all Commercialization activities in the Co-Commercialization Territory for Cost-Profit Sharing Products, which will be consistent with Biogen's global commercialization strategy with respect to the Cost-Profit Sharing Products. Such Co-Commercialization Plan/Budget shall include:

(a) [***];

(b) [***];

(c) an allocation and coordination between the Parties of the Commercialization activities to be conducted, including with respect to allocation and coordination of sales representatives, account managers, medical value liaisons (in the United States), and MSLs consistent with Section 5.1.4(a) (Co-Commercialization), Detail frequency and determination of customer targets;

(d) [***];

(e) [***];

(f) a non-binding sales and marketing expenditures forecast in each such country;

(g) non-binding projection of Net Sales of such Cost-Profit Sharing Products in the corresponding Cost-Profit Sharing Country(ies);

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(h) [***];

(i) [***];

(j) [***];

(k) [***]; and

(l) a Co-Commercialization Budget with respect to the Commercialization activities for Cost-Profit Sharing Products in the corresponding Cost-Profit Sharing Country(ies).

5.2.3 In addition, the Co-Commercialization Plan/Budget will provide that:

(a) Biogen will be [***]; and

(b) unless otherwise agreed by the Parties, [***].

5.2.4 **Amendments and Updates**. The JCC shall review the Commercialization Plans (including, if applicable, the associated Co-Commercialization Budget) on a regular basis, and in no event less frequently than once every [***] (as provided below), or more frequently as needed to take into account completion, commencement or cessation of Commercialization or Medical Affairs activities contemplated in the then-current applicable Commercialization Plan for, as well as any newly available Information related to such Commercialization or Medical Affairs activities. Either Party, through its representatives on the JCC, may propose amendments to, or comments on, the Co-Commercialization Plan/Budget from time to time. Biogen may update the Global Commercialization Plan from time to time, *provided* that Biogen shall provide an updated Global Commercialization Plan at least once every [***] and promptly provide any material update to the Global Commercialization Plan, in each case to the JCC and JSC for review. Amendments to the Co-Commercialization Plan/Budget shall be subject to approval in accordance with Section 2.4.5 (Joint Committee Decision-Making). In any event, the JCC shall provide to the JSC an updated Commercialization Plan, including the associated Co-Commercialization Budget (if applicable), no later than November 1 of each Calendar Year. If a revised Co-Commercialization Plan/Budget is not approved by the JSC by December 1 of a Calendar Year, then, until such time as such a revised Co-Commercialization Plan/Budget is approved in accordance with Section 2.4.5 (Joint Committee Decision-Making): (a) the then-current Co-Commercialization Plan/Budget shall continue to govern the Parties' commercialization activities under this Definitive LRRK2 Agreement with respect to Cost-Profit Sharing Product in the corresponding Cost-Profit Sharing Countries; and (b) each Party shall be permitted to conduct the activities allocated to such Party in such then-current Co-Commercialization Plan/Budget and to incur costs consistent with such associated Co-Commercialization Budget, which costs shall be shared by the Parties as Allowable Expenses in accordance with Section 7.7 (Cost-Profit Sharing).

5.3 **Cost-Profit Sharing Product Activities**. With respect to activities conducted for the Cost-Profit Sharing Products for a corresponding Cost-Profit Sharing Country pursuant to the Co-Commercialization Plan/Budget:

5.3.1 **Sales Representatives**.

(a) **Statements by Sales Representatives**. Denali (to the extent performing Co-Commercialization Activities) and Biogen shall each: (i) ensure that its sales representatives do not make any representation, statement, warranty or guaranty with respect to a Licensed Product that is not consistent with the applicable Product Labeling for such Licensed Product, including mutually approved limited warranty and disclaimers, if any; (ii) ensure that its sales representatives do not make any statements, claims or undertakings to any person with whom they discuss or promote Licensed Products that are not consistent with, nor provide or use any labeling, literature or other materials other than, those Promotional Materials provided by [***]; and (iii) [***]

(b) **Training Materials Review**. [***].

(c) **Compliance with Laws**. Denali and Biogen shall each cause its sales representatives performing activities under the Co-Commercialization Plan/Budget to comply with Applicable Law and industry guidelines related to the performance of its obligations hereunder.

(d) **Activity Recordkeeping**. Denali (to the extent performing Co-Commercialization Activities) and Biogen shall maintain records of its sales representatives' activities relating to Licensed Products and allow representatives of the other Party to inspect such records upon request during normal business hours and upon reasonable prior notice.

(e) **KPI Dashboards**. [***] Denali and Biogen shall cause its sales representatives to record and report their Detailing activities using an auditable customer relationship management tool.

5.3.2 **Calculation of Sales Force Costs**. For the purposes of calculating the FTE Costs of each Party's sales representatives performing activities under the Co-Commercialization Plan/Budget, the FTE Rate shall be deemed to be [***] of the applicable FTE Rate for such sales representative on a full-time basis; *provided* that for each sales representative who also engages in promotion activities for a product other than a Cost-Profit Sharing Product during the relevant Calendar Quarter, the cost of such sales representative (for purposes of calculating Allowable Expenses), shall be reduced proportionately based on (a) the Detail position of such Cost-Profit Sharing Product and such other product(s) during such sales activities and a reasonable apportionment of the value of such Detail position(s) for each such products, and (b) the time spent by such sales representative in performing Commercialization activities with respect to the Cost-Profit Sharing Product versus other products. For the purposes of calculating the FTE Costs of each Party's sales representatives performing activities in the Cost-Profit Sharing Countries under the applicable Co-Commercialization Plan/Budget, [***].

5.3.3 **Medical Affairs**. The Parties' responsibilities to conduct Medical Affairs activities with respect to Licensed Products inside and outside of the Co-Commercialization Territory (and to bear the costs and expenses associated therewith) will apply *mutatis mutandis* to each Party's respective responsibilities to Commercialize Licensed Products set forth in Section 5.1.3 (Allocation of Activities and Costs), *provided*, *however* that, unless otherwise agreed to by the JCC:

(a) Biogen will [***];

(b) Denali's Medical Affairs activities [***]; and

(c) the JCC will oversee all Medical Affairs activities with respect to Licensed Products inside and outside of the Co-Commercialization Territory.

5.4 **Advertising and Promotional Materials.** [***] shall develop relevant sales, promotion, market access and advertising materials relating to the Licensed Products (collectively, "**Promotional Materials**") in each case consistent with Applicable Law, the applicable Commercialization Plans and any determinations made by the JCC with respect to such matters including pursuant to Section 2.3.2 (Responsibilities). [***] shall be responsible for the medical, regulatory and legal review of Promotional Materials and for the interpretation and adherence to the Applicable Law governing the preparation of such Promotional Materials, including any advance review of the Promotional Materials required by the applicable Regulatory Authority. Each Party will be responsible for its respective use of such Promotional Materials. Notwithstanding the foregoing, [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

5.5 **Medical Inquiries**. [***] as part of the Co-Commercialization Plan/Budget, [***] medical questions or inquiries from members of the medical profession in any country regarding the Licensed Products. For Cost-Profit Sharing Products in each Cost-Profit Sharing Countries, [***] shall, and shall cause its sales representatives, MSLs, or other personnel (as applicable depending on the nature of the question or inquiry) to, [***] all such questions and inquiries within [***] of receipt, unless earlier notification is required pursuant to the Pharmacovigilance Agreement or Applicable Law. [***] shall respond appropriately to all such inquires in a timely manner.

5.6 **Product Packaging; Branding**. [***] with respect to the packaging and Product Labeling for each Licensed Product, which in all cases shall be consistent with the Commercialization Plans and in accordance with Applicable Law. [***] with respect to determining medical communications, positioning, messaging and branding for each Licensed Product in each jurisdiction or region; *provided* that medical communications, positioning, messaging and branding for each Licensed Product shall be consistent with the applicable Commercialization Plans and Applicable Law. Notwithstanding the foregoing, [***] on Product Labeling, as well as the strategy for positioning, messaging and branding for each Licensed Product, all in accordance with reasonable processes to be established by the JCC, and [***] regarding such matters, and any use of [***] shall be in accordance with reasonable guidelines and instructions provided by [***].

5.7 **Sales and Distribution.** [***] shall lead and [***] with respect to (a) booking all sales of Licensed Products and (b) warehousing and distributing the Licensed Products. If [***] receives any orders for a Licensed Product, then it shall refer such orders to [***].

5.8 **Shipping and Returns**. [***] shall lead and [***] with respect to handling all returns of the Licensed Products. If a Licensed Product sold is returned to [***], then [***]. [***] shall also lead and [***] with respect to handling all aspects of such Licensed Product order processing, invoicing and collection, distribution, inventory, and receivables for each jurisdiction or region.

5.9 **Recalls, Market Withdrawals or Corrective Actions**. In the event that any Regulatory Authority issues or requests a recall or takes a similar action in connection with a Licensed Product, or in the event either Party determines that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal, in each case, in any jurisdiction or region, the Party notified of such recall or similar action, or the Party that desires such recall or similar action, shall within [***], advise the other Party thereof orally or in writing. [***] shall decide whether to conduct a recall in such jurisdiction or region and the manner in which any such recall shall be conducted, *provided* that [***], except in the case of a government mandated recall or [***], in which case [***] may act without such advance notice or consultation but, shall notify [***] as soon as possible. [***] shall make available to [***], upon [***] reasonable request, all of [***] pertinent records that [***] requires to perform any such recall.

5.10 **Product Trademarks.** [***]

5.11 **Markings.** The Promotional Materials, packaging, and Product Labeling for the Licensed Products shall contain the Corporate Name of both Biogen and Denali.

ARTICLE 6
LICENSE GRANTS; EXCLUSIVITY

6.1 **License Grants to Biogen**. Subject to the terms and conditions of this Definitive LRRK2 Agreement, Denali hereby grants to Biogen:

6.1.1 a worldwide, co-exclusive (with Denali) royalty-bearing license, with the right to grant sublicenses through multiple tiers solely in accordance with Section 6.3.1 (By Biogen), under the Denali IP, to Develop, make, have made, use, Manufacture and import Licensed Compounds and Licensed Products and perform Medical Affairs with respect to, offer for sale, sell and Commercialize Licensed Products in the Field in the Territory; and

6.1.2 a non-exclusive royalty-bearing license, with the right to grant sublicenses solely in accordance with Section 6.3.1 (By Biogen), to use Denali's Corporate Names solely to Exploit Licensed Compounds and Licensed Products, in the Field in the Territory pursuant to the license granted under Section 6.1.1.

6.2 **License Grants to Denali**. Subject to the terms and conditions of this Definitive LRRK2 Agreement, Biogen hereby grants to Denali:

6.2.1 A non-exclusive license, with the right to grant sublicenses solely in accordance with Section 6.3.2 (By Denali), under the Biogen IP, to Develop, make, have made, use, Manufacture, and import Licensed Compounds and Licensed Products in accordance with the Global Development Plan/Budget or to perform Independent Studies in accordance with the terms of Section 3.1.4 (Independent Study), and to perform Medical Affairs with respect to Licensed Products in accordance with the Co-Commercialization Plan/Budget and to perform co-Commercialize Licensed Products in the Field in the Co-Commercialization Territory, all as described in this Definitive LRRK2 Agreement; and

6.2.2 a non-exclusive license, with the right to grant sublicenses solely in accordance with Section 6.3.2 (By Denali), to use Biogen's Product Trademarks and Biogen's Corporate Names to Exploit Licensed Compounds and Licensed Products, in the Field in the Territory pursuant to the license granted under Section 6.2.1.

6.3 **Sublicenses**.

6.3.1 **By Biogen**. Biogen shall have the right to grant or authorize sublicenses under the licenses granted by Denali to Biogen in Section 6.1 (License Grants to Biogen) (a) to Biogen's Affiliates, (b) to one or more Subcontractors in accordance with Section 6.4 (Subcontracting), (c) [***] or (d) [***]. Any such sublicense (or license) granted by Biogen pursuant to this Section 6.3.1 (By Biogen) shall be [***].

6.3.2 **By Denali**. Denali shall have the right to grant or authorize any sublicense under the licenses granted by Biogen to Denali under Section 6.2 (License Grants to Denali), and licenses under any Denali IP with respect to the Licensed Products and Licensed Compounds, (a) to Denali's Affiliates, (b) to one or more Subcontractors in accordance with Section 6.4 (Subcontracting), (c) [***]. Any such sublicense granted by Denali pursuant to this Section 6.3.2 (By Denali) shall be [***].

6.3.3 **Responsibility for Sublicensees and Affiliates**. Each Party (and such Party's Affiliates) shall remain liable under this Definitive LRRK2 Agreement for the performance of all its obligations or exercise of its rights under this Definitive LRRK2 Agreement by any licensee, Sublicensee, or Affiliate of such Party (and such Party's Affiliates) [***]

6.4 **Subcontracting**. Subject to Section 6.3.2(c) (By Denali), each Party and its Affiliates may subcontract the performance of any of its Development, Manufacturing, Medical Affairs or Commercialization activities in the Territory with respect to Licensed Compounds and Licensed Products undertaken in accordance with this Definitive LRRK2 Agreement to one or more Subcontractors solely pursuant to a Subcontract Agreement that shall be [***] including that: (a) each Party shall keep the other Party reasonably informed with respect to any material activities such Party intends to subcontract and [***]; and (b) each Subcontract Agreement shall (i) [***] and (ii) [***] Notwithstanding the foregoing, the subcontracting Party [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

6.5 **Third Party Technology**.

6.5.1 **Existing Denali Agreements**. It is understood that the Existing Denali Agreements may require that particular provisions be incorporated into an agreement pursuant to which Denali grants a Third Party a sublicense or other rights thereunder, which Existing Denali Agreements and the requirements of any such provisions in the Existing Denali Agreements are set out on Schedule 1.64 (Existing Denali Agreements and Provisions) attached hereto and shall be deemed incorporated by reference into this Definitive LRRK2 Agreement. Biogen agrees to be bound by and comply with the provisions of each Existing Denali Agreement set out on Schedule 1.64 (Existing Denali Agreements and Provisions) to the extent applicable to Biogen in its capacity as a sublicensee or recipient of rights under each such Existing Denali Agreement for so long as the applicable Existing Denali Agreement is in full force and effect and thereafter with respect to any surviving obligations. To the extent required by any such Existing Denali Agreement identified on Schedule 1.64 (Existing Denali Agreements and Provisions) as of the Execution Date, [***].

6.5.2 **New Technology**.

(a) **Acquisition**. If, after the Effective Date, a Party wishes to acquire [***], then such Party shall (i) promptly notify the other Party in writing and keep such other Party reasonably informed of any negotiations with respect to such [***] and consider in good faith any comments of such other Party with respect thereto and (ii) in any event comply with the procedures set out in Section 6.5.2(b) (Inclusion Process).

(b) **Inclusion Process**. If, after the Effective Date, a Party wishes to include [***] "**New Technology**") [***], then such Party shall so notify the other Party and provide the other Party with a summary of the terms of any license or agreement under which such Party acquired such subject matter prior to the Effective Date or, if after the Effective Date, would acquire or has acquired such subject matter in accordance with Section 6.5.2(a) (Acquisition) (such applicable terms, "**New Technology Terms**"). In the event the Parties agree in writing to include [***], then [***] shall be included in Denali IP or Biogen IP, as the case may be, and subject to the terms and conditions of this Definitive LRRK2 Agreement and the Parties shall be [***].[***]

(c) **Cost Sharing**. To the extent [***] and a payment is owed to a Third Party as a result of the grant to the other Party of [***], then (x) to the extent applicable to (A) the Development of a Cost-Profit Sharing Product or (B) the Commercialization of a Cost-Profit Sharing Product for a Cost-Profit Sharing Country, the Parties shall share amounts paid by the Parties in respect of such Third Party Patent as an Eligible Development Expenses (with respect to clause (A)) or Other Operating Expense (with respect to clause (B)), as applicable and (y) if clause (x) does not apply, then, subject to Section 7.6.6 (Cumulative Royalty Floor) below, Biogen may reduce the royalties otherwise payable to Denali under this Definitive LRRK2 Agreement with respect to a particular Licensed Product in a given country by [***] of any amounts paid to such Third Party with respect to such Third Party Patent that is attributable to the Commercialization of such Licensed Product in such country outside of the Co-Commercialization Territory. For clarity, Biogen shall not have the right under this Section 6.5.2(c) (Cost Sharing) to offset any amounts paid by Biogen that are shared by the Parties as Eligible Development Expenses or Allowable Expenses, as described above.

(d) **New Technology Disputes**. If a Party disputes whether certain Third Party Patents (or Patents together with Information) are necessary to Develop, Manufacture, or, in the Co-Commercialization Territory, Commercialize a Licensed Product, then each Party may refer the matter to the Chief IP Counsel of Biogen and the Head of IP/Legal of Denali or their designees (the "**IP Counsels**"). The IP Counsels will meet promptly to discuss and resolve the matter within [***] after referral of such matter to such IP Counsels. If the IP Counsels cannot agree on a resolution to the matter within such [***] period, then either Party may refer such matter for resolution to an independent Third Party expert agreed upon by the Parties within [***] after the IP Counsels have failed to resolve such matter. Such independent Third Party expert will be an attorney who has practiced United States patent law for at least [***] (or who has such other similar credentials as agreed by the Parties), and unless otherwise agreed in writing by the Parties, must not be a current or former employee, contractor, agent, or consultant of either Party or its Affiliates. The Party bringing a dispute pursuant to this Section 6.5.2(d) (New Technology Disputes) will promptly engage such expert and the Parties will share the Out-of-Pocket Costs incurred in connection with the engagement of such expert [***]. Within [***] of the engagement of such expert by the disputing Party, such expert will deliver its written decision to the Parties (including a detailed report as to such expert's rationale for such decision), and such decision will be binding on the Parties. [***]

6.6 **Retention of Rights**.

6.6.1 **By Denali**. Except as expressly provided herein, Denali grants no other right or license, including any rights or licenses to the Denali IP, the Regulatory Documentation, Denali's Corporate Names, or any other Patent or intellectual property rights not otherwise expressly granted herein, whether by implication, estoppel or otherwise and Biogen shall not Exploit (or authorize the use of) any Denali IP (other than Joint Program Know-How and Joint Program Patents) or use Denali's Corporate Names except as provided in Section 6.1 (License Grants to Biogen). Notwithstanding any provision to the contrary in this Definitive LRRK2 Agreement, [***].

6.6.2 **By Biogen**. Except as expressly provided herein, Biogen grants no other right or license, including any rights or licenses to the Biogen IP, the Regulatory Documentation, Biogen's Corporate Names, or any other Patent or intellectual property rights not otherwise expressly granted herein, whether by implication, estoppel or otherwise and Denali shall not Exploit (or authorize the use of) any Biogen IP (other than Joint Program Know-How and Joint Program Patents) or use Biogen's Corporate Names except as provided in Section 6.2 (License Grants to Denali).

6.7 **Confirmatory Patent License**. If requested to do so by the other Party, each Party shall promptly enter into confirmatory license agreements in the form or substantially the form reasonably requested by such other Party for purposes of recording the licenses granted under this Definitive LRRK2 Agreement with the applicable patent offices as such other Party considers appropriate. Until the execution of any such confirmatory licenses, so far as may be legally possible, Denali and Biogen shall have the same rights in respect of the Denali IP and Biogen IP, as the case may be, and be under the same obligations to each other in all respects as if the said confirmatory licenses had been executed.

6.8 **Exclusivity**.

6.8.1 **Joint Commitment**. Except with respect to the [***] or in the performance of activities under this Definitive LRRK2 Agreement (in the case of either Party), during the Term, neither Party will (and will not permit its Affiliates to), either alone or directly or indirectly with any Third Party, [***] (any such product [***], a "**LRRK2 Alternative Product**").

6.8.2 **Exceptions to Joint Commitment**. Notwithstanding the provisions of Section 6.8.1 (Joint Commitment), neither Party shall be prohibited from conducting activities with respect to [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

6.8.3 **Acquisitions of LRRK2 Alternative Products**. If either Party licenses, acquires or otherwise obtains Development or Commercialization rights from a Third Party for, any LRRK2 Alternative Product (such Party, the "**Acquiring Party**"), then such Acquiring Party shall promptly so notify the non-Acquiring Party. Within [***] from the closing date of such transaction pursuant to which the Acquiring Party obtained rights to such LRRK2 Alternative Product, as applicable, the Acquiring Party will notify the non-Acquiring Party in writing of its election to either (a) [***] or (b) [***]

6.8.4 **Acquisitions by a Third Party that Controls LRRK2 Alternative Products.** If a Party is acquired by a Third Party (including through a merger with such Third Party) that owns or Controls one or more LRRK2 Alternative Products and one or more products that are not LRRK2 Alternative Products, in each case, pursuant to programs that are in existence as of the effective date of such transaction (such Party, the "**Acquired Party**"), then such Acquired Party shall promptly so notify the non-Acquired Party. [***]

6.8.5 **Protective Provisions**.

(a) Without limiting anything set forth in Section 6.8.3 (Acquisitions of LRRK2 Alternative Products) or Section 6.8.4 (Acquisitions by a Third Party that Controls LRRK2 Alternative Products) each Acquiring Party and Acquired Party will ensure that (a) [***]. Notwithstanding the foregoing clause (b) and without limiting the obligations under clause (a), [***].

(b) Notwithstanding any provision in this Definitive LRRK2 Agreement to the contrary, nothing in this Section 6.8 (Exclusivity) shall [***] (i) [***] and (ii) [***]. Notwithstanding the foregoing, [***]: (x) [***]; (y) [***]; or (z) [***].

ARTICLE 7
PAYMENTS

7.1 **Upfront Payment**. In partial consideration for those rights granted to Biogen under this Definitive LRRK2 Agreement, Biogen shall pay to Denali an amount of Four Hundred Million Dollars ($400,000,000) within [***] after the Effective Date. Such payment shall not be refundable nor creditable against any future payments by Biogen to Denali under this Definitive LRRK2 Agreement.

7.2 **PD Milestones**.

7.2.1 **PD Development Milestone Payments**. Biogen shall pay to Denali, in accordance with Section 7.5 (Reports and Payments for Milestones) and Section 7.9 (Mode of Payment), the following [***] development milestone payments (the "**PD Development Milestone Payments**") upon the [***] of each of the following development milestone events for Parkinson's Disease (each, a "**PD Development Milestone Event**") by any Licensed Product:

PD Development Milestone Event	*PD Development Milestone Payment (US$)*
1. [***]	[***]
2. [***]	[***]
3. [***]	[***]
4. [***]	[***]
5. [***]	[***]

[***]

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

[***]

[***]

[***]

7.2.2 **PD Commercial Milestone Payments.** Biogen shall pay to Denali, in accordance with Section 7.5 (Reports and Payments for Milestones) and Section 7.9 (Mode of Payment), the following [***] commercial milestone payments (the "**PD Commercial Milestone Payments**") upon the [***] of each of the following commercial milestone events for Parkinson's Disease (each, a "**PD Commercial Milestone Event**") by any Licensed Product:

PD Commercial Milestone Event	*PD Commercial Milestone Payment (US$)*
6. [***]	[***]
7. [***]	[***]
8. [***]	[***]
9. [***]	[***]
10. [***]	[***]
11. [***]	[***]
12. [***]	[***]
13. [***]	[***]
14. [***]	[***]
15. [***]	[***]
16. [***]	[***]
17. [***]	[***]

[***]

7.2.3 **PD Milestone Details**. For purposes of Section 7.2.1 (PD Development Milestone Payments) and Section 7.2.2 (PD Commercial Milestone Payments):

(a) The Licensed Product with respect to which any of the PD Development Milestones Events [***] is achieved or any of the PD Development Milestone Events [***] is achieved, in each case, may, but need not, be the same Licensed Product.

(b) The PD Development Milestone Payment payable upon the achievement of PD Development Milestone Event [***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(c) If at the time of [***] (or [***]) of PD Development Milestone Event [***], PD Development Milestone Payment [***] has not been paid, then upon such achievement of PD Development Milestone Event [***], as applicable, PD Development Milestone Event [***], as applicable, shall be deemed to have been achieved and PD Development Milestone Payment [***], as applicable, shall become due and payable to Denali. If at the time of [***] (or first deemed achievement) of PD Development Milestone Event [***], any of PD Development Milestone Payment [***] has not been paid, then upon achievement of such PD Development Milestone Event [***], whichever of PD Development Milestone Events [***], as applicable, that has not yet been achieved shall be deemed to have been achieved as of such date and PD Development Milestone Payments [***], as applicable, shall become due and payable to Denali. Except as set forth in Section 7.2.3(f), PD Development Milestone Payment [***] shall only become due and payable if PD Development Milestone Event [***] is achieved (or [***]) before the achievement of PD Development Milestone Event [***].

(d) If (i) PD Development Milestone Payment [***] is made prior to the date on which PD Development Milestone Event [***] is achieved (or deemed achieved) and then PD Development Milestone Event [***] is later achieved (or deemed achieved) and (ii) PD Development Milestone Payment [***].

(e) The PD Commercial Milestone Events shall be deemed to be achieved for (i) [***] (ii) [***] and (iii) [***].

(f) Subject to Section 7.2.4(b), if at the time of the [***] (or first deemed achievement) of PD Commercial Milestone Event [***], either (i) PD Development Milestone Payment [***]or (ii) [***], then in each case ((i) and (ii)) upon the [***] of PD Commercial Milestone Event [***] PD Development Milestone Event [***] shall be deemed to have been achieved and Biogen will pay to Denali PD Development Milestone Payment [***], [***] For the avoidance of doubt, the total amounts payable pursuant to the foregoing sentence shall not exceed [***] in the aggregate. Subject to Section 7.2.4(b), if at the time of the [***] (or [***]) of PD Commercial Milestone Event [***], PD Development Milestone Payment [***] has not been paid, then upon the achievement of PD Commercial Milestone Event [***], PD Development Milestone Event [***] shall be deemed to have been achieved (if not already achieved) and in any event Biogen shall pay to Denali PD Development Milestone Payment [***] [***] If at the time of the [***] (or [***]) of PD Commercial Milestone Event [***], the aggregate PD Development Milestone Payments that have become due and payable to Denali are less than [***], then upon the [***] of PD Commercial Milestone Event [***], concurrently with the PD Commercial Milestone Payment [***], Biogen shall pay to Denali the amount equal to [***].

(g) [***].

(h) [***].

7.2.4 **PD Milestones Payable Once; Maximum Amount**.

(a) For clarity, each PD Development Milestone Event and each PD Commercial Milestone Event shall be payable no more than once with respect to [***]. If a particular PD Development Milestone Event or PD Commercial Milestone Event has been achieved (or deemed to have been achieved) and the corresponding milestone amount paid to Denali, then no additional milestone payments would be payable under this Section 7.2 (PD Milestones) for any subsequent or repeated achievements of such PD Development Milestone Event or PD Commercial Milestone Event, as applicable, by the same or a different Licensed Product.

(b) Notwithstanding the foregoing, and subject to the further limitation on payments of milestones included below in this Section 7.2.4(b), (i[***] and (ii) [***]. Accordingly, if payment by Biogen to Denali of any milestone amount specified in the table above in Section 7.2.1 (PD Development Milestone Payments) or Section 7.2.2 (PD Commercial Milestone Payments) [***].

(c) In no event shall PD Development Milestone Payments paid under Section 7.2.1 (PD Development Milestone Payments) with respect to Licensed Products exceed [***] in the aggregate (the "**Maximum Development Milestone Amount**") and in no event shall PD Commercial Milestone Payments paid under Section 7.2.2 (PD Commercial Milestone Payments) with respect to Licensed Products exceed [***] in the aggregate (the "**Maximum Commercial Milestone Amount**").

(d) For the avoidance of doubt, all milestone payments made under this Section 7.2 (PD Milestones) shall be in addition to any payments made by Biogen to Denali under Section 7.7 (Cost-Profit Sharing) for Denali's portion of the Cost-Profit Share.

7.3 **Non-PD Milestones**.

7.3.1 **Non-PD Development Milestone Payments**. If a Licensed Product is developed by or on behalf of the Parties for an Indication other than an Indication included in Parkinson's Disease (any such indication, a "**Non-PD Indication**"), then, subject to the remainder of this Section 7.3 (Non-PD Milestones), including the crediting and offsetting mechanism set forth in Section 7.3.3(a), Biogen shall pay to Denali, in accordance with Section 7.5 (Reports and Payments for Milestones) and Section 7.9 (Mode of Payment), the following [***], development milestone payments (the "**Non-PD Development Milestone Payments**") upon the [***] of each of the following development milestone events (each, a "**Non-PD Development Milestone Event**") by any Licensed Product for up to [***] Non-PD Indications [***]:

Non-PD Development Milestone Event	Milestone Payment for [***] ($US)	Milestone Payment for [***] (US$)
1. [***]	[***]	[***]
2. [***]	[***]	[***]
3. [***]	[***]	[***]

7.3.2 **Non-PD Commercial Milestone Payments.** If a Licensed Product is developed by or on behalf of the Parties for Non-PD Indications, then, subject to the remainder of this Section 7.3 (Non-PD Milestones), including the crediting and offsetting mechanism set forth in 7.3.3(a), Biogen shall pay to Denali, in accordance with Section 7.5 (Reports and Payments for Milestones) and Section 7.9 (Mode of Payment), the following [***] commercial milestone payments (the "**Non-PD Commercial Milestone Payments**") upon the [***] of each of the following commercial milestone events (each, a "**Non-PD Commercial Milestone Event**") by any Licensed Product for up to [***] Non-PD Indications [***]:

Non-PD Commercial Milestone Event	Milestone Payment for [***] ($US)	Milestone Payment for [***] (US$)
4. [***]	[***]	[***]
5. [***]	[***]	[***]
6. [***]	[***]	[***]
7. [***]	[***]	[***]

7.3.3 **Non-PD Milestone Details**. For purposes of Section 7.3.1 (Non-PD Development Milestone Payments) and Section 7.3.2 (Non-PD Commercial Milestone Payments):

(a) Any Non-PD Development Milestone Payments due to Denali shall be fully creditable against or offset by PD Development Milestone Payments paid by Biogen to Denali. Any Non-PD Commercial Milestone Payments due to Denali shall be [***]. If a particular Non-PD Development Milestone Event or Non-PD Commercial Milestone Event is achieved with respect to [***] or [***], then the amount payable upon achievement of the relevant Non-PD Development Milestone Event or Non-PD Commercial Milestone Event with respect to the [***], as the case may be, shall be equal to [***] of the corresponding milestone payment due upon the achievement of such Non-PD Development Milestone Event or Non-PD Commercial Milestone Event, as the case may be.

(b) [***] Without limiting Section 7.2.4 (PD Milestones Payable Once; Maximum Amount) or Section 7.3.4 (Non-PD Milestone Payable Once; Maximum Amount), if a milestone payment due and payable by Biogen for achievement of a milestone event under this Article 7 (Payments) will result in either (x) [***] or (y) [***].

(c) If the Non-PD Phase III Milestone is skipped for a particular indication, then the payment due upon achievement of such skipped Non-PD Phase III Milestone will become due and payable upon achievement of the next Non-PD Commercial Milestone Event.

(d) For the purposes of this Section 7.3 (Non-PD Milestones) [***]

7.3.4 **Non-PD Milestones Payable Once; Maximum Amount**. For clarity, each Non-PD Development Milestone Event and each Non-PD Commercial Milestone Event shall be payable no more than [***]. If a particular Non-PD Development Milestone Event or Non-PD Commercial Milestone Event has been achieved [***] (or deemed to have been achieved [***]) and the corresponding milestone amounts paid to Denali, no additional milestone payments would be payable under this Section 7.3 (Non-PD Milestones) for any subsequent or repeated achievements of such Non-PD Development Milestone Event or Non-PD Commercial Milestone Event, as applicable, by the same or a different Licensed Product. In no event shall Non-PD Development Milestone Payments paid under Section 7.3.1 (Non-PD Development Milestone Payments) with respect to Licensed Products exceed [***] in the aggregate and in no event shall Non-PD Commercial Milestone Payments paid under Section 7.3.2 (Non-PD Commercial Milestone Payments) with respect to Licensed Products exceed [***] in the aggregate. For the avoidance of doubt, all milestone payments made under this Section 7.3 (Non-PD Milestones) shall be in addition to any payments made by Biogen to Denali under Section 7.7 (Cost-Profit Sharing) for Denali's portion of the Cost-Profit Share.

7.4 **Sales Milestones**.

7.4.1 **Sales Milestone Payments**. Biogen shall pay to Denali, in accordance with Section 7.5 (Reports and Payments for Milestones) and Section 7.9 (Mode of Payment), the following [***] sales milestone payments (the "**Sales Milestone Payments**") upon the [***] of each of the following sales milestone events (each, a "**Sales Milestone Event**") by any Licensed Product:

Sales Milestone Event	***Sales Milestone Payment (US$)***
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

7.4.2 **Sales Milestones Payable Once; Maximum Amount**. For clarity, each Sales Milestone Event shall be payable no more than [***]. If a particular Sales Milestone Event has been achieved (or deemed to have been achieved) and the corresponding milestone amount paid to Denali, no additional milestone payments would be payable under this Section 7.4 (Sales Milestones) for any subsequent or repeated achievements of such Sales Milestone Event. [***] For the avoidance of doubt, all milestone payments made under this Section 7.4 (Sales Milestones) shall be in addition to any payments made by Biogen to Denali under Section 7.7 (Cost-Profit Sharing) for Denali's portion of the Cost-Profit Share.

7.5 **Reports and Payments for Milestones**. With respect to each PD Development Milestone Event and PD Commercial Milestone Event (each individually referred to as, a "**PD Milestone**" and collectively referred to as "**PD Milestones**") set out in Section 7.2 (PD Milestones), each Non-PD Development Milestone Event and Non-PD Commercial Milestone Event (each individually referred to as, a "**Non-PD Milestone**" and collectively referred to as "**Non-PD Milestones**") set out in Section 7.3 (Non-PD Milestones) and each Sales Milestone Event (each individually referred to as, a "**Sales Milestone**" and collectively referred to as "**Sales Milestones**") set out in Section 7.4 (Sales Milestones), the Party who achieves such PD Milestone, Non-PD Milestone or Sales Milestone, as applicable, (or under whose authority such PD Milestone, Non-PD Milestone or Sales Milestone, as applicable, is achieved) shall notify the other Party in writing within (a) [***] after the [***] of a PD Milestone or Non-PD Milestone and (b) [***] after the end of the Calendar Year in which a Sales Milestone is [***]. If Denali notifies Biogen of the achievement of a PD Milestone, a Non-PD Milestone or a Sales Milestone, Denali shall include an invoice for the corresponding milestone payment with such notice. If Biogen notifies Denali of the achievement of a PD Milestone, a Non-PD Milestone or a Sales Milestone or Denali otherwise becomes aware that such a milestone has been achieved, Denali shall submit an invoice to Biogen for the corresponding milestone amount. Biogen shall pay to Denali the corresponding milestone payment set out in Section 7.2 (PD Milestones), Section 7.3 (Non-PD Milestones) or Section 7.4 (Sales Milestones), as applicable, no later than [***] after receipt of the applicable invoice.

7.6 **Royalties**.

7.6.1 **Royalty Payments**.

(a) **Outside of the Co-Commercialization Territory**. Biogen will make royalty payments to Denali on annual Net Sales of each Licensed Product, on a Licensed Product-by-Licensed Product and country-by-country basis, in all countries other than the Co-Commercialization Territory as follows:

Portion of Annual Net Sales of a Licensed Product in all Countries other than the U.S. and China	***Royalty Rate***
[***]	***[***]***
[***]	***[***]***
[***]	***[***]***

(b) **In the Co-Commercialization Territory**. Effective from and after the Co-Funding End Date for a particular Opt-Out Product(s), Biogen shall thereafter pay Denali royalties on Net Sales of such Opt-Out Product in the corresponding Opt-Out Country(ies) in accordance with Section 7.6.1(b)(i) (Opt-Out Prior to First Commercial Sale) and Section 7.6.1(b)(ii) (Opt-Out Following First Commercial Sale) (which royalties shall, for clarity, be in addition to the royalties payable on such Licensed Product (and other Licensed Products) in all countries of the Territory other than any remaining Cost-Profit Sharing Countries).

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(i) **Opt-Out Prior to First Commercial Sale**. In the event of a Denali Opt-Out prior to the First Commercial Sale of any Licensed Product in the applicable Opt-Out Country, [***] Biogen will make royalty payments to Denali on Annual Net Sales of each Opt-Out Product in the applicable Opt-Out Country, on an Opt-Out Product-by-Opt-Out Product and Opt-Out Country-by-Opt-Out Country basis, [***], as follows:

Portion of Annual Net Sales of Licensed Products in China	***Royalty Rate***		
	[***]	**[***]**	**[***]**
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

Portion of Annual Aggregate Net Sales of Licensed Products in the U.S.	***Royalty Rate***		
	[***]	**[***]**	**[***]**
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

(ii) **Opt-Out Following First Commercial Sale**. In the event of a Denali Opt-Out after the First Commercial Sale of any Licensed Product in the applicable Opt-Out Country, Biogen will make royalty payments to Denali on Annual Net Sales of each Opt-Out Product in the applicable Opt-Out Country, on an Opt-Out Product-by Opt-Out Product and Opt-Out Country-by-Opt-Out Country basis, as follows:

Portion of Annual Net Sales of an Opt-Out Product in China	***Royalty Rate***
[***]	[***]
[***]	[***]
[***]	[***]

Portion of Annual Net Sales of an Opt-Out Product in the U.S.	***Royalty Rate***
[***]	[***]
[***]	[***]
[***]	[***]

7.6.2 **Royalty Term**. On a country-by-country and Licensed Product-by-Licensed Product basis, for countries outside the Co-Commercialization Territory (but including the Opt-Out Countries), Biogen will make royalty payments for each Licensed Product during the period commencing upon the First Commercial Sale of such Licensed Product in such country and continuing until the latest of: (a) [***] (the "**Royalty Term**")[***].

7.6.3 **Generic Competition**. On a Licensed Product-by-Licensed Product and country-by-country basis, in the event a Third Party obtains approval for and sells a Generic Product with respect to a particular Licensed Product in a given country outside the Co-Commercialization Territory, [***].

7.6.4 **[***]**

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

7.6.5 **Pre-Existing Financial Obligations**. Biogen shall be responsible for [***] of any amounts paid to [***] with respect to any payment obligation thereunder accruing after the Effective Date. Accordingly, Biogen shall promptly reimburse Denali for such amounts within [***] of receipt of an invoice (or other written request) from Denali with respect thereto.

7.6.6 **Cumulative Royalty Floor**. In no event will the aggregate amount of royalties due to Denali for a particular Licensed Product in a given Calendar Quarter during the Royalty Term for such Licensed Product be reduced by more than [***] of the amount that would otherwise be payable to Denali in such Calendar Quarter for such Licensed Product pursuant to [***].

7.6.7 **Manner of Royalty Payment**.

(a) Within [***] following the end of each Calendar Quarter after the First Commercial Sale of a Licensed Product in the Territory, unless such timing is adjusted by the Finance Working Group, Biogen shall provide to Denali a written report detailing the following information: (i) the amount of gross sales of the Licensed Products in such Calendar Quarter; and (ii) the amount of Net Sales in such Calendar Quarter.

(b) Within [***] following the end of each Calendar Quarter after the First Commercial Sale of a Licensed Product in the Territory, unless such timing is adjusted by the Finance Working Group, Biogen shall provide Denali with a written report detailing the following information for the applicable Calendar Quarter and on a Licensed Product-by-Licensed Product and country-by-country basis (to the extent applicable): [***] (such report, the "**Final Royalty Report**").

(c) In addition, (i) at Denali's request, Biogen shall provide to Denali with at least such information pertaining to Net Sales as may be necessary for Denali to comply with its external reporting requirements as determined by Applicable Law, or as otherwise set forth on Schedule 7.6.7(c) (Existing Denali Agreement Reporting Requirements) and such information shall be provided by Biogen together with each Final Royalty Report (or within forty [***] following the applicable request by Denali, if a Final Royalty Report for the applicable Calendar Quarter has already been delivered), and (ii) without limiting subclause (i), to the extent raised by either Party, the Finance Working Group will discuss any questions regarding the deductions included in the Net Sales calculation in a given Calendar Quarter. Biogen shall pay all royalty payments due to Denali under this Section 7.6 (Royalties) within [***] after the end of each Calendar Quarter.

7.7 **Cost-Profit Sharing**. Starting on the Effective Date and unless and until Denali exercises the Denali Opt-Out with respect to such Licensed Product and such country(ies) pursuant to Section 7.8.1(a) (Denali Election to Opt-Out) [***], the Parties will share Eligible Development Expenses *plus* Allowable Overruns with respect thereto ("**Reimbursable Development Expenses**") for each Licensed Product in the Territory and Allowable Expenses *plus* Allowable Overruns with respect thereto ("**Reimbursable Expenses**") and Net Revenues for each Licensed Product in the U.S. and China as provided in, and subject to the terms of, this Section 7.7 (Cost-Profit Sharing) (each such Licensed Product for so long as such sharing is in effect, a "**Cost-Profit Sharing Product**", each such country, a "**Cost-Profit Sharing Country**", and such cost-profit sharing, the "**Cost-Profit Share**").

7.7.1 **Sharing Percentages**. During the Term, and unless and until Denali exercises the Denali Opt-Out with respect to such Licensed Product and such country(ies) pursuant to Section 7.8.1(a) (Denali Election to Opt-Out) [***], Denali and Biogen shall be responsible for and shall share their respective portions of Reimbursable Development Expenses and Reimbursable Expenses and Net Revenues at the percentages set forth in the table below and otherwise in accordance with the terms set forth in this Section 7.7 (Cost-Profit Sharing).

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Category	Denali	Biogen
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

7.7.2 **Eligible Development Expenses and Allowable Expenses**.

(a) **Reporting Obligations for Eligible Development Costs**. During the Interim Development Period, no later than the [***] of each calendar month, Denali will provide to Biogen a reasonably detailed report of the Pre-Definitive LRRK2 Agreement Eligible Development Expenses incurred during the preceding calendar month. Thereafter, so long as any Party incurs any Eligible Development Expenses, each such Party shall submit to the other Party: (i) within [***] after the end of each Calendar Quarter in which such Party or its Affiliates performs Development activities under the Global Development Plan/Budget, [***]; and (ii) [***]; *provided* that, with respect to Denali and the first Calendar Quarter following the Effective Date or in which the Effective Date occurs, such actual and estimate reports shall also include [***]. So long as any Party incurs Eligible Development Expenses, Biogen will also submit to Denali, within [***] after the end of each Calendar Quarter, a written report of the total Reimbursable Development Expenses of both Parties for such Calendar Quarter ("**Development Expense Report**"). Each actuals and estimate report for Reimbursable Development Expenses provided by a Party under this Section 7.7.2(a) (Reporting Obligations for Eligible Development Costs), as well as any Development Expense Report, shall include a detail and itemized calculation of all such Reimbursable Development Expenses, as established by the Finance Working Group from time to time in order for each Party to satisfy its internal reporting requirements, and for each reported Reimbursable Development Expense, a breakdown of the corresponding Eligible Development Expenses and Allowable Overruns with respect thereto. In addition to the annual approval of the Global Development Budget, prior to the end of each Calendar Year, each Party will provide the Finance Working Group with a non-binding estimate of its Eligible Development Expenses for the next [***] Calendar Years (detailed on a Calendar Year basis) and the Parties shall review and discuss such estimated costs through the Finance Working Group or the JSC.

(b) **Reporting Obligations for Allowable Expenses**. So long as any Party incurs any Allowable Expenses, each such Party shall submit to the other Party: (i) [***] after the end of each Calendar Quarter in which such Party incurs Allowable Expenses [***]; and (ii) [***]. So long as any Party incurs Allowable Expenses, Biogen will also submit to Denali, within [***] after the end of each Calendar Quarter, a written report of the total Reimbursable Expenses on a Cost-Profit Sharing Product-by-Cost-Profit Sharing Product and Cost-Profit Sharing Country-by-Cost Profit Sharing Country basis for such Calendar Quarter ("**Shared Expense Report**"), which report shall be [***]. Each actuals and estimates report for Reimbursable Expenses provided by a Party under this Section 7.7.2(b) (Reporting Obligations for Allowable Expenses), as well as any Shared Expense Report, shall include [***]. In addition to the annual approval of the Co-Commercialization Budget, prior to the end of each Calendar Year, each Party will provide [***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(c) **Expense Review**. A Party may (i) reasonably request that the Party that incurred Reimbursable Development Expenses or Reimbursable Expenses provide any invoices or other supporting documentation for any payments to a Third Party or with respect to which documentation is otherwise reasonably requested, or (ii) submit a reasonable objection to the Reimbursable Development Expenses or Reimbursable Expenses reported by the other Party, in either case of clause (i) or (ii), within [***] after receipt of the incurring Party's actuals report pursuant to Section 7.7.2(a) (Reporting Obligations for Eligible Development Costs) or Section 7.7.2(b) (Reporting Obligations for Allowable Expenses), as applicable. Without limiting a Party's rights under Section 7.14 (Audit) or Section 14.6 (Dispute Resolution), if a Party fails to object to any Reimbursable Development Expenses or Reimbursable Expenses, as applicable, submitted by the other Party within such [***] period, then such Reimbursable Development Expenses or Reimbursable Expenses, as applicable, will be considered accepted. If a Party requests any invoices or supporting documentation for any Reimbursable Development Expenses or Reimbursable Expenses of the other Party as provided above, such other Party shall promptly (and in any event within [***]) provide such documentation to the requesting Party as may be reasonably necessary to allow the requesting Party to understand the applicable Reimbursable Development Expenses or Reimbursable Expenses, as the case may be. Any costs or expenses incurred by or on behalf of a Party or its Affiliates with respect to the Development, Manufacture or Commercialization of, or conduct of Medical Affairs for, Licensed Products and Licensed Compounds that do not fall within the definition of Reimbursable Development Expenses or Reimbursable Expenses will be borne solely by such Party, unless the JSC otherwise agrees in writing.

7.7.3 **Operating Profits or Losses**. During the Term, and unless and until Denali exercises the Denali Opt-Out with respect to all Licensed Products and country(ies) pursuant to Section 7.8.1 (Denali Opt-Out), Biogen will submit to Denali, within [***] after the end of each Calendar Quarter, a consolidated report of the profits or losses calculated in accordance with Schedule 7.7.2 (Profit & Loss Statement) ("**Operating Profits or Losses**"), which shall be [***] (such report, the "**Consolidated Report**").

7.7.4 **Balancing Payment**. If, taking into account the Reimbursable Development Expenses incurred by each Party during a Calendar Quarter and the Operating Profits or Losses for such Calendar Quarter reflected in a Consolidated Report, as applicable, an amount is due from one Party to the other to effect the sharing of Reimbursable Development Expenses, Reimbursable Expenses and Net Revenues as set forth in Section 7.7.1 (Sharing Percentages) above, then the Party to whom payment is owed will invoice the other Party for an amount necessary to effect such sharing; *provided* that for the first Calendar Quarter following the Effective Date, or in which the Effective Date occurs, such the calculation of such balancing payment shall also take into account any Pre-Definitive LRRK2 Agreement Eligible Development Expenses. The owing Party will make payment in full of any undisputed invoiced amounts to other Party within [***] after the date of such invoice. In the event of any disagreement with respect to the calculation of payments owed by one Party to the other Party, the owing Party will pay any undisputed portion of such payment in accordance with the foregoing timetable and will pay the remaining, disputed portion within [***] after the date on which the Parties, using good faith efforts, resolve the dispute, which dispute, at the request of either Party, will be resolved by the Finance Working Group in accordance with Section 7.7.7 (Financial Disputes).

7.7.5 **Certain Other Matters Relating to Cost Calculations**.

(a) **Budget Overruns**. On a Calendar Year basis, if the Eligible Development Expenses or Allowable Expenses incurred by a Party are in excess of the Global Development Plan/Budget or Co-Commercialization Plan/Budget, then such excess amounts may be included in calculating the amount of Reimbursable Development Expenses or Reimbursable Expenses, as applicable, incurred in such Calendar Year and to be shared by the Parties only to the extent that such amounts constitute Allowable Overruns for such Calendar Year.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(b) **Allocation of FTE Costs and Out-of-Pocket Costs**. It is understood that Eligible Development Expenses and Allowable Expenses shall (i) [***], and (ii) [***]. To the extent that any activity conducted (or an Out-of-Pocket Cost or FTE Cost is incurred) is not solely attributable to a Development activities for Cost-Profit Sharing Products in the Territory or Commercialization activities for the Cost-Profit Sharing Products in and for a Cost-Profit Sharing Country (including, for example and not by way of limitation, Manufacturing Costs incurred with respect to the scale up of Manufacturing activities for a particular Cost-Profit Sharing Product), then such Out-of-Pocket Costs and FTE Costs for the applicable activity shall be included in Eligible Development Expenses and Allowable Expenses only to the extent specifically allocated to the Development activities for the Cost-Profit Sharing Products in the Territory or Commercialization activities for the Cost-Profit Sharing Products in and for a Cost-Profit Sharing Country, as the case may be, and in each case in accordance with Accounting Standards. [***].

(c) **Treatment of Overhead; Other Matters**. The Parties acknowledge and agree that Eligible Development Expenses and each category of Allowable Expenses shall not include any allocation of Overhead Costs [***]. Except to the extent already included [***], Eligible Development Expenses and each category of Allowable Expenses shall not include either Party's costs to the extent pertaining to [***] activities associated with overseeing execution of and compliance with this Agreement, unless expressly set forth in this Agreement or otherwise agreed by the Parties in writing. Eligible Development Expenses and each category of Allowable Expenses shall also exclude any costs [***] a breach of this Agreement by either Party.

7.7.6 **Financial Reporting Activities; Finance Working Group**. With respect to the financial reporting activities between the Parties, the JSC (or the Parties if the JSC does not exist) shall establish a finance working group ("**Finance Working Group**") to coordinate the activities and reporting by the Parties as set forth in Section 7.6.7 (Manner of Royalty Payment), Section 7.7.2 (Eligible Development Expenses and Allowable Expenses) through Section 7.7.4 (Balancing Payment) and to assist the JSC in its responsibilities with respect to the review and resolution of financial matters. In particular, the Finance Working Group shall:

(a) facilitate the creation of Global Development Budget and Co-Commercialization Budget, including the annual updates thereto;

(b) reconcile financial and accounting matters between the Parties;

(c) initiate and execute an effective and efficient revenue and cost sharing process (cross-charges);

(d) cooperate to ensure that the Global Development Budget and Co-Commercialization Budget agreed to for a Calendar Year (or any other given period) can be interpreted for the purposes of both Parties' internal financial and audit reporting requirements, including each Party's fiscal year reporting;

(e) monitor the budget, expense and revenue reporting requirements between the Parties related to Licensed Products and Licensed Compounds to ensure that each Party is able to comply with its respective internal financial and audit reporting requirements and, as appropriate, recommending to the JSC for approval, changes to the reporting requirements under this Agreement;

(f) discuss and review any anticipated costs and expenses incurred by a Party in excess of the Eligible Development Expenses specified in the then-current Global Development Budget or Allowable Expenses specified in the then-current Co-Commercialization Budget to be incurred by a Party for a particular Calendar Year and, if applicable, determine whether such excess costs and expenses should be referred to the JSC for approval and Allowable Overruns; and

(g) undertake such other tasks with respect to the calculation, implementation and reporting for the Parties' sharing of Eligible Development Expenses, Allowable Expenses, Allowable Overruns and Net Revenues as the Parties agree.

7.7.7 **Financial Disputes**. The Finance Working Group shall endeavor, on a reasonable basis, to resolve good faith differences in or disputes regarding calculation and reporting of Net Sales and royalties in accordance with Section 7.6 (Royalties) and the calculation and sharing of Eligible Development Expenses, Allowable Expenses, Allowable Overruns and Net Revenues in accordance with this Section 7.7 (Cost-Profit Sharing). In the event the Finance Working Group is unable to resolve any such difference or dispute, the matter shall be resolved in accordance with Section 2.4.5(c) (Dispute Escalation) (as if the issue was referred by the JSC).

7.8 **Opt-Out and Consequences**.

7.8.1 **Denali Opt-Out**.

(a) **Denali Election to Opt-Out**. Upon [***] prior written notice to Biogen (any such notice, a "**Denali Opt-Out Notice**"), Denali shall have the right to opt-out of sharing (i) future Eligible Development Expenses with respect to all Cost-Profit Sharing Products or with respect to [***] under the Global Development Plan/Budget for all countries (the "**Denali Development Opt-Out**") or (ii) Allowable Expenses and Net Revenues with respect to all Cost-Profit Sharing Products or [***] for the U.S. or China (the "**Denali Commercialization Opt-Out**"), and in each case, receive a royalty on sales of the applicable Licensed Product(s) as specified below (each such opt-out, a "**Denali Opt-Out**"). CNS Penetrance of any such Licensed Compound shall be determined in accordance with Schedule 7.8.1(a) (CNS Penetrance Determination). Denali shall specify in any Denali Opt-Out Notice the Cost-Profit Sharing Products to which Denali wishes the Denali Opt-Out to apply, whether such Denali Opt-Out is a Denali Development Opt-Out or Denali Commercialization Opt-Out, and in the case of a Denali Commercialization Opt-Out, the country(ies) to which such opt out applies. Any Cost-Profit Sharing Product with respect to which Denali exercises the Denali Opt-Out and all other Licensed Products containing the same Licensed Compound as any such Cost-Profit Sharing Product shall be referred to as an "**Opt-Out Product**," and in the case of a Denali Commercialization Opt-Out for the United States or China, any such affected country shall be referred to as an "**Opt-Out Country**" for the applicable Opt-Out Product(s). If Denali provides a Denali Development Opt-Out, then for each applicable Opt-Out Product to which the Denali Development Opt-Out applies, Denali shall provide a Denali Commercialization Opt-Out for the U.S. and China. "**Co-Funding End Date**" means [***]. Notwithstanding the foregoing, if Denali provides a Denali Commercialization Opt-Out during the Launch Window, then no Denali Commercialization Opt-Out activities described under Section 7.8.3 (Consequences of Denali Commercialization Opt-Out) for a Cost-Profit Sharing Product pursuant to this Section 7.8.1(a) (Denali Election to Opt-Out) shall commence at any time during the Launch Window for the first Cost-Profit Sharing Product (in the case of an opt-out by Denali with respect to all Cost-Profit Sharing Products) or [***] in either the U.S. or China, as applicable.

(b) [***]

7.8.2 **Consequences of Denali Development Opt-Out**. Notwithstanding any provision to the contrary in Article 2 (Collaboration Management), Article 3 (Development and Regulatory Activities), Article 4 (Manufacturing) or Article 5 (Commercialization), in the event of a Denali Development Opt-Out, the following shall also apply from and after the Co-Funding End Date:

(a) [***]

(b) [***]

(c) [***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(d) [***]

(e) [***]

(f) [***]

7.8.3 **Consequences of Denali Commercialization Opt-Out**. Notwithstanding any provision to the contrary in Article 2 (Collaboration Management), Article 3 (Development and Regulatory Activities), Article 4 (Manufacturing) or Article 5 (Commercialization) above, in the event of a Denali Commercialization Opt-Out, the following shall also apply from and after the Co-Funding End Date:

a. [***]

b. [***]

c. [***]

d. [***]

e. [***]

7.9 **Mode of Payment**. All payments to either Party by the other Party under this Definitive LRRK2 Agreement shall be made by such other Party or its Affiliate by deposit of Dollars in the requisite amount to such bank account as the receiving Party may from time to time designate by notice to the paying Party. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Definitive LRRK2 Agreement (including the calculation of Net Sales expressed in currencies other than Dollars), in the case of any amounts designated in another currency, each Party shall convert such foreign currency into Dollars using its standard conversion method consistent with its Accounting Standards in a manner consistent with the respective Party's customary and usual conversion procedures used in preparing its audited financial reports applied on a consistent basis, provided that such procedures use a widely accepted source of published exchange rates.

7.10 **Payment Allocation**.

7.10.1 Subject to the remainder of this Section 7.10, payments under this Definitive LRRK2 Agreement shall be paid by BIMA and BIG separately [***]; *provided* that [***].

7.10.2 With respect to the upfront payment described in Section 7.1 (Upfront Payments), BIG will pay a portion of such amount in consideration of the rights granted outside of the U.S., which shall equal [***] and BIMA will pay a portion of such amount in consideration of the rights granted in the U.S., which shall equal [***].

7.10.3 With respect to the PD Development Milestone Payments in Section 7.2 (PD Milestones) and the Non-PD Development Milestone Payments in Section 7.3 (Non-PD Milestones), BIG will pay a percentage of each such amount in consideration of the rights granted outside of the U.S. and BIMA will pay a percentage each such amount in consideration to the rights granted in the U.S., such percentages, in each case, to be determined by Biogen at the time at which such amounts are due.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

7.10.4 BIG will pay the milestone payments for PD Commercial Milestone Events and Non-PD Commercial Milestone Events that are achieved outside of the U.S. when such amounts become due and payable in accordance with Section 7.2.2 (PD Commercial Milestone Payments) and Section 7.3.2 (Non-PD Commercial Milestone Payments). BIMA will pay the milestone payments for PD Commercial Milestone Events and Non-PD Commercial Milestone Events that are achieved in the U.S. when such amounts become due and payable in accordance with Section 7.2.2 (PD Commercial Milestone Payments) and Section 7.3.2 (Non-PD Commercial Milestone Payments). Notwithstanding the foregoing, (a) BIG will pay the PD Commercial Milestone Payments for [***] and BIMA will pay the PD Commercial Milestone Payments [***] and (b) BIG will pay the Non-PD Commercial Milestone Payments [***], and BIMA will pay the Non-PD Commercial Milestone Payment [***].

7.10.5 BIMA will pay the portion of the milestone payments for Sales Milestone Events and royalties based on the pro rata allocation of the Annual Net Sales attributable to sales of the applicable Licensed Product(s) in the U.S., and BIG will pay the portion of the milestone payments for Sales Milestone Events and royalties based on the pro rata allocation of the Annual Net Sales attributable to sales of the applicable Licensed Product outside of the U.S.

7.10.6 With respect to all milestone payments set forth in this Article 7 (Payments) that are not described in Section 7.10.2 through Section 7.10.5 above, BIG will pay a percentage of each such amount in consideration of the rights granted outside of the U.S. and BIMA will pay a percentage each such amount in consideration to the rights granted in the U.S., such percentages, in each case, to be determined by Biogen at the time in which such amounts are due.

7.10.7 For clarity, nothing in this Section 7.10 (Payment Allocation) is intended to limit Section 14.16 (Coordination between BIMA and BIG) of this Definitive LRRK2 Agreement.

7.11 **Taxes**.

7.11.1 **General**. Each Party will be responsible for all Taxes imposed on such Party's net income, or on net income allocated to such Party under Applicable Law. To the extent one Party pays Taxes imposed on net income of the other Party, the other Party shall reimburse the paying Party for any such Taxes paid. The amounts payable pursuant to this Definitive LRRK2 Agreement ("**Payments**") shall not be reduced on account of any Taxes unless required by Applicable Law. A payor Party shall deduct and withhold from the Payments any Taxes that it is required by Applicable Law to deduct or withhold including from subsequent Payments. Notwithstanding the foregoing, if the recipient Party is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, or recovery of, applicable withholding tax, it may deliver to the payor Party or the appropriate governmental authority the prescribed forms necessary to reduce the applicable rate of withholding or to relieve the payor Party of its obligation to withhold tax. In such case the payor Party shall apply the reduced rate of withholding, or not withhold, as the case may be, provided that the payor Party is in receipt of evidence, in a form reasonably satisfactory to the payor Party of the recipient Party's entitlement to a reduced or no withholding rate. If, in accordance with the foregoing, a payor Party withholds any amount, it shall pay to the recipient Party the balance when due, make timely payment to the proper taxing authority of the withheld amount, and send the recipient Party proof of such payment within [***] following that payment. The Parties shall use reasonable efforts to reduce any withholding required under Applicable Law. The Parties hereto agree that as of the date hereof, no U.S. or Swiss withholding taxes are required on the upfront payment described in Section 7.1 (Upfront Payment) under Applicable Law [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

7.11.2 **Assignment**. If a Party that owes a Payment assigns its rights and obligations to any person as permitted in accordance with Section 14.3 (Change of Control; Assignment) of this Definitive LRRK2 Agreement (or any successor provision) and if, solely as a result of such assignment, the withholding of taxes required by Applicable Law with respect to the Payments is increased, then any Payments shall be increased to take into account such withheld taxes so that, after making all required withholding tax (including withholding tax on amounts payable pursuant to Section 7.11.1 (General)), the recipient Party receives an amount equal to the sum it would have received had no such assignment been made.

7.11.3 **VAT**.

(a) All payments or amounts due under this Definitive LRRK2 Agreement, whether monetary or non-monetary are exclusive of VAT. Any Party receiving a supply under this Definitive LRRK2 Agreement hereby covenants that it will pay any such VAT correctly charged in addition to any amounts due under this Definitive LRRK2 Agreement. Where the prevailing legislation requires the recipient to self-account for VAT (for example, but not limited to, the reverse charge mechanism), then the receiving Party covenants that it shall correctly account for VAT in respect of the services received. The supplying Party agrees that it will raise a tax invoice (or equivalent document) to support the charge to VAT.

(b) For the purposes of VAT, the services, rights and licenses provided by Denali under this Definitive LRRK2 Agreement shall be considered to be taxed under by Art 44 of Council Directive 2006/112/EC or any equivalent provision in the country of performance if performed outside the European Union and as such will be considered to be taxed for VAT purposes in the country of the recipient. For the purposes of this clause, BIG warrants that it is established in Switzerland for the purposes of receiving any such services, rights or licenses.

(c) Any supply of goods under this Definitive LRRK2 Agreement shall be taxed in accordance with the prevailing VAT legislation. All Parties agree that they will reasonably cooperate to ensure the use of any VAT exemptions, zero-ratings, reduced-ratings, suspensions or other reliefs.

(d) In the event that the local competent tax authority determines that VAT is chargeable, Denali in the first instance shall undertake all reasonable steps to refute any such assertions by the local tax authority. Only once this process is completed should Denali raise valid tax invoices for the additional VAT liability.

(e) The Parties shall take all reasonable steps to recover any additional VAT liability from the same local tax authorities by submitting regular claims (for example, through periodical VAT returns and discrete non-resident claims such as 8th Directive claims, 13th Directive claims and non-EU equivalents) and shall use commercially reasonable efforts to provide necessary assistance to facilitate the recovery of VAT. If the VAT cannot be recovered, then the supplying Party shall be entitled to invoice the receiving Party directly for these amounts.

(f) Each Party shall be responsible for any penalties or interest accruing due to incorrect VAT treatment of the supplies of goods or services made by that Party or any failure to correctly account for VAT on any receipt of a supply of goods or services under this Definitive LRRK2 Agreement except where those penalties or interest arise as a result of the actions of the other Party, in which case that Party shall be liable to reimburse the value of the penalties and interest.

(g) Each Party shall be responsible for reporting its own transactions to the local tax authorities if required for VAT purposes. There shall be no shared, mutual or otherwise collective VAT filings that may suggest that the Parties are anything other than separately operational entities for VAT purposes.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

7.11.4 **Orphan Credit**. Denali shall cooperate with Biogen in seeking any tax exemption or credits that may be available to Biogen with respect to any Licensed Compound, including the tax credit available under section 45C of the Internal Revenue Code by reason of Biogen's research and development expenditures contributing to the any compound under this Definitive LRRK2 Agreement being granted Orphan Drug status by the FDA. Notwithstanding any provision to the contrary set forth in this Definitive LRRK2 Agreement, Denali accepts no responsibility for, and expressly disclaims all liability arising from, Biogen's failure to qualify for any tax exemptions or credits for any reason.

7.11.5 **[***]**

7.12 **Interest on Late Payments**. If any payment or portion thereof due to either Party under this Definitive LRRK2 Agreement is not paid when due, then such paying Party shall pay interest thereon at a rate equal to [***] or, if lower, the maximum rate permitted by Applicable Law.

7.13 **Financial Records**. Each Party shall keep complete and accurate books and records pertaining to Net Sales of Licensed Products, Eligible Development Expenses, Allowable Expenses and Net Revenues with respect to the Licensed Compounds and Licensed Products, and Development of the Licensed Compounds or Licensed Products, including books and records of actual expenditures with respect to the Global Development Budget and the Co-Commercialization Budget, in sufficient detail to calculate all amounts payable hereunder and to verify compliance with its obligations under this Definitive LRRK2 Agreement. Such books and records shall be retained by such Party until the later of (a) [***] after the end of the period to which such books and records pertain, and (b) the expiration of the applicable tax statute of limitations (including any extensions thereof), or for such longer period as may be required by Applicable Law.

7.14 **Audit**. At the request of the other Party, each Party shall permit an independent public accounting firm of nationally recognized standing designated by the other Party and reasonably acceptable to the audited Party, at reasonable times during normal business hours and upon reasonable notice, to audit the books and records maintained pursuant to Section 7.13 (Financial Records) to ensure the accuracy of all financial reports and notices delivered and payments made hereunder. Such examinations may not (a) be conducted for any Calendar Year more than [***] after the end of such Calendar Year, (b) be conducted more than once in any Calendar Year or (c) be repeated for any audited period; except for cause. The accounting firm shall disclose to the auditing Party whether the reports are correct or not, and the details concerning any discrepancies sufficient for the auditing Party to understand any such discrepancies. Except as provided below, the cost of this audit shall be borne by the auditing Party, unless the audit reveals a variance of greater than [***] from the reported amounts for the inspected period, in which case the audited Party shall bear the cost of the audit. If such audit concludes that (i) additional amounts were owed by the audited Party, the audited Party shall pay the additional undisputed amounts, with interest from the date originally due as provided in Section 7.12 (Interest on Late Payments), or (ii) excess payments were made by the audited Party, the auditing Party shall, at its election, reimburse such undisputed excess payments or elect that such excess payments shall be offset against future payments due to the auditing Party under this Definitive LRRK2 Agreement, in either case ((i) or (ii)), within [***] after the date on which such audit is completed by the auditing Party. Any disputes with respect to the findings of such accounting firm may be referred by either Party to the dispute resolution procedure set forth in Section 14.6 (Dispute Resolution). The auditing Party will treat all financial information disclosed by its accounting firm pursuant to this Section 7.14 (Audit) as Confidential Information of the audited Party for purposes of Article 10 (Confidentiality and Non-Disclosure) of this Agreement, and will cause its accounting firm to do the same.

7.15 **Confidentiality**. The receiving Party shall treat all information subject to review under this Article 7 (Payments) in accordance with the confidentiality provisions of Article 10 (Confidentiality and Non-Disclosure) and the Parties shall enter into a reasonably acceptable confidentiality agreement with the independent accountant obligating such accountant to retain all such financial information in confidence pursuant to such confidentiality agreement.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

7.16 **No Other Compensation**. Each Party hereby agrees that the terms of this Definitive LRRK2 Agreement fully define all consideration, compensation and benefits, monetary or otherwise, to be paid, granted or delivered by a Party to the other Party in connection with the transactions contemplated herein. Neither Party previously has paid or entered into any other commitment to pay, whether orally or in writing, any of the other Party's employees, directly or indirectly, any consideration, compensation or benefits, monetary or otherwise, in connection with the transaction contemplated herein.

ARTICLE 8
INTELLECTUAL PROPERTY

8.1 **Ownership of Intellectual Property**.

8.1.1 **Ownership of Patents and Information Generated under this Definitive LRRK2 Agreement**. As between the Parties: [***].

8.1.2 **Assignment, Disclosure and Assistance Obligation**. [***].

8.1.3 **Ownership of Corporate Names**. [***].

8.2 **Maintenance and Prosecution of Patents**. As between the Parties,[***].

8.2.1 **[***]**.

(a) [***]**.**

(b) [***].

(c) [***].

8.2.2 **[***].**

8.2.3 **[***].**

8.3 **[***].**

8.3.1 **[***].**

8.3.2 **Prosecuted Infringements**.

(a) [***].

(b) [***].

8.3.3 **[***].**

8.3.4 **[***].**

8.3.5 **[***].**

8.3.6 **[***].**

8.4 **[***].**

8.5 **Invalidity or Unenforceability Defenses or Actions**. As between the Parties, and subject to the requirements of the Existing Denali Agreements [***]:

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

8.5.1 **Notice**. [***].

8.5.2 **[***].**

8.5.3 **[***].**

8.5.4 **[***]**.

8.5.5 **[***]**.

8.6 **Product Trademarks**.

8.6.1 **[***]**.

8.6.2 **[***]**.

8.6.3 **[***].**

8.6.4 **[***].**

8.6.5 **[***]**.

ARTICLE 9
PHARMACOVIGILANCE AND SAFETY

9.1 **Pharmacovigilance**. The Parties will cooperate with each other with regard to the reporting and handling of safety information involving the Licensed Products in accordance with Applicable Law and regulatory requirements on pharmacovigilance and clinical safety. Within [***] following the Effective Date or as otherwise agreed by the Parties, the Parties will negotiate in good faith and enter into a pharmacovigilance agreement related to the Licensed Products, which will define the pharmacovigilance responsibilities of the Parties and include safety data exchange procedures governing the exchange of information affecting the class and products to enable each Party to comply with all of its legal and regulatory obligations related to such Licensed Products (the "**Pharmacovigilance Agreement**").

9.2 **Global Safety Database**. Denali shall initially set up, hold and maintain the global safety database for Licensed Products with respect to safety data obtained in connection with the Denali Development Activities, and shall be responsible for all safety signaling activities and pharmacovigilance activities related thereto. Following the execution of the Pharmacovigilance Agreement, the Parties will agree to a written plan for the transfer of the contents and ownership of the global safety database for all Licensed Products created by Denali, and pursuant to such plan Denali will transfer such global safety database to Biogen in an electronic format agreed upon by the Parties. Following the completion of such transfer, Biogen will own and maintain the global safety database for all Licensed Products, and shall be responsible for all safety signaling activities and pharmacovigilance activities related thereto.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

9.3 **Costs**. Each Party's and its Affiliates' costs incurred in connection with receiving, recording, reviewing, communicating, reporting, and responding to adverse events with respect to Licensed Compounds and Licensed Products and in establishing and maintaining a global safety database for such Licensed Compounds and Licensed Products shall be allocated as follows: (a) costs pertaining to a Cost-Profit Sharing Product (or any Licensed Compound within such Cost-Profit Sharing Product) incurred prior to receipt of Regulatory Approval of the applicable Cost-Profit Sharing Product shall be included in Eligible Development Expenses and shared in accordance with Section 7.7 (Cost-Profit Sharing); (b) costs pertaining to a Cost-Profit Sharing Product (or any Licensed Compound within such Cost-Profit Sharing Product) in a Cost-Profit Sharing Country incurred after receipt of Regulatory Approval of the applicable Cost-Profit Sharing Product in such Cost-Profit Sharing Country shall be included in Allowable Expenses and shared in accordance with Section 7.7 (Cost-Profit Sharing); or (c) [***].

ARTICLE 10
CONFIDENTIALITY AND NON-DISCLOSURE

10.1 **Confidentiality Obligations**. At all times beginning on the Effective Date and ending upon expiration of the [***] period following termination or expiration of this Definitive LRRK2 Agreement in its entirety, each Party shall, and shall cause its Affiliates and its and their respective officers, directors, employees and agents to, keep confidential and not publish or otherwise disclose to a Third Party and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Definitive LRRK2 Agreement and is necessary for the performance of such Party's obligations, or the exercise of rights expressly granted to such Party under, this Definitive LRRK2 Agreement. The terms, but not the mere existence, of this Definitive LRRK2 Agreement will also be considered Confidential Information for which each Party is a receiving Party for purposes of this Article 10 (Confidentiality and Non-Disclosure). Notwithstanding the foregoing, the confidentiality and non-use obligations under this Section 10.1 (Confidentiality Obligations) shall not apply to any information that the receiving Party can demonstrate by documentation or other competent proof:

10.1.1 has been published by a Third Party or otherwise is or becomes part of the public domain by public use, publication, general knowledge or the like through no wrongful act, fault or negligence on the part of the receiving Party;

10.1.2 is in the receiving Party's possession prior to disclosure by the disclosing Party, to the extent the receiving Party has the right to use and disclose such information;

10.1.3 is subsequently lawfully received by the receiving Party from a Third Party, to the extent the receiving Party has the right to use and disclose such information without breach of any agreement between such Third Party and the disclosing Party;

10.1.4 is published or otherwise generally made available to Third Parties by the disclosing Party without restriction on disclosure; or

10.1.5 is independently developed by or for the receiving Party without reference to, or use or disclosure of, the disclosing Party's Confidential Information.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the receiving Party unless the combination is in the public domain or in the possession of the receiving Party.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

10.2 **Permitted Disclosures**. Each Party may disclose Confidential Information to the extent that such disclosure is:

10.2.1 in the reasonable opinion of the receiving Party's legal counsel, required to be disclosed pursuant to law, regulation or a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial and local governmental body of competent jurisdiction, (including by reason of filing with securities regulators, but subject to Section 10.4 (Public Announcements)); *provided* that the receiving Party shall, unless otherwise prohibited or impractical, first have given advanced written notice (and to the extent possible, at least [***] notice) to the disclosing Party and (other than with regard to disclosures to securities regulators or to comply with applicable securities law, which disclosures must be made in accordance with Section 10.4 (Public Announcements)) give the disclosing Party a reasonable opportunity to take whatever action it deems necessary to protect its Confidential Information. In the event that no such protective order or other remedy is obtained, or the disclosing Party waives compliance with the terms of this Definitive LRRK2 Agreement, the receiving Party shall furnish only that portion of Confidential Information that the receiving Party is advised by counsel is legally required to be disclosed;

10.2.2 made by or on behalf of the receiving Party to the Regulatory Authorities in connection with any filing, application or request for Regulatory Approval in accordance with the terms of this Definitive LRRK2 Agreement; *provided* that reasonable measures shall be taken to assure confidential treatment of such Confidential Information to the extent practicable and consistent with Applicable Law;

10.2.3 made to its or its Affiliates' strategic, financial or legal advisors who have a need to know such disclosing Party's Confidential Information and are either under professional codes of conduct giving rise to expectations of confidentiality and non-use or under written agreements of confidentiality and non-use substantially similar to the obligations of confidentiality and non-use of the receiving Party pursuant to this Article 10 (Confidentiality and Non-Disclosure);

10.2.4 [***];

10.2.5 [***];

10.2.6 [***]); or

10.2.7 a disclosure of the terms of this Definitive LRRK2 Agreement that is made only on a need-to-know basis to Persons who are subject to enforceable obligations of confidentiality and non-use substantially similar to the obligations of confidentiality and non-use in this Article 10 (Confidentiality and Non-Disclosure).

In any case where the foregoing disclosure must be subject to obligations of confidentiality and non-use substantially similar to those under this Article 10 (Confidentiality and Non-Disclosure), it is understood that the duration of such confidentiality and non-use obligations shall be no less than [***] from the date of disclosure, or in the case of a disclosure pursuant to Section 10.2.5 only, such other period as is customary given the context.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

10.3 **Use of Name**. Except as expressly provided in this Definitive LRRK2 Agreement, neither Party shall use the name, logo or Trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material, website or other form of publicity, without the prior written approval of such other Party. Notwithstanding the foregoing, the restrictions imposed by this Section 10.3 (Use of Name) shall not prohibit either Party from using the name, logo or Trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any disclosure: (a) identifying the other Party that, in the opinion of the disclosing Party's counsel, is required by Applicable Law (including stock exchange rules); *provided* that such Party shall submit the proposed disclosure identifying the other Party in writing to the other Party as far in advance as reasonably practicable (and in no event less than [***] prior to the anticipated date of disclosure unless such proposed disclosure is required under Applicable Law, or the rules of an applicable securities exchange, in each case to be made in [***] or less) so as to provide a reasonable opportunity to comment thereon; (b) in connection with a disclosure permitted pursuant to Section 10.2 (Permitted Disclosures); or (c) following a press release or other announcement issued pursuant to Section 10.4 (Public Announcements) using such name, logo or Trademark included in such press release or other announcement in connection with a general description of the arrangement between the Parties or any other subsequent announcement specified as not requiring the other Party's approval under Section 10.4 (Public Announcements).

10.4 **Public Announcements**. The Parties have agreed upon the content of a press release to announce the collaboration, which shall be issued by Denali substantially in the form attached hereto as Schedule 10.4 (Press Release) upon execution of this Definitive LRRK2 Agreement. Each Party may each disclose to Third Parties the information contained in such press release or any other announcement previously approved by the other Party without the need for further approval by the other Party. Neither Party shall issue any other public announcement, press release or other public disclosure regarding this Definitive LRRK2 Agreement or the Parties' activities hereunder without the other Party's prior written consent (which shall not be unreasonably withheld, delayed or conditioned), except for any such disclosure (a) regarding [***], or (b) any other disclosure that is, in the opinion of the disclosing Party's counsel, required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed, or (c) is otherwise expressly permitted in accordance with this Article 10 (Confidentiality and Non-Disclosure). In the event a Party desires to make such a public announcement regarding (i) [***] or (ii) any other disclosure that is, in the opinion of its counsel, required by Applicable Law or the rules of a stock exchange on which its securities are listed, in each case, such Party shall submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable (and in no event less than [***] prior to the anticipated date of disclosure, unless such proposed disclosure is required under Applicable Law, or the rules of an applicable securities exchange, in each case, to be made in [***] or less) so as to provide a reasonable opportunity to comment thereon.

10.5 **Publications**.

10.5.1 [***].

10.5.2 [***].

10.5.3 [***].

10.6 **Prior Confidentiality**. Any Information disclosed by a Party or its Affiliate to the other Party or its Affiliate prior to the Effective Date under that certain Confidentiality Agreement between the Parties or their respective Affiliates dated [***], as amended [***] ("**Prior CDA**") or the Provisional Collaboration and License Agreement, to the extent related to Licensed Compounds or Licensed Products, shall be deemed to have been disclosed under this Definitive LRRK2 Agreement and subject to the provisions of this Article 10 (Confidentiality and Non-Disclosure).

10.7 [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

10.8 **Survival**. All Confidential Information shall continue to be subject to the terms of this Definitive LRRK2 Agreement for the period set forth in Section 10.1 (Confidentiality Obligations).

ARTICLE 11
REPRESENTATIONS, WARRANTIES AND COVENANTS

11.1 **Mutual Representations and Warranties**. Denali and Biogen each represents and warrants to the other, as of the Effective Date, as follows:

11.1.1 **Organization**. It is duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform its obligations under this Definitive LRRK2 Agreement.

11.1.2 **Authorization**. The execution and delivery of this Definitive LRRK2 Agreement and the performance by it of its obligations hereunder have been duly authorized by all necessary corporate action, and do not violate: (a) such Party's charter documents, bylaws, or other organizational documents; (b) in any material respect, any agreement, instrument, or contractual obligation to which such Party is bound; (c) any requirement of any Applicable Law existing as of the Effective Date and applicable to such Party; or (d) any order, writ, judgment, injunction, decree, determination, or award of any court or governmental agency in effect as of the Effective Date and applicable to such Party.

11.1.3 **Binding Agreement**. This Definitive LRRK2 Agreement is a legal, valid, and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity).

11.1.4 **No Inconsistent Obligation**. It is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Definitive LRRK2 Agreement.

11.1.5 **No Consents**. Except for any filings that may be required to comply with Antitrust Law (as defined in the Stock Purchase Agreement), no governmental authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any Applicable Laws currently in effect, is or will be necessary for, on in connection with, the transaction contemplated by this Definitive LRRK2 Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of its obligations under this Definitive LRRK2 Agreement and such other agreements.

11.1.6 **Debarment**. Neither it nor any of its employees nor to its knowledge, any of the agents performing hereunder, has ever been, is currently, or is the subject of a proceeding that could lead to it or such employees or agents becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual. For purposes of this provision, the following definitions shall apply:

(a) A "**Debarred Individual**" is an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from providing services in any capacity to a Person that has an approved or pending drug or biological product application.

(b) A "**Debarred Entity**" is a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or Affiliate of a Debarred Entity.

(c) An "**Excluded Individual**" or "**Excluded Entity**" is (i) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services, or (ii) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA).

(d) A "**Convicted Individual**" or "**Convicted Entity**" is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §335a (a) or 42 U.S.C. §1320a - 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

11.2 **Additional Representations and Warranties of Denali**. Denali further represents and warrants to Biogen, as of the [***] as follows:

11.2.1 It has the full right, power and authority to grant all of the licenses and rights granted to Biogen under this Definitive LRRK2 Agreement.

11.2.2 No claim, suit, proceeding, settlement, arbitration, citation, summons, or subpoena of any nature, civil, criminal, regulatory or otherwise, in law or in equity, has been brought or obtained against Denali or any of its Affiliates relating to the Denali IP. No claim, suit, proceeding, arbitration, citation, summons, or subpoena of any nature, civil, criminal, regulatory or otherwise, in law or in equity, to Denali's knowledge, has been threatened in writing by any person: [***].

11.2.3 To Denali's knowledge: [***].

11.2.4 (a) [***] that are owned or Controlled by Denali or any of its Affiliates that are [***] to Develop, Manufacture, Commercialize or otherwise Exploit any Licensed Compound or Licensed Product; (b) [***]; and (c) [***].

11.2.5 To Denali's knowledge, the Denali Patents with respect to which Denali controls Prosecution and Maintenance activities are being prosecuted in the respective patent offices in the Territory in accordance with Applicable Law.

11.2.6 To Denali's knowledge, all fees required to be paid by Denali in any jurisdiction where a Denali Patent with respect to which Denali controls prosecution and maintenance activities has issued in order to maintain such Denali Patent in such jurisdiction have been timely paid and to Denali's knowledge, the Denali Patents that have issued are subsisting, valid and enforceable.

11.2.7 [***].

11.2.8 Denali has not previously assigned, transferred, conveyed or granted any license or other rights under the Denali IP that would conflict with or limit the scope of any of the rights or licenses granted to Biogen hereunder.

11.2.9 To Denali's knowledge, no Person is infringing or threatening to infringe or misappropriating or threatening to misappropriate or otherwise violating or threatening to violate the Denali IP.

11.2.10 Denali's rights, title and interests to all Denali IP are free of any lien or security interest.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

11.2.11 No written claim has been filed, or to Denali's knowledge, threatened in writing, against it by any Third Party alleging that the conception, development, or reduction to practice of the Denali IP owned by Denali involve the misappropriation of trade secrets or other violation of the rights or property of any Person.

11.2.12 Denali has conducted, and to Denali's knowledge, its contractors and consultants have conducted, all Development and Manufacturing of the Licensed Compounds in accordance with Applicable Law.

11.2.13 Denali has obtained, or caused its Affiliates, as applicable, to obtain, assignments from the inventors of any Denali IP who were employees of Denali or its Affiliates at the time of the invention, of all inventorship rights to such Denali IP, and, to Denali's knowledge, all such assignments are valid and enforceable.

11.2.14 Except for Existing Denali Agreements, there are no Third Party agreements pursuant to which Denali is granted an exclusive license under any Patents or Information included in the Denali IP, and no Third Party has any rights, title or interests in or to, or any license under, any such Denali IP that would conflict with the rights and licenses granted to Biogen hereunder.

11.2.15 Denali has provided Biogen with a redacted copy of each Existing Denali Agreements, and each such agreement is in full force and effect, and no written notice of default or termination has been received or given under any such agreement, and, to Denali's knowledge, there is no act or omission by Denali or its Affiliates that would provide a right to terminate any such agreement.

11.2.16 Denali and its Affiliates have taken commercially reasonable measures consistent with industry practices to protect the secrecy, confidentiality and value of all Denali Know-How that constitutes trade secrets under Applicable Law (including requiring all employees, consultants and independent contractors to execute binding and enforceable agreements requiring all such employees, consultants, and independent contractors to maintain the confidentiality of such Denali Know-How) and, to Denali's knowledge, such Denali Know-How has not been used or disclosed to any Third Party except pursuant to such confidentiality agreements, and to Denali's knowledge, there has not been a material breach by any party to such confidentiality agreements.

11.2.17 To Denali's knowledge, [***]

11.3 **Additional Covenants of Denali**. Denali covenants to Biogen as follows:

11.3.1 [***];

11.3.2 [***];

11.3.3 [***];

11.3.4 [***]; and

11.3.5 If Denali, or any of its employees (and to the extent Denali is aware of the situation, its agents performing hereunder), became, become or are the subject of a proceeding that could lead to a Person becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual, Denali shall promptly notify Biogen, and Biogen shall have the option, at its sole discretion, to prohibit such Person from performing work under this Definitive LRRK2 Agreement.

11.4 **Additional Representations and Warranties of Biogen**. Biogen further represents and warrants to Denali, as of the Effective Date, as follows:

11.4.1 [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

11.4.2 [***].

11.5 **Additional Covenants of Biogen**. Biogen covenants to Denali as follows:

11.5.1 [***];

11.5.2 [***];

11.5.3 [***]; and

11.5.4 If Biogen or its Affiliates, or any of its or their respective employees (and to the extent Biogen is aware of the situation, its or their respective agents performing hereunder), became, become or are the subject of a proceeding that could lead to a Person becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual, Biogen shall promptly notify Denali, and Denali shall have the option, at its sole discretion, to prohibit such Person from performing work under this Definitive LRRK2 Agreement.

11.6 **DISCLAIMER**. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

ARTICLE 12
INDEMNITY; LIMITATIONS OF LIABILITY; INSURANCE

12.1 **Indemnification of Denali**. Biogen shall indemnify Denali, its Affiliates and its and their respective directors, officers, employees and agents ("**Denali Indemnitees**") and defend and hold each of them harmless, from and against any and all losses, damages, liabilities, penalties, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Indemnified Losses**") in connection with any and all suits, investigations, claims, or demands of Third Parties (collectively, "**Third Party Claims**") incurred by or rendered against the Denali Indemnitees after the Effective Date and arising from or occurring as a result of:

(a) the Development, Manufacture, Commercialization or other Exploitation of Licensed Compounds or Licensed Products, including any Independent Study, by or under the authority of Biogen (other than by or under the authority of Denali or Denali's Affiliates or Sublicensees) at any time after the Effective Date; or

(b) the gross negligence, reckless conduct or willful misconduct on the part of Biogen or its Affiliates or their respective directors, officers, employees or agents in performing its or their obligations under this Definitive LRRK2 Agreement; or

(c) a breach by Biogen of this Definitive LRRK2 Agreement, including any breach of a representation, warranty or covenant by Biogen made under Article 11 (Representations, Warranties and Covenants);

except in the case of clauses (a) through (c), to the extent of those Indemnified Losses for which Denali, in whole or in part, has an obligation to indemnify Biogen pursuant to Section 12.2 (Indemnification of Biogen) hereof, as to which Indemnified Losses each Party shall indemnify the other to the extent of their respective liability for such Indemnified Losses.

12.2 **Indemnification of Biogen**. Denali shall indemnify Biogen, its Affiliates and its and their respective directors, officers, employees and agents ("**Biogen Indemnitees**"), and defend and hold each of them harmless, from and against any and all Indemnified Losses in connection with any and all Third Party Claims incurred by or rendered against the Biogen Indemnitees after the Effective Date and arising from or occurring as a result of:

(a) the Development, Manufacture, Commercialization or other Exploitation of the Licensed Compounds and Licensed Products, including any Independent Study, by or under the authority of Denali (other than by or under the authority of Biogen or Biogen's Affiliates or Sublicensees), whether before, during or after the Term;

(b) the gross negligence, reckless conduct or willful misconduct on the part of Denali or its Affiliates or its or their respective directors, officers, employees, and agents in performing its obligations under this Definitive LRRK2 Agreement;

(c) a breach by Denali of this Definitive LRRK2 Agreement, including any breach of a representation, warranty or covenant by Denali made under Article 11 (Representations, Warranties and Covenants).

except, in the case of clauses (a) through (c) above to the extent of those Indemnified Losses for which Biogen, in whole or in part, has an obligation to indemnify Denali pursuant to Section 12.1 (Indemnification of Denali) hereof, as to which Indemnified Losses each Party shall indemnify the other to the extent of their respective liability for the Indemnified Losses.

12.3 **Certain Indemnified Losses**. Any Indemnified Losses and all Out-of-Pocket Costs incurred by a Party to conduct its indemnification obligations under Section 12.1 (Indemnification of Denali) or 12.2 (Indemnification of Biogen), (other than those Indemnified Losses and Out-of-Pocket Costs that result from (a) [***], in connection with any Third Party Claim brought against either Party resulting directly or indirectly from (i) [***] or (ii) [***]. If either Party learns of any Third Party Claim with respect to Indemnified Losses covered by this Section 12.3 (Certain Indemnified Losses), then such Party shall provide the other Party with prompt written notice thereof. The Parties shall confer with respect to how to respond to such Third Party Claim and how to handle such Third Party Claim in an efficient manner. In the absence of such an agreement, each Party shall have the right to take such action as it deems appropriate.

12.4 **Notice of Claim**. All indemnification claims in respect of a Party, its Affiliates, or their respective directors, officers, employees and agents shall be made solely by such Party to this Definitive LRRK2 Agreement ("**Indemnified Party**"). Subject to Section 12.3 (Certain Indemnified Losses) above, the Indemnified Party shall give the indemnifying Party prompt written notice (an "**Indemnification Claim Notice**") of any Indemnified Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under this Article 12 (Indemnity; Limitations of Liability; Insurance), but in no event shall the indemnifying Party be liable for any Indemnified Losses to the extent such Indemnified Losses arise from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Indemnified Loss (to the extent that the nature and amount of such Indemnified Loss is known at such time). The Indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Indemnified Losses and Third Party Claims.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

12.5 **Control of Defense**.

12.5.1 **In General**. Subject to the provisions of Section 8.4 (Infringement Claims by Third Parties), Section 8.5 (Invalidity or Unenforceability Defenses or Actions), and 8.6.3 (Third Party Claims) and Section 12.3 (Certain Indemnified Losses) above, at its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within [***] after the indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgment that the indemnifying Party is liable to indemnify the Indemnified Party in respect of the Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. Upon assuming the defense of a Third Party Claim pursuant to this Section 12.5.1 (In General), the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party that must be reasonably acceptable to the Indemnified Party. In the event the indemnifying Party assumes the defense of such a Third Party Claim, the Indemnified Party shall immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with such Third Party Claim. Should the indemnifying Party assume the defense of such a Third Party Claim, except as provided in Section 12.5.2 (Right to Participate in Defense), the indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim unless specifically requested in writing by the indemnifying Party. In the event that it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against such Third Party Claim, the Indemnified Party shall reimburse the indemnifying Party for any Indemnified Losses incurred by the indemnifying Party in its defense of such Third Party Claim.

12.5.2 **Right to Participate in Defense**. Without limiting Section 12.5.1 (In General), any Indemnified Party shall be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; *provided* that such employment shall be at the Indemnified Party's own expense unless: (a) the employment thereof, and the assumption by the indemnifying Party of such expense, has been specifically authorized by the indemnifying Party in writing; (b) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 12.5.1 (In General) (in which case the Indemnified Party shall control the defense); or (c) the interests of the Indemnified Party and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under Applicable Law, ethical rules or equitable principles.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

12.5.3 **Settlement**. With respect to any Indemnified Losses relating solely to the payment of money damages in connection with a Third Party Claim and that shall not result in the Indemnified Party's becoming subject to injunctive or other relief or otherwise adversely affect the business of the Indemnified Party in any manner, and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Indemnified Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Indemnified Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 12.5.1 (In General), the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Indemnified Loss; *provided* that it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, delayed or conditioned). If the indemnifying Party does not assume and conduct the defense of a Third Party Claim as provided above, then the Indemnified Party may defend against such Third Party Claim. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnified Party shall admit any liability with respect to, or settle, compromise or dispose of, any Third Party Claim in a manner that would have a material adverse effect on the Indemnified Party or admit wrongdoing on behalf of the Indemnified Party without the prior written consent of the indemnifying Party.

12.5.4 **Cooperation**. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall, and shall cause each indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making Indemnified Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the indemnifying Party shall reimburse the Indemnified Party for all its reasonable Out-of-Pocket Costs in connection therewith.

12.6 **Special, Indirect and Other Losses**. EXCEPT (A) [***], (B) [***] AND (C) TO [***], NEITHER PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE FOR INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR CONSEQUENTIAL DAMAGES, INCLUDING LOSS OF PROFITS OR BUSINESS INTERRUPTION (TO THE EXTENT THE SAME ARE CONSEQUENTIAL DAMAGES), HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE IN CONNECTION WITH OR ARISING IN ANY WAY OUT OF THE TERMS OF THIS DEFINITIVE LRRK2 AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THE USE OF A LICENSED COMPOUND OR LICENSED PRODUCT, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

12.7 **Insurance**. Each Party will procure and maintain liability insurance with carriers rated "A-" AM Best rating or equivalent, including product liability insurance, with minimum limits of [***] per claim and in the aggregate, with respect to its activities hereunder and which are consistent with normal business practices of prudent companies similarly situated at all times during which any Licensed Product is being commercially distributed or sold. It is understood that such insurance will not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 12 (Indemnity; Limitations of Liability; Insurance). Clinical Study insurance must be implemented by the sponsor of the Clinical Study in compliance with local Applicable Laws. Each Party will provide the other with written evidence of such insurance upon request. Product liability policies will be maintained for [***] following termination of this Definitive LRRK2 Agreement. Notwithstanding the foregoing, Biogen may self-insure, in whole or in part, the insurance requirements described above, *provided* that Biogen is and continues to be investment grade as determined by reputable and accepted financial rating agencies.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

ARTICLE 13
TERM AND TERMINATION

13.1 **Term**. This Definitive LRRK2 Agreement shall commence on the Effective Date and, unless earlier terminated as set forth below, shall continue in force and effect until the expiration of Biogen's payment obligations under this Definitive LRRK2 Agreement (such period, the "**Term**").

13.2 **Termination for Material Breach**.

13.2.1 Either Party (the "**Non-Breaching Party**") shall have the right to terminate this Definitive LRRK2 Agreement in the case of a material breach of this Definitive LRRK2 Agreement by the other Party (the "**Breaching Party**") if such material breach remains uncured after [***] (or if applicable, the cure period specified in this Section 13.2 (Termination for Material Breach) below) following delivery by the Non-Breaching Party of written notice of such material breach to the Breaching Party (a "**Breach Notice**"). The Breaching Party shall have [***] from its receipt of such Breach Notice to cure such material breach (subject to the dispute resolution procedures set forth in Section 13.2.2). [***].

13.2.2 Notwithstanding any provision in this Definitive LRRK2 Agreement to the contrary, during the [***] cure period described in Section 13.2.1, the Breaching Party may dispute that it has committed such material breach. If the Breaching Party disputes the applicable Breach Notice within such cure period, then such cure period shall be tolled until the dispute is resolved pursuant to the dispute resolution procedures set forth in Section 14.6 (Dispute Resolution), and this Definitive LRRK2 Agreement will remain in full force and effect during the pendency of any such dispute. If, as a result of the application of such dispute resolution procedures, the Breaching Party is determined by the Panel to be in material breach of this Definitive LRRK2 Agreement (an "**Adverse Ruling**") and the Breaching Party fails to complete the actions specified by the Adverse Ruling to cure such material breach within the applicable remainder of such cure period after such ruling is issued (or such longer period as the Panel may determine appropriate), then the Non-Breaching Party may terminate this Definitive LRRK2 Agreement in its entirety upon written notice to the Breaching Party.

13.3 **Termination for Convenience**. Beginning on the date that is [***] following the Effective Date, and on not less than [***] prior written notice to Denali, Biogen will have the right, at its sole discretion, to terminate this Definitive LRRK2 Agreement for convenience (a) in its entirety or (b) with respect to any Region. Any such Region for which this Definitive LRRK2 Agreement is terminated will be referred to hereunder as a "**Terminated Region**", or if this Definitive LRRK2 Agreement is terminated in its entirety, then all Regions in the world will be referred to herein as Terminated Regions.

13.4 **Termination for Shelving**. Denali will have right to terminate this Definitive LRRK2 Agreement in its entirety upon [***] written notice if Biogen has not conducted any [***] activities to advance the [***] for at least [***] and such suspension of activities is not (a) [***], (b) [***], (c) [***], (d) [***] or (e) [***]; *provided* that [***].

13.5 [***]

13.6 **Termination for Insolvency**. To the extent permitted by Applicable Law, either Party may terminate this Definitive LRRK2 Agreement upon the filing or institution of bankruptcy, reorganization, liquidation, or receivership proceedings, upon the appointment of a receiver or trustee over all or substantially all property, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; *provided*, *however*, that in the case of any involuntary bankruptcy proceeding such right to terminate will only become effective if the Party consents to the involuntary bankruptcy or such proceeding is not dismissed within [***] after the filing thereof.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

13.7 **Effects of Termination**. In the event of termination of this Definitive LRRK2 Agreement in its entirety pursuant to Section 13.2 (Termination for Material Breach), Section 13.3 (Termination for Convenience), Section 13.4 (Termination for Shelving), [***] or Section 13.6 (Termination for Insolvency), or with respect to a Region pursuant to Section 13.3 (Termination for Convenience), the Licensed Compounds and Licensed Products within such Terminated Regions will become "**Terminated Compounds**" and "**Terminated Products**", and the following terms of this Section 13.7 (Effects of Termination) shall apply.

13.7.1 **Intellectual Property; Exclusivity; Regulatory Matters; Tech Transfer**.

(a) **Terminating Rights and Obligations.** All rights and licenses granted by Denali to Biogen under Section 6.1 (License Grants to Biogen) through Section 6.7 (Confirmatory Patent License), and all rights and obligations of Biogen with respect thereto, shall immediately terminate with respect to the Terminated Regions, and all rights and licenses granted by Biogen to Denali under Section 6.1 (License Grants to Biogen) through Section 6.7 (Confirmatory Patent License), and all obligations of Denali with respect thereto, shall immediately terminate with respect to the Terminated Regions.

(b) **Licenses Granted by Biogen for Terminated Regions**.

(i) Biogen shall, and hereby does effective as of the effective date of termination, grant Denali: (A) an exclusive license, with the right to grant multiple tiers of sublicenses, to Develop, Manufacture, perform Medical Affairs activities and Commercialize the Terminated Compounds and Terminated Products and, to the extent controlled by Denali following the effective date of termination hereof, other LRRK2 Inhibitors and products containing such LRRK2 Inhibitors ("**Other LRRK2 Inhibitors**") in or for the Terminated Regions under (x) that Information Controlled by Biogen or its Affiliates [***] to Develop, Manufacture, perform Medical Affairs activities or Commercialize Terminated Compounds or Terminated Products in the Terminated Regions and (y) Patents Controlled by Biogen or its Affiliates in the Terminated Regions [***]; and (B) to the extent not licensed under Section 13.7.1(b)(i)(A), a non-exclusive license, with the right to grant multiple tiers of sublicenses, to Develop, Manufacture, perform Medical Affairs activities and Commercialize the Terminated Compounds and Terminated Products and Other LRRK2 Inhibitors, under (i) the Information Controlled by Biogen or its Affiliates [***], and (ii) Patents in the Terminated Regions Controlled by Biogen or its Affiliates [***].

(ii) [***].

(iii) [***].

(iv) [***].

(v) Denali agrees to indemnify the Biogen Indemnitees and defend and hold each of them harmless, from and against any and all Indemnified Losses in connection with any and all Third Party Claims incurred or rendered against the Biogen Indemnitees arising from or occurring as a result of the Development, Manufacture, Commercialization or other Exploitation of any Terminated Product or Terminated Compounds included in the Terminated Region(s) in accordance with Section 12.2 (Indemnification of Biogen) after the effective date of termination.

(c) **[***]**

(d) **[***]**

(e) **[***]**

(f) **Other Matters**.

(i) [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(ii) [***].

(iii) [***].

13.7.2 **Transition**. [***]

(a) **[***]**

(i) [***]

(b) **[***]**

(c) **[***]**

(d) **[***]**

(e) **[***]**

13.8 **Remedies**. Except as otherwise expressly provided herein, termination of this Definitive LRRK2 Agreement (either in its entirety or with respect to a Terminated Region) in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

13.9 **Accrued Rights; Surviving Obligations**.

13.9.1 Termination or expiration of this Definitive LRRK2 Agreement (either in its entirety or with respect to a particular Region) for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Definitive LRRK2 Agreement. Without limiting the foregoing, [***] shall survive the termination or expiration of this Definitive LRRK2 Agreement for any reason.

13.9.2 If this Definitive LRRK2 Agreement is terminated with respect to a Terminated Region but not in its entirety, then following such termination, the foregoing provisions of this Definitive LRRK2 Agreement shall remain in effect with respect to the Terminated Region (to the extent such provisions would survive and apply in the event this Definitive LRRK2 Agreement expires or is terminated in its entirety), and all other provisions not surviving in accordance with the foregoing shall terminate upon termination of this Definitive LRRK2 Agreement with respect to the Terminated Region (other than Biogen's obligations under Section 6.8 (Exclusivity), which shall continue to apply worldwide until termination of this Definitive LRRK2 Agreement in its entirety) and be of no further force and effect (and, for purposes of clarity, all provisions of this Definitive LRRK2 Agreement shall remain in effect with respect to any Region that is not a Terminated Region).

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

13.10 **Rights in Bankruptcy**.

13.10.1 All rights and licenses now or hereafter granted by one Party to the other Party under or pursuant to this Definitive LRRK2 Agreement are, for all purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined in the U.S. Bankruptcy Code. Upon the filing or institution of bankruptcy, reorganization, liquidation, or receivership proceedings, upon the appointment of a receiver or trustee over all or substantially all property, or upon an assignment of a substantial portion of the assets for the benefit of creditors by a Party, such Party agrees that the other Party, as licensee of such rights under this Definitive LRRK2 Agreement, will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. Each Party will, during the Term, create and maintain current copies or, if not amenable to copying, other appropriate embodiments, to the extent feasible, of all intellectual property rights licensed under this Definitive LRRK2 Agreement. Each Party acknowledges and agrees that "embodiments" of intellectual property rights within the meaning of Section 365(n) include laboratory notebooks, cell lines, product samples, and inventory, research studies and data, all Regulatory Approvals (and all applications for Regulatory Approval) and rights of reference therein, in each case, to the extent licensed by a Party to the other Party hereunder, as well as the Denali IP and the Biogen IP (as the case may be), and all information related to the Denali IP and the Biogen IP (as the case may be). If (x) a case under the U.S. Bankruptcy Code is commenced by or against the debtor Party, (y) this Definitive LRRK2 Agreement is rejected as provided in the U.S. Bankruptcy Code, and (z) the non-debtor Party elects to retain its rights hereunder as provided in Section 365(n) of the U.S. Bankruptcy Code, then the debtor Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) will:

(a) provide the non-debtor Party with all such intellectual property rights (including all embodiments thereof) licensed hereunder and held by the debtor Party and such successors and assigns, or otherwise available to them, immediately upon the non-debtor Party's written request. Whenever the debtor Party or any of its successors or assigns provides to the non-debtor Party any of the intellectual property rights licensed hereunder (or any embodiment thereof) pursuant to this Section 13.10 (Rights in Bankruptcy), the non-debtor Party will have the right to perform the debtor Party's obligations hereunder with respect to such intellectual property rights, but neither such provision nor such performance by the non-debtor Party will release the debtor Party's from liability resulting from rejection of the license or the failure to perform such obligations; and

(b) not interfere with the non-debtor Party's rights under this Definitive LRRK2 Agreement, or any agreement supplemental hereto, with respect to such intellectual property rights (including such embodiments), including any right to obtain such intellectual property rights (or such embodiments) from another entity, to the extent provided in Section 365(n) of the U.S. Bankruptcy Code.

13.10.2 All rights, powers and remedies of the non-debtor Party provided in this Section 13.10 (Rights in Bankruptcy) are in addition to and not in substitution for any other rights, powers, and remedies now or hereafter existing at law or in equity (including the U.S. Bankruptcy Code) in the event of the commencement of a case under the U.S. Bankruptcy Code with respect to the debtor Party. The Parties intend the following rights to extend to the maximum extent permitted by Applicable Law, and to be enforceable under U.S. Bankruptcy Code Section 365(n):

(a) the right of access to any intellectual property rights (and all embodiments thereof) of the debtor Party licensed hereunder, or any Third Party with whom the debtor Party contracts to perform any obligation of the debtor Party under this Definitive LRRK2 Agreement, and, in the case of any such Third Party, that is necessary for the Exploitation of Licensed Products and licensed hereunder; and

(b) the right to contract directly with any Third Party to complete the contracted work.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

ARTICLE 14
Miscellaneous

14.1 **Force Majeure**. Neither Party will be held liable to the other Party nor be deemed to have defaulted under or breached this Definitive LRRK2 Agreement for failure or delay performing any obligation under this Definitive LRRK2 Agreement to the extent that such failure or delay is caused by or results from acts of God, embargoes, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotions, strikes, lockouts, or other labor disturbances (other than strikes, lockouts, or labor disturbances involving a Party's own employees), government actions, fire, earthquakes, floods, [***](**Force Majeure**") beyond such Party's reasonable control, and renders the performance impossible or illegal. [***] The affected Party will notify the other Party in writing of any Force Majeure circumstances that may so affect its performance under this Definitive LRRK2 Agreement as soon as reasonably practical (but in any event within [***] after such Force Majeure occurrence), will provide a good faith estimate of the period for which its failure or delay in performance under this Definitive LRRK2 Agreement is expected to continue based on currently available information, and will undertake reasonable efforts necessary to mitigate and overcome such Force Majeure circumstances and resume normal performance of its obligations hereunder as soon a reasonably practicable under the circumstances. If the Force Majeure circumstance continues, then the affected Party will update such notice to the other Party on a [***] basis to provide updated summaries of its mitigation efforts and its estimates of when normal performance under this Definitive LRRK2 Agreement will be able to resume.

14.2 **Export Control**. This Definitive LRRK2 Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Definitive LRRK2 Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity in accordance with Applicable Law.

14.3 **Change of Control; Assignment**.

14.3.1 Without the prior written consent of the other Party, neither Party shall sell, transfer, assign, delegate (except as expressly permitted under this Definitive LRRK2 Agreement), pledge, or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Definitive LRRK2 Agreement or any of its rights or duties hereunder; *provided*, that (a) either Party may make such an assignment without the other Party's consent to: (i) [***] or (ii) [***]. [***] Any attempted assignment or delegation in violation of this Section 14.3 (Change of Control; Assignment) shall be void and of no effect. All validly assigned and delegated rights and obligations of the Parties hereunder shall be binding upon and inure to the benefit of and be enforceable by and against the successors and permitted assigns of Denali or Biogen, as the case may be. The permitted assignee or transferee shall assume all obligations of its assignor or transferor under this Definitive LRRK2 Agreement. Without limiting the foregoing, the grant of rights set forth in this Definitive LRRK2 Agreement shall be binding upon any successor or permitted assignee of a Party, and the obligations of the other Party, including the payment obligations, shall run in favor of any such successor or permitted assignee of such Party's benefits under this Definitive LRRK2 Agreement.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

14.4 **Severability**. If any provision of this Definitive LRRK2 Agreement is held to be illegal, invalid, or unenforceable under any present or future law, and if the rights or obligations of either Party under this Definitive LRRK2 Agreement will not be materially and adversely affected thereby, then: (a) such provision shall be fully severable; (b) this Definitive LRRK2 Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof; (c) the remaining provisions of this Definitive LRRK2 Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom; and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Definitive LRRK2 Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties. In the event a Party seeks to avoid a provision of this Definitive LRRK2 Agreement by asserting that such provision is invalid, illegal or otherwise unenforceable, the other Party shall have the right to terminate this Definitive LRRK2 Agreement upon [***] prior written notice, unless such assertion is eliminated and its effect is cured within such [***] period. Any such termination in accordance with this Section 14.4 (Severability) with respect to as assertion by a Party shall be deemed a termination for breach by such Party pursuant to Section 13.2 (Termination for Material Breach). To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid, or unenforceable in any respect.

14.5 **Governing Law, Jurisdiction and Service**.

14.5.1 **Governing Law**. This Definitive LRRK2 Agreement or the performance, enforcement, breach or termination hereof shall be interpreted, governed by and construed in accordance with the laws of the State of [***], United States, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Definitive LRRK2 Agreement to the substantive law of another jurisdiction; *provided*, that all questions concerning: (a) determination of whether Information and inventions are conceived, discovered, developed or otherwise made by a Party for the purpose of allocating proprietary rights (including Patent, copyright or other intellectual property rights) therein, shall, for purposes of this Definitive LRRK2 Agreement, be made in accordance with Applicable Law in the United States; and (b) the construction or effect of Patents shall be determined in accordance with the laws of the country or other jurisdiction in which the particular Patent has been filed or granted, as the case may be. The Parties agree to exclude the application to this Definitive LRRK2 Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

14.5.2 Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 14.7 (Notices) shall be effective service of process for any action, suit, or proceeding brought against it under this Definitive LRRK2 Agreement in any such court.

14.6 **Dispute Resolution**. Except for disputes resolved by the procedures set forth in Section 2.4.5 (Joint Committee Decision-Making) or 14.10 (Equitable Relief) or for which Biogen has final decision-making authority as provided in Section 2.4.5(c) (Dispute Escalation), if a dispute arises between the Parties in connection with or relating to this Definitive LRRK2 Agreement or any document or instrument delivered in connection herewith or the breach, termination, enforcement, interpretation or validity hereof (a "**Dispute**"), then it shall be resolved pursuant to this Section 14.6 (Dispute Resolution). For the avoidance of doubt, any suit, action or other proceeding arising out of or based upon the Stock Purchase Agreement shall be subject to resolution in accordance with Section 9.13 of the Stock Purchase Agreement and any suit, action or other proceeding arising out of or based upon the Standstill Agreement shall be subject to resolution in accordance with Section 7(d) of the Standstill Agreement.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

14.6.1 **General**. Any Dispute shall first be referred to the Biogen Executive and the Chief Executive Officer of Denali (or his/her executive-level designee) (the "**Chief Executive Officers**"), who shall confer in good faith on the resolution of the issue. Any final decision agreed to by the Chief Executive Officers shall be conclusive and binding on the Parties. If the Chief Executive Officers are not able to agree on the resolution of any such issue within [***] (or such other period of time as mutually agreed by the Chief Executive Officers) after such issue was first referred to them, then [***]

14.6.2 **Intellectual Property Disputes**. In the event that a Dispute arises with respect to the validity, scope, enforceability, inventorship or ownership of any Patent, Trademark or other intellectual property rights, and such Dispute cannot be resolved in accordance with Section 14.6.1 (General), either Party may initiate litigation in a court of competent jurisdiction, notwithstanding Section 14.5 (Governing Law, Jurisdiction and Service), in any country or other jurisdiction in which such rights apply.

14.6.3 **Jurisdiction**. Each of the Parties hereby submits to the jurisdiction of the [***] in any proceeding arising out of or relating to this Agreement, agrees not to commence any suit, action or proceeding relating thereto except in such court, and waives, to the fullest extent permitted by Applicable Law, the right to move or dismiss or transfer any action brought in such court on the basis of any objection to personal jurisdiction, venue or inconvenient jurisdiction. Any rights to trial by jury with respect to any suit, action, proceeding or claim (whether based upon contract, tort or otherwise), directly or indirectly, arising out of or relating to this Agreement hereunder are expressly and irrevocably waived by each of the Parties.

14.6.4 **Disputes Regarding LRRK2 Inhibitor or CNS Penetrant**. In the event of a Dispute as to whether [***], then, either Party may, on written notice to the other Party, refer such matter to an independent Third Party laboratory, acceptable to the other Party (such acceptance not to be unreasonably withheld, conditioned or delayed) ("**Independent Third Party Lab**"). Such Independent Third Party Lab shall perform [***]. The conclusions of the Independent Third Party Lab shall be final and binding on the Parties and the Parties shall share equally the costs of any Independent Third Party Lab engaged by a Party pursuant to this Section 14.6.4 (Disputes Regarding LRRK2 Inhibitor or CNS Penetrant).

14.6.5 **Expert Arbitration**. [***].

(a) [***].

(b) [***].

(c) [***].

(d) [***].

(e) [***].

(f) [***].

(g) [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

14.7 **Notices**.

14.7.1 **Notice Requirements**. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Definitive LRRK2 Agreement shall be in writing, shall refer specifically to this Definitive LRRK2 Agreement and shall be deemed given only if: (a) delivered by hand; (b) sent by facsimile or other reliable electronic transmission (with complete transmission confirmed); or (c) sent by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 14.7.2 (Address for Notice) or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 14.7.1 (Notice Requirements). Such notice shall be deemed to have been given as of the date delivered by hand or transmitted by facsimile or other electronic transmission (with complete transmission confirmed) or on the [***] (at the place of delivery) after deposit with an internationally recognized overnight delivery service. Any notice delivered by facsimile or other electronic transmission shall be confirmed by a hard copy delivered as soon as practicable thereafter by the method described in clause (c) above. This Section 14.7.1 (Notice Requirements) is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Definitive LRRK2 Agreement.

14.7.2 **Address for Notice**.

If to Biogen, to:

Biogen MA Inc.
225 Binney Street
Cambridge, MA 02142
[***]

with a copy (which shall not constitute notice) to:

Ropes & Gray LLP
Prudential Tower
800 Boylston Street
Boston, MA 02199-3600
[***]

If to Denali, to:

Denali Therapeutics Inc.
161 Oyster Point Blvd
South San Francisco, CA 94080
[***]

with a copy (which shall not constitute notice) to:

Wilson Sonsini Goodrich and Rosati P.C.
12235 El Camino Real, Suite 200
San Diego, California 92130
[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

14.8 **Entire Agreement; Amendments**. This Definitive LRRK2 Agreement, together with the Schedules attached hereto, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises, and representations, whether written or oral, with respect thereto are superseded hereby (including that certain Prior CDA and the aspects of the Provisional Collaboration and License Agreement pertaining to Licensed Compounds and Licensed Products). Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Definitive LRRK2 Agreement. Except for amendments and modifications to the Global Development Plan/Budget, and Commercialization Plans in accordance with Article 2 (Collaboration Management), Section 3.1.2 (Amendments and Updates), Section 3.1.4(e)(iv) (Independent Study Opt-In Notice) and Section 5.2.4 (Amendments and Updates), no amendment, modification, release, or discharge shall be binding upon the Parties, unless in writing and duly executed by authorized representatives of both Parties.

14.9 **English Language**. This Definitive LRRK2 Agreement shall be written and executed in, and all other communications under or in connection with this Definitive LRRK2 Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

14.10 **Equitable Relief**. Notwithstanding any provision herein to the contrary, nothing in Section 14.6 (Dispute Resolution) shall preclude either Party from seeking interim or provisional relief, including a temporary restraining order, preliminary injunction or other interim equitable relief concerning a Dispute, if necessary to protect the interests of such Party. This Section 14.10 (Equitable Relief) shall be specifically enforceable. Additionally, each Party acknowledges and agrees that the restrictions set forth in [***] are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered into this Definitive LRRK2 Agreement in the absence of such restrictions, and that any breach or threatened breach of any provision of such Section or Articles may result in irreparable injury to such other Party for which there may be no adequate remedy at law. In the event of an actual or threatened breach of any provision of such Sections or Article, or other default or non-performance with respect to such Section or Article, the aggrieved Party may seek equitable relief (including restraining orders, specific performance or other injunctive relief) in any court or other forum, without first submitting to the dispute resolution procedures set forth in Section 14.6 (Dispute Resolution). Nothing in this Section 14.10 (Equitable Relief) is intended, or should be construed, to limit either Party's right to equitable relief or any other remedy for a breach of any other provision of this Definitive LRRK2 Agreement.

14.11 **Waiver and Non-Exclusion of Remedies**. Any term or condition of this Definitive LRRK2 Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

14.12 **No Benefit to Third Parties**. Except as provided in Article 12 (Indemnity; Limitations of Liability; Insurance) and Section 6.5.1 (Existing Denali Agreements), covenants and agreements set forth in this Definitive LRRK2 Agreement are for the sole benefit of the Parties hereto and successors and permitted assigns of the Parties, and shall not be construed as conferring any rights on any other Persons.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

14.13 **Further Assurance**. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Definitive LRRK2 Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Definitive LRRK2 Agreement.

14.14 **Relationship of the Parties**. Unless otherwise required by applicable tax law, this Definitive LRRK2 Agreement shall not constitute a partnership or a joint venture in whole or in part between any of BIG, BIMA or Denali. [***] Except to the extent expressly stated in this Definitive LRRK2 Agreement, neither Denali, on the one hand, nor Biogen, on the other hand, shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

14.15 **Performance by BIMA and BIG**. [***]

14.16 **Coordination between BIMA and BIG**. [***]

14.17 **Counterparts; Execution**. This Definitive LRRK2 Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. Counterparts may be delivered via electronic mail, including Adobe™ Portable Document Format (PDF) or any electronic signature complying with the U.S. Federal ESIGN Act of 2000, and any counterpart so delivered will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Definitive LRRK2 Agreement.

14.18 **References**. Unless otherwise specified: (a) references in this Definitive LRRK2 Agreement to any Article, Section or Schedule shall mean references to such Article, Section or Schedule of this Definitive LRRK2 Agreement; (b) references in any Section to any clause are references to such clause of such Section; and (c) references to any agreement, instrument, or other document in this Definitive LRRK2 Agreement refer to such agreement, instrument, or other document as originally executed or, if subsequently amended, replaced, or supplemented from time to time, as so amended, replaced, or supplemented and in effect at the relevant time of reference thereto.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

14.19 **Construction**. Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (b) the words "include", "includes" and "including" will be deemed to be followed by the phrase "without limitation," (c) the word "will" will be construed to have the same meaning and effect as the word "shall," (d) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person or entity will be construed to include the person's or entity's successors and assigns, (f) the words "herein," "hereof" and "hereunder", and words of similar import, will be construed to refer to this Definitive LRRK2 Agreement in its entirety and not to any particular provision hereof, (g) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Definitive LRRK2 Agreement, (h) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent," or "approve" or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (i) references to any specific law, rule or regulation, or article, section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, (j) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or," (k) references to any Sections include Sections and subsections that are part of the related Section (*e.g.*, a section numbered "Section 2.2" would be part of "Section 2", and references to "Section 2.2" would also refer to material contained in the subsection described as "Section 2.2(a)") and (l) neither Party or its Affiliates or (sub)licensees shall be deemed acting "on behalf of" or "under the authority of" the other Party. The language of this Definitive LRRK2 Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto. Each Party represents that it has been represented by legal counsel in connection with this Definitive LRRK2 Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Definitive LRRK2 Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions. All amounts (including payment amounts and calculation thereof) are stated in U.S. Dollars unless another currency is specified. To the extent there exists any discrepancy between any internal, alphabetical or numerical cross-reference to a Section, Article or Schedule of this Definitive LRRK2 Agreement and the parenthetical immediately following such cross-reference, the parenthetical shall govern.

[SIGNATURE PAGE FOLLOWS]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

This Definitive LRRK2 Collaboration and License Agreement is executed by the authorized representatives of the Parties as of the Effective Date.

Denali Therapeutics Inc.
By: /s/ Ryan J. Watts
Name: Ryan Watts, Ph.D.
Title: President and CEO

Biogen MA, Inc.
By: /s/ Alfred W. Sandrock, Jr.
Name: Alfred W. Sandrock, Jr.
Title: EVP, R&D

Biogen International GmbH
By: /s/ Frederick Lawson
Name: Frederick Lawson
Title: Senior Director

[SIGNATURE PAGE TO DEFINITIVE LRRK2 COLLABORATION AND LICENSE AGREEMENT]

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Schedule 1.32

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Schedule 1.37

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Schedule 1.57

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Schedule 1.60

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Schedule 1.64

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Schedule 1.75

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Schedule 4.2

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Schedule 7.6.7(c)

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Schedule 7.8.1(a)

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Schedule 10.4

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Exhibit 10.5

Right of First Negotiation, Option and License Agreement

Between

Denali Therapeutics Inc.,

Biogen MA, Inc.

and

Biogen International GmbH

Dated October 6, 2020

[***]

Right of First Negotiation, Option and License Agreement

This **Right of First Negotiation, Option and License Agreement** (this "**Agreement**") is entered into as of October 6, 2020 (the "**Effective Date**") by and among Denali Therapeutics Inc., a Delaware corporation with its principal place of business located at 161 Oyster Point Blvd., South San Francisco, California 94080 ("**Denali**"), Biogen MA, Inc., a corporation organized under the laws of the Commonwealth of Massachusetts having an office at 225 Binney Street, Cambridge, MA 02142 ("**BIMA**"), and Biogen International GmbH, a Gesellschaft mit beschränkter Haftung organized under the laws of Switzerland, whose registered office is at Neuhofstrasse 30, 6340 Baar, Switzerland ("**BIG**," together with BIMA, collectively, "**Biogen**"). Biogen and Denali are each individually referred to as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, the Parties previously entered into that certain Provisional Collaboration and License Agreement, dated as of August 5, 2020 (the "**Provisional Agreement**"), pursuant to which (a) Denali granted to Biogen an exclusive option to obtain an exclusive license under certain intellectual property rights relating to the ATV:Abeta Program, (b) Denali granted to Biogen an exclusive option to obtain an exclusive license under certain intellectual property rights relating to the Option TV Program, and (c) with respect to each of the ROFN Programs, Denali granted Biogen an exclusive right of first negotiation to exclusively negotiate the terms and conditions of a definitive agreement pursuant to which Denali would grant exclusive rights to Biogen with respect to such ROFN Programs to develop, commercialize or otherwise exploit ROFN Products that are the subject of each such ROFN Program; and

WHEREAS, pursuant to Section 1.1 of the Provisional Agreement, the Parties seek to enter into an agreement containing a more detailed set of terms governing the options and rights of first negotiation granted to Biogen as provided in Article 4 of the Provisional Agreement, as provided herein.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, Biogen and Denali hereby agree as follows:

ARTICLE 1 DEFINITIONS

1.1 [***].

1.2 "**Acquired Party**" has the meaning set forth in Section 4.4.3 (Acquisitions by a Third Party that Controls Alternative Option Products).

1.3 "**Acquiring Party**" has the meaning set forth in Section 4.4.2 (Acquisitions of Alternative Option Products).

1.4 "**AD**" means [***].

1.5 "**Adverse Ruling**" has the meaning set forth in Section 14.3.2 (Disputes Regarding Material Breach).

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.6 "**Affiliates**" means, with respect to a Person, any other Person that, directly or indirectly, through one (1) or more intermediaries, controls, is controlled by or is under common control with such Person. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" means (a) the possession, directly or indirectly, of the power to direct the management or policies of a Person, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise or (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of a Person (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity). The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that, in such case, such lower percentage shall be substituted in the preceding sentence, *provided* that such foreign investor has the power to direct the management or policies of such entity.

1.7 "**Agreement**" has the meaning set forth in the preamble.

1.8 "**Alliance Manager**" has the meaning set forth in Section 6.1.1 (Alliance Managers).

1.9 "**ALS**" means [***].

1.10 "**Alternative Option Product**" has the meaning set forth in Section 4.4.1 (Exclusivity).

1.11 [***]

1.12 "**Amyloid Beta**" means [***].

1.13 "**Annual Net Sales**" means the total Net Sales of all Option Products in the Territory in a given Calendar Year.

1.14 "**Applicable Law**" means federal, state, local, national and supra-national laws, statutes, rules, and regulations, including any rules, regulations, regulatory guidelines, or other requirements of the Regulatory Authorities, major national securities exchanges or major securities listing organizations, that may be in effect from time to time during the Term and applicable to a particular activity or country or other jurisdiction hereunder.

1.15 "**Assigned TV Platform IP**" means Assigned TV Platform Patent Rights and Assigned TV Platform Know-How.

1.16 "**Assigned TV Platform Know-How**" means [***].

1.17 "**Assigned TV Platform Patent Rights**" means [***].

1.18 "**ATV:Abeta Program**" means all ATV:Abeta Therapeutics that are Controlled by or on behalf of Denali or its Affiliates prior to the Effective Date [***], and pharmaceutical products containing such ATV:Abeta Therapeutics, including [***].

1.19 "**ATV:Abeta Therapeutic**" means [***]that incorporates (a) [***]and (b) [***]Directed to Amyloid Beta, but for clarity, excluding any viral vector (including adeno-associated virus), any oligonucleotide, or any small molecule.

1.20 [***]

1.21 "**BIG**" has the meaning set forth in the preamble.

1.22 "**BIMA**" has the meaning set forth in the preamble.

1.23 "**Binding Target**" has the meaning set forth in Section 1.261 (Target).

1.24 "**Biogen**" has the meaning set forth in the preamble.

1.25 "**Biogen Background Patent Rights**" means all Patent Rights Controlled by Biogen or its Affiliates as of the Effective Date or at any time during the Term, expressly excluding all Biogen Program Patent Rights and any Joint Program Patent Rights.

1.26 "**Biogen-Enabled Product**" means [***].

1.27 "**Biogen-Enabled Protein**" means [***].

1.28 [***]

1.29 "**Biogen Indemnified Party**" has the meaning set forth in Section 13.1 (Indemnification by Denali).

1.30 "**Biogen IP**" means Biogen Know-How and Biogen Patent Rights.

1.31 "**Biogen Know-How**" means any and all Know-How that is: (a) Controlled by Biogen or its Affiliates as of the Effective Date or during the Term; (b) [***] for the Development of Option Proteins or Option Products or the sale or offer for sale or other Commercialization of Option Products [***].

1.32 "**Biogen Option Development Activities**" has the meaning set forth in Section 5.1 (Development and Manufacturing Activities during the Option Term).

1.33 "**Biogen Patent Rights**" means all Biogen Program Patent Rights and any other Patent Rights Controlled by Biogen or its Affiliates, in each case, that are [***] for the conduct of the Denali Option Development Activities, the Denali Manufacturing Activities, or to perform Denali's other obligations under this Agreement.

1.34 "**Biogen Program IP**" means Biogen Program Know-How and Biogen Program Patent Rights.

1.35 "**Biogen Program Know-How**" means [***].

1.36 "**Biogen Program Patent Rights**" means [***].

1.37 [***]

1.38 [***]

1.39 "**Biosimilar Product**" means, with respect to a given Option Product in a given country, a biological product that is (a) not marketed or sold by or under the authority of Biogen, its Affiliates or Sublicensees and (b) (i) approved by the applicable Regulatory Authority [***] with such Option Product and (ii) with respect to the United States, is a product [***] and with respect to any jurisdiction outside of the United States, [***] in such jurisdiction.

1.40 "**Breach Notice**" has the meaning set forth in Section 14.3.1 (Breach Notice).

1.41 "**Breaching Party**" has the meaning set forth in Section 14.3.1 (Breach Notice).

1.42 "**Business Day**" means a day, other than a Saturday or Sunday, on which banking institutions in Boston, Massachusetts, U.S.A. and San Francisco, California, U.S.A. are open for business.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.43 "**Calendar Quarter**" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter shall end on the last day of the Term.

1.44 "**Calendar Year**" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

1.45 "**CD TV Moiety Protein**" means [***].

1.46 [***]

1.47 "**Change of Control**" with respect to a Party, means any transaction or a series of related transactions in which such Party: (a) sells, conveys or otherwise disposes of all or substantially all, whether directly or indirectly, of its assets or business to any Person (other than to an Affiliate of such Party; *provided* that such Person was an Affiliate of such Party prior to the Effective Date); or (b) (i) merges, consolidates with, or is acquired by any other Person (other than an Affiliate of such Party, *provided* that such Person was an Affiliate of such Party prior to the Effective Date); or (ii) effects any other transaction or series of related transactions; in each case of subsection (i) or (ii), such that the stockholders of such Party immediately prior thereto, in the aggregate, no longer own, directly or indirectly, beneficially or legally, more than fifty percent (50%) of the outstanding voting securities, capital stock or other ownership interest of the surviving Person following the closing of such merger, consolidation, other transaction or series of related transactions (such Person described in clauses (a), (b) or (c), a "**Third Party Acquiror**"). Notwithstanding the foregoing, a bona fide financing transaction (including any public offering of a Party's capital stock) shall not be deemed a Change of Control.

1.48 "**Chief Executive Officers**" has the meaning set forth in Section 15.6.1 (General).

1.49 "**Clinical Data**" means the original source patient data and case report forms (CRFs) collected or generated by, on behalf of, or under the authority of Biogen with respect to Clinical Trials of any Option Protein or Option Product, together with all analysis, reports, and results with respect thereto.

1.50 "**Clinical Trial**" means any Phase I Trial, Phase II Trial, Phase III Trial, or any such other test or study in human subjects.

1.51 "**Clinical Trial Material**" means an Option Product that is intended for administration and dosing to humans in Clinical Trials, but not intended for commercial sale (for example, in a form that does not include external packaging).

1.52 "**CMC**" means the chemistry, Manufacturing and controls of a given product.

1.53 "**CMC Budget**" has the meaning set forth in Section 8.2.3 (CMC Plan).

1.54 "**CMC Plan**" has the meaning set forth in Section 8.2.3 (CMC Plan).

1.55 "**CMO**" has the meaning set forth in Section 8.2.4 (CMOs).

1.56 "**Co-Co Amendment**" has the meaning set forth in Section 2.4.2(a) (Co-Co Opt In Notice).

1.57 "**Co-Co Opt In Notice**" has the meaning set forth in Section 2.4.2(a) (Co-Co Opt In Notice).

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.58 "**Co-Co Rights**" means, with respect to a Product and a given Party, [***].

1.59 "**Combination Product**" means an Option Product that is (a) sold in the form of a combination that contains or comprises an Option Protein together with one or more other therapeutically active pharmaceutical agents (whether coformulated or copackaged or otherwise sold together as a single unit) ("**Other Component**"), and (b) sold for a single invoice price. For purposes of the foregoing, none of the following shall be deemed to be an Other Component [***]

1.60 "**Commercial Milestone Event**" has the meaning set forth in Section 9.3.2 (Commercial Milestones).

1.61 "**Commercial Milestone Payment**" has the meaning set forth in Section 9.3.2 (Commercial Milestones).

1.62 "**Commercialization**," means with respect to any product, any and all activities directed to: the marketing, advertising, promotion, distribution, import, export, offering for sale, and sale of such product, product samples, pre-launch activities to prepare a market for potential sales; modeling and pharmaco-economic studies, epidemiological studies, expanded access programs and associated registries and activities required to fulfill ongoing regulatory obligations; government affairs, and public policy activities; patient services, patient advocacy engagement, and adverse event reporting; the preparation and submission of Regulatory Submissions and interacting with Regulatory Authorities regarding any of the foregoing; and pricing and reimbursement activities, including seeking and maintaining any required Reimbursement Approvals; but excluding, in each case, any activities directed to Manufacturing, Development, or Medical Affairs. "**Commercialize**," "**Commercializing**," and "**Commercialized**" will be construed accordingly.

1.63 [***]

1.64 "**Commercially Reasonable Efforts**" means, [***].

1.65 [***]

1.66 "**Confidential Information**" means any proprietary Know-How or data provided orally, visually, in writing or other form by or on behalf of one (1) Party (or an Affiliate or representative of such Party or such Party's Affiliate) to the other Party (or to an Affiliate or representative of such Party or such Party's Affiliate) in connection with this Agreement, whether prior to, on, or after the Provisional Agreement Execution Date, including Know-How pertaining to the terms of the Provisional Agreement (to the extent pertaining to Option Proteins, Option Products, ROFN Proteins, or ROFN Products) or this Agreement, any Option Protein, Option Product, ROFN Protein or ROFN Product (including relevant Regulatory Submissions and Clinical Data), any Exploitation of an Option Protein, Option Product, ROFN Protein or ROFN Product, any Know-How with respect thereto developed by or on behalf of the disclosing Party or its Affiliates (including Biogen Know-How, Option Know-How or TV Platform Know-How), or the scientific, regulatory or business affairs or other activities of either Party. Notwithstanding the foregoing, Joint Program Know-How and all Regulatory Submissions generated after the Provisional Agreement Execution Date and owned by a Party pursuant to this Agreement shall be deemed to be the Confidential Information of both Parties, and the restrictions on use and disclosure in Section 11.2 (Non-Disclosure and Non-Use Obligation) and Section 11.4 (Permitted Disclosures) shall be deemed to apply to each Party as a receiving Party, regardless of which Party initially generated or disclosed the relevant Joint Program Know-How or Regulatory Submissions, as applicable, to the other Party in connection with this Agreement.

1.67 "**Confidentiality Agreement**" means that certain Confidentiality Agreement between the Parties dated as of October 17, 2019, as amended on July 12, 2020.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.68 "**Contingent Right**" has the meaning set forth in Section 3.2.6 (Contingent Rights).

1.69 "**Control**" or "**Controlled**" means the possession by a Party or its Affiliate (whether by ownership, license or otherwise other than pursuant to this Agreement) of (a) with respect to any tangible Know-How, the legal authority or right to physical possession of such tangible Know-How, with the right to provide such tangible Know-How to the other Party on the applicable terms set forth herein, or (b) with respect to Patent Rights, Regulatory Approvals, Regulatory Submissions, intangible Know-How or other Intellectual Property or subject matter, the legal authority or right to grant a license, sublicense, access, or right to use (as applicable) to the other Party under such Patent Rights, Regulatory Approvals, Regulatory Submissions, intangible Know-How or other Intellectual Property or subject matter on the applicable terms set forth herein, in each case ((a) and (b)), without breaching or otherwise violating the terms of any arrangement or agreement with a Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such access, right to use, licenses or sublicense, and (c) with respect to any product or a component thereof, the possession by a Party of the ability (whether by sole or joint ownership, license or otherwise, other than pursuant to the license grants under this Agreement) to grant a license or sublicense on the applicable terms set forth herein of Patent Rights within clause (b) above that claim such product or component or proprietary Know-How within clause (a) or (b) above that is used in connection with the exploitation of such product or component. Notwithstanding any provision to the contrary set forth in this Agreement, a Party and its Affiliates will not be deemed to "Control" any Patent Rights, Regulatory Approvals, Regulatory Submissions, Know-How or other Intellectual Property or subject matter that is [***].

1.70 "**Convicted Entity**" has the meaning set forth in Section 10.1.6(d).

1.71 "**Convicted Individual**" has the meaning set forth in Section 10.1.6(d).

1.72 "**Cover**," "**Covering**," or "**Covered**" means, with respect to a product, technology, process, method, or mode of administration that, in the absence of ownership of or a license granted under a particular claim of a Patent Right, the manufacture, use, offer for sale, sale, or importation of such product or the practice of such technology, process, method, or mode of administration would infringe such claim or, in the case of a claim that has not yet issued, would infringe such claim if it were to issue as currently pending.

1.73 "**Debarred Entity**" has the meaning set forth in Section 10.1.6(b).

1.74 "**Debarred Individual**" has the meaning set forth in Section 10.1.6(a).

1.75 "**Definitive LRRK2 Agreement**" means the Definitive LRRK2 Collaboration and License Agreement, dated as of October 4, 2020, by and between the Parties.

1.76 "**Denali**" has the meaning set forth in the preamble.

1.77 [***]

1.78 "**Denali Indemnified Party**" has the meaning set forth in Section 13.2 (Indemnification by Biogen).

1.79 "**Denali IP**" has the meaning set forth in Section 10.2.2.

1.80 "**Denali Know-How**" has the meaning set forth in Section 10.2.17.

1.81 "**Denali Manufacturing Activities**" has the meaning set forth in Section 8.2.4 (CMOs).

1.82 "**Denali Manufacturing Know-How**" means all Option Know-How that is used by or on behalf of Denali to Manufacture any Option Product (for which Biogen has exercised its Option) or component thereof.

1.83 "**Denali Option Development Activities**" means, with respect to a given Option Program, all Development activities conducted by or on behalf of Denali with respect to such Option Program during the applicable Option Term for such Option Program.

1.84 [***]

1.85 "**Denali Program IP**" means Denali Program Know-How and Denali Program Patent Rights.

1.86 "**Denali Program Know-How**" means all Program Know-How that is developed or invented solely by Denali's Representatives.

1.87 "**Denali Program Patent Rights**" means all Program Patent Rights that claim any Denali Program Know-How.

1.88 [***]

1.89 [***]

1.90 "**Develop**" or "**Development**" means, with respect to any product, any and all internal and external research or development activities regarding such product, including (a) research, non-clinical testing and activities, IND-enabling pre-clinical studies and other pre-clinical activities, and Clinical Trials, (b) test method development and stability testing, process development and formulation development and toxicology, and (c) preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct Clinical Trials or to obtain Regulatory Approval of such product (excluding any activities reasonably necessary for obtaining Reimbursement Approval, but not for other elements of the Regulatory Approval) and interacting with Regulatory Authorities regarding any of the foregoing; but excluding, in each case, any activities directed to Manufacturing, Medical Affairs, or Commercialization. "**Develop**," "**Developing**," and "**Developed**" will be construed accordingly.

1.91 "**Development Milestone Event**" has the meaning set forth in Section 9.3.1 (Development Milestones).

1.92 "**Development Milestone Payment**" has the meaning set forth in Section 9.3.1 (Development Milestones).

1.93 "**Directed**" means: (a) in the context of a therapeutic and a Binding Target, that the primary mechanism of action of such therapeutic is [***] such Binding Target; or (b) in the context of a therapeutic and a Function Target, that the primary intended mechanism of action of such therapeutic is [***] such Function Target.

1.94 "**Disclosing Party**" has the meaning set forth in Section 11.2 (Non-Disclosure and Non-Use Obligations).

1.95 [***]

1.96 "**Dispute**" has the meaning set forth in Section 15.6 (Dispute Resolution).

1.97 "**Divestiture**" means (a) the divestiture of an Alternative Option Product through (i) an outright sale or assignment of all rights in such Alternative Option Product to a Third Party or (ii) an exclusive out-license to a Third Party of all Development and Commercialization rights with respect to such Alternative Option Product, in each case, with no further role, influence, or authority of the applicable Party, directly or indirectly, with respect to such Alternative Option Product or (b) the complete cessation of all Development and Commercialization activities with respect to such Alternative Option Product, *provided* that [***]. When used as a verb, "**Divest**" and "**Divested**" means to cause a Divestiture.

1.98 "**Dollar**" means the U.S. dollar, and "$" will be interpreted accordingly.

1.99 "**Drug Approval Application**" means a New Drug Application as defined in the FD&C Act ("**NDA**"), or any corresponding application for Regulatory Approval in the Territory, including, with respect to the European Union, a marketing authorization application (an "**MAA**") filed with the EMA pursuant to the Centralized Approval Procedure or an MAA filed with the PMDA, including, in each case, all supplements, amendments, variations, extensions and renewals thereof.

1.100 "**Effective Date**" has the meaning set forth in the preamble.

1.101 "**EMA**" means the European Medicines Agency and any successor agency(ies) or authority having substantially the same function.

1.102 "**Excluded Entity**" has the meaning set forth in Section 10.1.6(c).

1.103 "**Excluded Individual**" has the meaning set forth in Section 10.1.6(c).

1.104 "**Excluded Targets**" means [***].

1.105 "**Existing Third Party Agreements**" means the agreements listed on Schedule 1.105 (Existing Third Party Agreements).

1.106 "**Existing Third Party Manufacturing IP**" has the meaning set forth in Section 8.7.2.

1.107 "**Exploit**" means to make, have made, use, import, export, offer to sell, sell, Develop, Manufacture, perform Medical Affairs activities, Commercialize or otherwise exploit. "**Exploitation**" will be construed accordingly.

1.108 "**F-Star Agreements**" means [***].

1.109 "**FD&C Act**" means the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*., as the same may be amended or supplemented from time to time, together with any rules, regulations, and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.110 "**FDA**" means the U.S. Food and Drug Administration, or any successor agency thereto.

1.111 "**Field**" means any and all uses.

1.112 "**Final Royalty Report**" has the meaning set forth in Section 9.4.3(b).

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.113 "**First Commercial Sale**" means, with respect to a particular Option Product in a particular country in the Territory, the first sale of such Option Product to a Third Party (other than a Sublicensee) for distribution, use or consumption in such country or region. First Commercial Sale excludes transfers of Option Product to Third Parties as *bona fide* samples, as donations, for the performance of Clinical Trials, or for similar purposes in accordance with Applicable Law pertaining to any expanded access program, any compassionate sales or use program (including named patient program or single patient program), or any indigent program.

1.114 "**Force Majeure**" has the meaning set forth in Section 15.1 (Force Majeure).

1.115 "**FTE**" means the equivalent of the work of one (1) employee full time for one (1) Calendar Year (consisting of at least a total of [***] hours per Calendar Year). Each employee utilized by a Party in connection with its performance under this Agreement may be less than or greater than one FTE based on the hours actually worked by such employee performing Development, Medical Affairs, Commercialization or Manufacturing activities with respect to an Option Product (or Option Proteins included in an Option Product) and shall be treated as an FTE on a pro rata basis based upon the actual number of such hours worked divided by [***].

1.116 "**FTE Costs**" means, with respect to a Party for any period, the applicable FTE Rate multiplied by the applicable number of FTEs of such Party performing Development, Medical Affairs, Commercialization or Manufacturing activities during such period.

1.117 "**FTE Rate**" means an initial rate of [***] for the Calendar Years [***]; *provided* that, commencing with Calendar Year [***] and for each subsequent Calendar Year thereafter, the FTE Rate shall be adjusted annually, effective January 1 of the applicable Calendar Year, to [***], unless the Parties otherwise agree.

1.118 "**Function Target**" has the meaning set forth in Section 1.261 (Target).

1.119 "**GAAP**" means United States generally accepted accounting principles, which principles are currently used at the relevant time and consistently applied by the applicable Party.

1.120 [***]

1.121 "**Good Clinical Practices**," "**GCP**" or "**cGCP**" means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in the guidelines adopted by the International Conference on Harmonization ("**ICH**"), titled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," (or any successor document) including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the EMA, PMDA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time.

1.122 "**Good Laboratory Practices**," "**GLP**" or "**cGLP**" means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in 21 C.F.R. Part 58 (or any successor statute or regulation), including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the EMA, PMDA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time, including applicable guidelines promulgated under the ICH.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.123 "**Good Manufacturing Practice**," "**GMP**" or "**cGMP**" means the then-current good manufacturing practices required by the FDA, as set forth in the FD&C Act, as amended, and the regulations promulgated thereunder, for the manufacture and testing of pharmaceutical materials, and comparable Applicable Law related to the manufacture and testing of pharmaceutical materials in jurisdictions outside the U.S., including the quality guideline promulgated by the ICH designated ICH Q7A, titled "Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients" and the regulations promulgated thereunder, in each case as they may be updated from time to time.

1.124 "**Governmental Authority**" means any court, tribunal, arbitrator, agency, commission, department, ministry, official, authority or other instrumentality of any national, state, county, city or other political subdivision.

1.125 [***]

1.126 "**ICH**" has the meaning set forth in Section 1.121 (Good Clinical Practices).

1.127 "**In-License Agreement**" means any Product In-License Agreements or Platform In-License Agreement.

1.128 "**IND**" means an Investigational New Drug application as defined in 21 C.F.R. Part 312 or any comparable filings outside of the United States that are required to commence Clinical Trials in such country or region, and all supplements or amendments that may be filed with respect to the foregoing.

1.129 "**IND-Enabling Study**" means a toxicology study of a product (a) that is conducted in compliance with GLP regulations in an animal species appropriate to satisfy applicable regulatory requirements, (b) that is otherwise designed to satisfy applicable regulatory requirements, and (c) the data and results from which are intended to support the filing of an IND for such product with the applicable Regulatory Authority.

1.130 "**Indemnification Claim Notice**" has the meaning set forth in Section 13.3.1 (Notice of Claim).

1.131 "**Indemnified Party**" has the meaning set forth in Section 13.3.1 (Notice of Claim).

1.132 "**Indication**" means a disease or pathological condition [***]

1.133 [***]

1.134 [***]

1.135 [***]

1.136 "**Initiation**" means, with respect to a Clinical Trial or IND-Enabling Study of an Option Product, the [***] in such Clinical Trial or the [***] in such IND-Enabling Study.

1.137 "**Intellectual Property**" means all Patent Rights, rights to inventions, copyrights, design rights, trademarks, trade secrets, Know-How, and all other intellectual property rights (whether registered or unregistered) and all applications and rights to apply for any of the foregoing, anywhere in the world.

1.138 "**IP Counsels**" has the meaning set forth in Section 4.3.2(c) ([***] Third Party IP Dispute).

1.139 "**Joint Program IP**" means all Joint Program Know-How and Joint Program Patent Rights.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.140 "**Joint Program Know-How**" means any Program Know-How, other than Assigned TV Platform Know-How, developed or invented jointly by a Party's Representatives, on the one hand, and the other Party's Representatives, on the other hand.

1.141 "**Joint Program Patent Rights**" means those Program Patent Rights that claim Joint Program Know-How, but do not claim any Assigned TV Platform Know-How.

1.142 "**JSC**" has the meaning set forth in Section 6.2.1 (Formation).

1.143 "**Know-How**" means all knowledge of a technical, scientific, business and other nature, including know-how, inventions, technology, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, Clinical Data, and other biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, materials, reagents (*e.g.*, plasmids, proteins, cell lines, assays and compounds) and biological methodology; in each case (whether or not confidential, proprietary, patented or patentable, or of commercial advantage) in written, electronic or any other form now known or hereafter developed.

1.144 "**Liability**" has the meaning set forth in Section 13.1 (Indemnification by Denali).

1.145 "**MAA**" has the meaning set forth in Section 1.98 (Drug Approval Application).

1.146 "**Major European Market**" means France, Germany, Italy, Spain and United Kingdom.

1.147 "**Major Market**" means the United States, each Major European Market, Japan and China.

1.148 "**Manufacture**" means, with respect to any product, any and all activities directed to manufacturing, processing, packaging, labeling, filling, finishing, assembly, quality assurance, quality control, testing, and release, shipping, supply, or storage of such product (or any components or process steps involving such product [***]), placebo, or comparator agent, as the case may be, including qualification, validation, and scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, quality assurance technical support activities qualification and audit of clinical and commercial manufacturing facilities, and stability testing, but excluding any activities directed to Development, Medical Affairs, or Commercialization. "**Manufacturing**" and "**Manufactured**" will be construed accordingly.

1.149 "**Manufacturing Costs**" means the [***] manufacturing cost incurred by a Party or its Affiliate for an Option Protein or Option Product and in accordance with GAAP (consistently applied by such Party and its Affiliates with respect to all protein therapeutics and products), which will be the sum of:

(a) [***]

1.150 "**Manufacturing Technology Transfer**" has the meaning set forth in Section 8.7.1.

1.151 "**Materials**" has the meaning set forth in Section 5.5 (Materials).

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.152 "**Medical Affairs**" means any and all activities conducted by or on behalf of a Party's or any of its Affiliates' personnel designated as medical science liaisons (or similar title) as well as other personnel within their respective medical affairs departments interacting with physicians or other healthcare professionals who utilize or conduct research related to a drug or biological product, including communications with key opinion leaders, medical education, symposia, advisory boards (to the extent related to medical affairs or clinical guidance), and other medical programs and communications, including educational grants and fellowships, research grants (including conducting investigator-initiated studies following Regulatory Approval), charitable donations, medical resourcing and allocation, medical and scientific platform, content development, publications, and communications, KME and KOL engagement, congress planning, real-world evidence generation through registry or phase IV studies, conducting advisory board meetings or other consultant programs, the purpose of which is to obtain advice and feedback related to the launch of a given product, post-approval investigator initiated trials or scientific research agreements, activities related to patient registries, physician and nurse services, education and support, in each case, to the extent related to medical affairs and not to activities that involve the promotion, marketing, sale, or other Commercialization of Option Products. Medical Affairs excludes any activities directed to Manufacturing, Development, or Commercialization.

1.153 "**Milestone Payments**" has the meaning set forth in Section 9.3.3 (Sales Milestones).

1.154 "**MS**" means [***].

1.155 "**NDA**" has the meaning set forth in Section 1.98 (Drug Approval Application).

1.156 "**Net Sales**" means with respect to an Option Product, the gross amount invoiced or received in a country by or on behalf of Biogen or its Affiliates or Sublicensees (each of the foregoing Persons, a "**Selling Party**") for the sale or other disposition of such Option Product in such country to Third Parties (including Third Party Distributors) in *bona fide* arms' length transactions in the Territory, less the following deductions, in each case, pertaining specifically to such Option Product and actually allowed or taken by such Third Party and not otherwise received by or reimbursed to a Selling Party:

(a) sales returns and allowances actually paid, granted, or accrued on such Option Product, including reasonable and customary trade, quantity, prompt pay, and cash discounts, and any adjustments granted on account of price adjustments or billing errors;

(b) credits or allowances given or made for rejection, recall, return, or wastage replacement of [***] such Option Product or for rebates or retroactive price reductions (including Medicare, Medicaid, copay assistance, managed care, and similar types of rebates and chargebacks);

(c) taxes, duties, or other governmental charges levied on or measured by the billing amount for such Option Product, as adjusted for rebates and refunds [***];

(d) charges for freight, customs, [***] specifically related to the distribution of such Option Product [***]; and

(e) [***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Such amounts will be determined consistent with a Selling Party's customary practices and in accordance with GAAP. It is understood that any accruals for individual items reflected in Net Sales are periodically (at least quarterly) trued up and adjusted by each Selling Party consistent with its customary practices and in accordance with GAAP.

Notwithstanding anything to the contrary set forth in this Agreement, Net Sales will not be imputed to transfers of Option Product to Third Parties as *bona fide* samples, as donations, for the performance of Clinical Trials or for similar purposes in accordance with Applicable Law pertaining to any expanded access program, any compassionate sales or use program (including named patient program or single patient program), or any indigent program.

Sale or transfer of Option Products between any of the Selling Parties will not result in any Net Sales, with Net Sales to be based only on any subsequent sales or dispositions to a non-Selling Party. To the extent that any Selling Party receives consideration other than or in addition to cash upon the sale or disposition of an Option Product to a non-Selling Party, Net Sales will be [***]. For clarity, Net Sales will not include [***].

In the case of any Combination Product sold in a given country and reporting period, Net Sales for the purpose of determining royalties and Sales Milestone Events of the Combination Product in such country will be calculated by [***]

If, on a country-by-country basis in a particular reporting period, the Option Product is sold separately in the same indication in a country, but the Other Components in the Combination Product are not sold separately in the same indication in such country, then Net Sales for the purpose of determining royalties and Sales Milestone Events of the Combination Product for such country will be [***]

If, on a country-by-country basis in a particular reporting period, the Option Product in the Combination Product is not sold separately in the same indication in such country, but the Other Components included in the Option Product are sold separately in the same indication in such country, then Net Sales for the purpose of determining royalties and Sales Milestone Events of the Combination Product for such country will be [***]

If neither the Option Product nor the Other Components are sold separately in the same indication in a given country during a particular reporting period, then Net Sales will be [***]

Any disputes between the Parties relating to the calculation of Net Sales under this Section 1.155 (Net Sales) will be resolved pursuant to the dispute resolution procedures in Section 15.6 (Dispute Resolution).

1.157 [***]

1.158 "**Non-Breaching Party**" has the meaning set forth in Section 14.3.1 (Breach Notice).

1.159 **[***]**

1.160 **[***]**

1.161 **"Option"** has the meaning set forth in Section 2.2 (Grant of Option).

1.162 **"Option Data Package"** means, on an Option Program-by-Option Program basis, a data package that includes [***] set forth on Schedule 1.162 (Option Data Package) for such Option Program, subject to any amendments to the [***] to be included in such package that the Parties may agree to from time to time.

1.163 **"Option Development Activities"** has the meaning set forth in Section 5.1 (Development and Manufacturing Activities during the Option Term).

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.164 **"Option Exercise Fee"** has the meaning set forth in Section 9.3 (Option Exercise Fee).

1.165 **"Option Exercise Notice"** has the meaning set forth in Section 2.3 (Option Exercise).

1.166 **"Option Exercise Period**" means, with respect to an Option Program, the period beginning on the Provisional Agreement Effective Date and expiring upon the earliest of (a) [***] following the delivery of the Option Data Package or Partial Option Data Package, as the case may be, for such Option Program in accordance with Section 2.4 (Option Data Package), as such period may be extended in accordance with Section 2.4.3 (Incomplete Option Data Package), unless earlier terminated, (b) thirty (30) Business Days after the fifth (5th) anniversary of the Provisional Agreement Effective Date, and (c) the termination of this Agreement.

1.167 **"Option IP"** means Option Know-How and Option Patent Rights.

1.168 **"Option Know-How"** means, with respect to an Option Program, any and all Know-How (including Joint Program Know-How and Denali Program Know-How) that is: (a) Controlled by Denali or its Affiliates as of the Provisional Agreement Effective Date, during the Term, or during the term of the Provisional Agreement; and (b) [***] for the Development, Manufacture, or use of the Option Proteins and Option Products that are the subject of such Option Program or the performance of Medical Affairs activities with respect to, or Commercialization of, Option Products that are the subject of such Option Program [***]; but in each case, (a) and (b), excluding the TV Platform Know-How with respect to such Option Program.

1.169 **"Option MTA"** has the meaning set forth in Section 5.5 (Materials).

1.170 **"Option Patent Rights"** means, with respect to an Option Program, all Patent Rights (including Joint Program Patent Rights and Denali Program Patent Rights) that are: (a) Controlled by Denali or its Affiliates as of the Provisional Agreement Effective Date, during the Term, or during the term of the Provisional Agreement; and (b) [***] for the Development, Manufacture, or use of the Option Proteins and Option Products that are the subject of such Option Program or the performance of Medical Affairs activities with respect to, or the Commercialization of, Option Products that are the subject of such Option Program [***]; but, in each case, (a) and (b), excluding the TV Platform Patent Rights with respect to such Option Program. [***]

1.171 **"Option Product"** means any product (a) containing an ATV:Abeta Therapeutic or Option TV Therapeutic or (b) that is an Alternative Option Product included under this Agreement pursuant to clause (a) of Section 4.4.2 (Acquisitions of Alternative Option Products) or Section 2.6.2, in each case ((a) or (b)), alone or in combination with one or more other active ingredients, and in any formulation, dosage strength or method of delivery.

1.172 **"Option Programs"** means either of the ATV:Abeta Program or the Option TV Program.

1.173 **"Option Protein"** means any ATV:Abeta Therapeutic or Option TV Therapeutic.

1.174 **"Option Target"** means (a) with respect to the ATV:Abeta Program, Amyloid Beta, or (b) with respect to the Option TV Program, the Option TV Target.

1.175 **"Option Term"** means, with respect to an Option Program, the period beginning on the Provisional Agreement Effective Date and expiring on the earliest of (a) the fifth (5th) anniversary of the Provisional Agreement Effective Date, (b) expiration of the Option Exercise Period for such Option Program, and (c) the termination of this Agreement.

1.176 **"Option TV Program"** means all Option TV Therapeutics that are Controlled by or on behalf of Denali or its Affiliates prior to the Provisional Agreement Effective Date [***] and pharmaceutical products containing such Option TV Therapeutics, including [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.177 **"Option TV Target"** means the Target selected by Biogen pursuant to the procedures set forth in Section 2.1 (Selection of Option TV Target).

1.178 **"Option TV Target Selection Period"** has the meaning set forth in Section 2.1.1 (Option TV Target Notice).

1.179 **"Option TV Therapeutic"** means any [***] that (a) [***] and (b) is Directed to the Option TV Target, but for clarity, excluding any viral vector (including adeno-associated virus), any oligonucleotide, or any small molecule.

1.180 "**Option Update Report**" means, on an Option Program-by-Option Program basis, with respect to a given Option Program, a written update prepared by or on behalf of Denali that includes (a) a summary of Development activities conducted by or on behalf of Denali with respect to such Option Program, (b) a summary of data and results generated in the performance of such activities, and (c) a high-level overview of Development activities planned to be conducted by or on behalf of Denali over the following [***], in each case ((a)-(c)), subject to any amendments to the [***] to be included in such report that the Parties may agree to from time to time.

1.181 "**Other Component(s)**" has the meaning set forth in Section 1.156 (Net Sales).

1.182 [***]

1.183 [***]

1.184 "**Partial Option Data Package**" has the meaning set forth in Section 2.4.1 (Option Data Package).

1.185 "**Party**" and "**Parties**" has the meaning set forth in the preamble.

1.186 "**Patent Rights**" means: (a) all national, regional and international patents and patent applications, including provisional patent applications; (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications; (c) any and all patents that have issued or in the future issue from the foregoing patent applications (*i.e.*, described in clauses (a) and (b) above), including utility models, petty patents and design patents and certificates of invention; (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications (*i.e.*, described clauses (a), (b), and (c) above); and (e) any similar rights, including so-called pipeline protection.

1.187 "**Patent Term Extension**" has the meaning set forth in Section 12.8 (Patent Term Extensions).

1.188 "**Payments**" has the meaning set forth in Section 9.9.1.

1.189 "**PD**" means [***].

1.190 "**Per Product Annual Net Sales**" has the meaning set forth in Section 9.4.1 (Royalty Payments).

1.191 "**Person**" means any individual, firm, corporation, partnership, limited liability company, trust, business trust, joint venture, Governmental Authority, association or other entity.

1.192 "**Phase I Trial**" means a human clinical trial of a product, the principal purpose of which is a preliminary determination of safety, tolerability or pharmacokinetics in healthy individuals or patients or similar clinical study prescribed by the Regulatory Authorities, including the trials

referred to in 21 C.F.R. §312.21(a), as amended (and any equivalent Clinical Trial in any jurisdiction outside the United States).

1.193 "**Phase II Trial**" means a human clinical trial of a product, the principal purpose of which is to explore dose ranges, efficacy, pharmacodynamics, biomarkers, or biological activity in one (1) or more specified doses in the target patient population, or a similar clinical study recommended by the Regulatory Authorities, from time to time, pursuant to Applicable Law or otherwise, including the trials referred to in 21 C.F.R. §312.21(b), as amended (and any equivalent Clinical Trial in any jurisdiction outside the United States).

1.194 [***]

1.195 "**Phase III Trial**" means [***].

1.196 "**PHSA**" means the U.S. Public Health Service Act, as may be amended or supplemented from time to time.

1.197 "**Platform In-License Agreement**" means any agreement between a Party and a Third Party existing as of the Effective Date or entered into during the Term pursuant to which such Party obtains rights to any Intellectual Property that is [***]. Those Platform In-License Agreements existing as of the Effective Date are listed in Schedule 1.197 (Platform In-License Agreements).

1.198 [***]

1.199 "**PMDA**" means Japan's Pharmaceuticals and Medical Devices Agency and any successor agency(ies) or authority having substantially the same function.

1.200 "**Post-Grant Proceedings**" means proceedings conducted with respect to a Patent Right before a patent office or other administrative agency that is not a court of law and that has jurisdiction to grant and review such Patent Right following the grant or issuance of such Patent Right and pursuant to which the validity, enforceability, or scope of such Patent Right is challenged by a Third Party, including a post-grant opposition proceeding, *ex parte* re-examination (but only if such re-examination is requested by a Third Party), *inter partes* review, and other post-grant review proceedings. An appeal, including to a court of law, from such Post-Grant Proceeding, shall be understood to be encompassed by the term Post-Grant Proceedings.

1.201 "**Product**" means a ROFN Product or Option Product, as applicable.

1.202 "**Product In-License Agreement**" means any agreement between a Party and a Third Party pursuant to which such Party has obtained rights to any Intellectual Property that is [***], but excluding in all cases any Platform In-License Agreement. Those Product In-License Agreements existing as of the Effective Date are listed in Schedule 1.202 (Product In-License Agreements).

1.203 "**Product Labeling**" or "**Product Label**" means, with respect to an Option Product in a country or other jurisdiction in the Territory: (a) the full prescribing information for such Option Product for such country or other jurisdiction, including any required patient information, approved by the applicable Regulatory Authority; and (b) all labels and other written, printed or graphic matter upon a container, wrapper or any package insert utilized with or for such Option Product in such country or other jurisdiction, including material labeling supplements.

1.204 "**Product Trademarks**" means the product specific trademark(s) to be used by Biogen or its Affiliates or its or their respective Sublicensees for the Development, performance of Medical Affairs activities with respect to, or Commercialization of Option Products in the Territory and any registrations thereof or any pending applications relating thereto in the Territory (excluding, in any event, any trademarks, service marks, names, or logos that include any corporate name or logo of the Parties or their Affiliates).

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.205 [***]

1.206 “**Program Know-How**” means any [***].

1.207 “**Program Patent Rights**” means any [***].

1.208 [***]

1.209 “**Prosecution and Maintenance**” (including variations such as “**Prosecute and Maintain**”) means, with respect to a Patent Right or Patent Rights, the preparing, filing, prosecuting and maintenance, and strategy for each of the foregoing, of such Patent Right or Patent Rights, including paying to the applicable patent office or other governmental agency all maintenance or governmental fees to maintain such Patent Right or Patent Rights in force, and requests for patent term extensions, supplementary protection certificates, and the like with respect to such Patent Right or Patent Rights, together with the conduct of interferences, Post-Grant Proceedings and other similar proceedings with respect to such Patent Right or Patent Rights, but excluding any Post-Grant Proceedings or counter-claims or defenses arising in connection with prosecution of any Infringement Action.

1.210 “**Provisional Agreement**” has the meaning set forth in the Recitals.

1.211 “**Provisional Agreement Effective Date**” means the Effective Date (as such term is defined in the Provisional Agreement).

1.212 “**Provisional Agreement Execution Date**” means the Execution Date (as such term is defined in the Provisional Agreement).

1.213 “**Quality Agreement**” has the meaning set forth in Section 8.2.2 (Supply Agreement).

1.214 “**Receiving Party**” has the meaning set forth in Section 11.2 (Non-Disclosure and Non-Use Obligation).

1.215 “**Region**” means each of the following: [***].

1.216 “**Regulatory Approval**” means, with respect to a particular country or other regulatory jurisdiction, all approvals, licenses, registrations, or authorizations of any Regulatory Authority necessary to market and sell a pharmaceutical product or biologic in such country or regulatory jurisdiction, excluding, in each case, Reimbursement Approvals in such country.

1.217 “**Regulatory Authority**” means any applicable supra-national, federal, national, regional, state, provincial or local Governmental Authority or Regulatory Authority, agency, department, bureau, commission, council, or other entities (*e.g.*, the FDA, EMA, and PMDA) regulating or otherwise exercising authority with respect to the Development, Manufacture, or Commercialization of a pharmaceutical or biologic product in a particular country or other regulatory jurisdiction.

1.218 “**Regulatory Exclusivity**” means any exclusive marketing rights or exclusivity rights or protection conferred by any Regulatory Authority with respect to a pharmaceutical or biologic product in a particular country or other regulatory jurisdiction, including any regulatory protection exclusivity such as orphan drug designation or pediatric exclusivity, but in all cases excluding Patent Rights and Patent Term Extensions.

1.219 "**Regulatory Submissions**" means all (a) applications (including all INDs and Drug Approval Applications and other Co-Commercialization Territory Regulatory Filings), registrations, licenses, authorizations and approvals (including Regulatory Approvals, Reimbursement Approvals and Product Labeling) and designations (including designations of a product as an "orphan" drug or its equivalent outside of the United States), (b) correspondence, materials and reports submitted to or received from Regulatory Authorities (including meeting requests, pre-meeting submissions and minutes and official contact reports relating to any communications with any Regulatory Authority and reports issued by a Regulatory Authority in connection with any audit conducted by such Regulatory Authority) and all supporting documents with respect thereto, including all investigator brochures, regulatory drug lists, advertising and promotion documents, drug safety and signaling update reports, adverse event files, complaint files (including product technical complaints communications and handling) and other material regulatory submissions and (c) Clinical Data and data contained or relied upon in any of the foregoing, including core data sheets, in each case (*i.e.*, clauses (a), (b) and (c) above), to the extent pertaining to an Option Protein or Option Product.

1.220 "**Reimbursement Approval**" means, in a country in which Regulatory Authorities authorize reimbursement for, or approve or determine pricing for, pharmaceutical or biologic products to be marketed and sold or reimbursed in such country, receipt (or, if required to make such authorization, approval or determination effective, publication) of such reimbursement authorization or pricing approval or determination (as the case may be).

1.221 [***]

1.222 "**Reservation Period**" has the meaning set forth in Section 2.1.2 (Reserved Targets).

1.223 "**Reserved Target**" means each of [***] and [***].

1.224 [***]

1.225 [***]

1.226 [***]

1.227 [***]

1.228 "**ROFN**" has the meaning set forth in Section 3.1.1(a) (ROFN Interest Notice Period).

1.229 [***]

1.230 "**ROFN Definitive Agreement**" has the meaning set forth in Section 3.1.1(a) (ROFN Interest Notice Period).

1.231 "**ROFN Definitive Agreement Period**" has the meaning set forth in Section 3.1.1(c) (ROFN Definitive Agreement Period).

1.232 [***]

1.233 "**ROFN Interest Notice**" has the meaning set forth in Section 3.1.1(a) (ROFN Interest Notice Period).

1.234 "**ROFN Interest Notice Period**" has the meaning set forth in Section 3.1.1(a) (ROFN Interest Notice Period).

1.235 "**ROFN IP**" means ROFN Know-How and ROFN Patent Rights.

1.236 **"ROFN Know-How"** means, with respect to a ROFN Program, any and all Know-How that is: (a) Controlled by Denali or its Affiliates as of the Provisional Agreement Effective Date, during the Term, or during the term of the Provisional Agreement; and (b) [***] for the Development, Manufacture, or use of the ROFN Proteins and ROFN Products that are the subject of such ROFN Program or the performance of Medical Affairs activities with respect to or Commercialization of ROFN Products that are the subject of such ROFN Program [***]; but in each case, (a) and (b), excluding the TV Platform Know-How with respect to such ROFN Program.

1.237 **"ROFN Patent Rights"** means, with respect to a ROFN Program, all Patent Rights that are: (a) Controlled by Denali or its Affiliates as of the Provisional Agreement Effective Date, during the Term, or during the term of the Provisional Agreement; and (b) [***] for the Development, Manufacture, or use of the ROFN Proteins and ROFN Products that are the subject of such ROFN Program or the performance of Medical Affairs activities with respect to or Commercialization of ROFN Products that are the subject of such ROFN Program [***]; but in each case, (a) and (b), excluding the TV Platform Patent Rights with respect to such ROFN Program.

1.238 "**ROFN Product**" means any product containing a ROFN Protein, alone or in combination with one or more other active ingredients, and in any formulation, dosage strength, or method of delivery.

1.239 "**ROFN Program**" means, with respect to a ROFN Target, all ROFN Proteins Directed to such ROFN Target that are Controlled by or on behalf of Denali or its Affiliates prior to the Effective Date or during the ROFN Term and pharmaceutical products containing such ROFN Proteins.

1.240 "**ROFN Protein**" means any protein-based molecule that (a) [***] and (b) is Directed to a Target (other than an Excluded Target) for which the primary indication is an indication within AD, ALS, MS, or PD, and for clarity, is not a lysosomal storage disease or within oncology indications (such Target, the "**ROFN Target**"), but excluding all Option Proteins and any molecule incorporating any viral vector (including adeno-associated virus), any oligonucleotide, or any small molecule.

1.241 "**ROFN Target**" has the meaning set forth in Section 1.240 (ROFN Protein).

1.242 "**ROFN Term**" means the period beginning on the Provisional Agreement Effective Date and expiring on the earliest of (a) the seventh (7^{th}) anniversary of the Provisional Agreement Effective Date, (b) the date on which Biogen has provided ROFN Interest Notices to Denali in respect of two (2) ROFN Programs in accordance with Article 3 (ROFN), and (c) the termination of this Agreement with respect to the ROFN Programs.

1.243 "**ROFN Term Sheet Period**" has the meaning set forth in Section 3.1.1(b) (ROFN Term Sheet Period).

1.244 "**ROFN Update Report**" means a written update prepared by or on behalf of Denali that includes the information set forth on Schedule 1.244 (ROFN Update Report), subject to any amendments to the [***] to be included in such report that the Parties may agree to from time to time.

1.245 [***]

1.246 [***]

1.247 [***]

1.248 [***]

1.249 [***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.250 "**Royalty Term**" has the meaning set forth in Section 9.4.2 (Royalty Term).

1.251 [***]

1.252 "**Sales Milestone Event**" has the meaning set forth in Section 9.3.3 (Sales Milestones).

1.253 "**Sales Milestone Payment**" has the meaning set forth in Section 9.3.3 (Sales Milestones).

1.254 "**Selling Party**" has the meaning set forth in Section 1.156 (Net Sales).

1.255 "**Specifications**" has the meaning set forth in Section 8.2.1 (Supply Requirements).

1.256 "**Standstill Agreement**" shall have the meaning set forth in the Provisional Agreement.

1.257 "**Stock Purchase Agreement**" means the Stock Purchase Agreement, dated as of the Provisional Agreement Execution Date, by and between BIMA and Denali.

1.258 "**Subcontractor**" means a Third Party contractor (including contract research organizations or CMO) engaged by a Party or its Affiliates on a fee-for-service basis or other payment arrangement to perform certain services or activities on behalf of and for the benefit of such Party or its Affiliates or exercise certain rights on behalf of such Party or its Affiliates, in each case, under this Agreement.

1.259 "**Sublicensees**" means any Third Party to whom Biogen or any of its Affiliates grants (directly or indirectly) a sublicense of its rights hereunder to Develop, perform Medical Affairs activities with respect to, or Commercialize any Option Protein or Option Product, other than any Subcontractor that is granted any such sublicense or other rights solely for the purpose of performing specific limited services or activities solely on behalf of and for the benefit of a Party or its Affiliate.

1.260 "**Supply Agreement**" has the meaning set forth in Section 8.2.2 (Supply Agreement).

1.261 "**Target**" means any biological target(s) (a) to which a protein binds in order to elicit a therapeutic or other pharmacodynamic response (any such biological target, a "**Binding Target**") or (b) that is a protein molecule, such as non-antibody protein molecule, the level of which may be modulated, including by supplementation or replacement, to elicit a therapeutic or other pharmacodynamic response (any such biological target, a "**Function Target**").

1.262 [***]

1.263 [***]

1.264 "**Tax**" means all forms of taxation whether direct or indirect and whether levied by reference to income, profits, gains, net wealth, asset values, turnover, added value or other reference and statutory, governmental, state, provincial, local or foreign governmental or municipal impositions, duties (including but not limited to stamp duties), contributions, rates, and levies (including social security contributions and any other payroll taxes), whenever and wherever imposed (whether imposed by way of a withholding or deduction for or on account of tax or otherwise) and in respect of any Person (including taxes imposed on another Person for which a Person is liable by reason of being a member of a consolidated, combined, unitary or similar tax group, as a transferee or successor, by contract or otherwise) and all penalties, charges, costs and interest relating thereto.

1.265 "**Term**" has the meaning set forth in Section 14.1 (Term).

1.266 "**Terminated Product**" has the meaning set forth in Section 14.6.1(a) (Terminating Rights and Obligations).

1.267 "**Terminated Program**" has the meaning set forth in Section 14.6.1(a) (Terminating Rights and Obligations).

1.268 "**Terminated Protein**" has the meaning set forth in Section 14.6.1(a) (Terminating Rights and Obligations).

1.269 "**Terminated Region**" has the meaning set forth in Section 14.6.1(a) (Terminating Rights and Obligations).

1.270 "**Territory**" means worldwide.

1.271 "**Third Party**" means any Person other than Biogen, Denali and their respective Affiliates.

1.272 "**Third Party Acquiror**" has the meaning set forth in Section 1.47 (Change of Control).

1.273 "**Third Party Claim**" has the meaning set forth in Section 13.1 (Indemnification by Denali).

1.274 "**Third Party Distributor**" means, with respect to a country, any Third Party that purchases its requirements for Products in such country from Biogen or its Affiliates or Sublicensees and is appointed as a distributor to distribute and resell such Product in such country, even if such Third Party is granted ancillary rights to Develop, package, or obtain Regulatory Approval of such Product in order to distribute or sell such Product in such country.

1.275 [***]

1.276 "**TV Moiety**" means [***].

1.277 "**TV Platform**" means the proprietary platform technology Controlled by Denali or its Affiliates that [***].

1.278 "**TV Platform IP**" means, with respect to an Option Program or a ROFN Program, the TV Platform Know-How and the TV Platform Patent Rights, in each case, related to such Option Program or such ROFN Program, as the case may be.

1.279 "**TV Platform Know-How**" means [***].

1.280 "**TV Platform Patent Rights**" means [***].

1.281 "**TV Target Notice**" has the meaning set forth in Section 2.1.1 (Option TV Target Notice).

1.282 "**United States**" or "**U**.**S**." means the United States of America and its territories and possessions (including the District of Columbia and Puerto Rico).

1.283 "**Valid Claim**" means [***].

1.284 "**VAT**" means (a) in relation to any jurisdiction within the European Union, the tax imposed by the EC Council Directive on the common system of value added tax (2006/112/EC) and any successor or equivalent legislation and any national legislation implementing that directive together with legislation supplemental thereto and the equivalent tax (if any) in that jurisdiction; and (b) in any other jurisdiction, any other value added, goods and services, consumption, or similar tax chargeable on the supply or deemed supply of goods or services under applicable legislation or regulation.

1.285 [***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

ARTICLE 2 OPTION

2.1 **Selection of Option TV Target**.

2.1.1 **Option TV Target Notice**. During the period commencing on the Provisional Agreement Execution Date and ending [***] thereafter (the "**Option TV Target Selection Period**"), Biogen shall have a one-time right (but not the obligation) to select one (1) Reserved Target as the Option TV Target by sending written notice to Denali, which notice will identify such proposed target (such notice, a "**TV Target Notice**"). The Reserved Target selected by Biogen will become the Option TV Target upon Denali's receipt of such TV Target Notice.

2.1.2 **Reserved Targets.** During the period commencing on the Provisional Agreement Execution Date and ending upon the earlier of (a) the end of the Option TV Target Selection Period, (b) the date on which the Reserved Target selected by Biogen becomes the Option TV Target in accordance with Section 2.1.1 (Option TV Target Notice), and (c) the termination of this Agreement, either in its entirety or with respect to the Option TV Program (such period, the "**Reservation Period**"), Denali [***].

2.2 **Grant of Option**. Denali hereby grants to Biogen during the applicable Option Exercise Period (a) an exclusive option to obtain the licenses set forth in Section 4.1 (Licenses to Biogen) with respect to the ATV:Abeta Program, and (b) an exclusive option to obtain the licenses set forth in Section 4.1 (Licenses to Biogen) with respect to the Option TV Program (each such exclusive option described in the foregoing clauses (a) and (b), an "**Option**").

2.3 **Option Exercise**. Biogen may exercise the Option for each Option Program by providing to Denali written notice ("**Option Exercise Notice**") prior to the expiration of the Option Exercise Period for such Option Program. Upon Biogen's delivery to Denali of an Option Exercise Notice for a given Option Program, Biogen will be granted the licenses set forth in Section 4.1 (Licenses to Biogen) for such Option Program.

2.4 **Option Data Package**.

2.4.1 **Option Data Package**. On an Option Program-by-Option Program basis with respect to a given Option Program, Denali will deliver to Biogen the following items as soon as reasonably practicable after Denali's completion of the activities required to generate and review the information to be provided in the Option Data Package for such Option Program if such activities are completed prior to the expiration of the Option Term, but in any event no later than [***] prior to the anticipated date for Initiation of the first IND-Enabling Studies for a given Option Program:

(a) the Option Data Package for such Option Program;

(b) [***]; and

(c) if such Option Data Package is for the Option TV Program, then at Denali's election in accordance with Section 2.4.2(a) (Co-Co Opt In Notice), a Co-Co Opt In Notice.

On an Option-Program-by-Option Program basis, if Denali reasonably believes [***], then no later than [***] prior to [***] anniversary of the Provisional Agreement Effective Date, instead of providing a full Option Data Package for such Option Program, Denali will deliver to Biogen a data package that includes [***] (the "**Partial Option Data Package**"), [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

2.4.2 **Co-Co Opt In [***]**.

(a) **Co-Co Opt In Notice**. Along with Denali's delivery of an Option Data Package or Partial Option Data Package, as the case may be, if such Option Data Package or Partial Option Data Package is with respect to the Option TV Program, then Denali may also elect to provide Biogen a notice that Denali wishes to receive Co-Co Rights with respect to the Option Products under the Option TV Program (a "**Co-Co Opt In Notice**"). If Denali provides a Co-Co Opt In Notice with respect to the Option TV Program, and Biogen provides an Option Exercise Notice for the Option TV Program in accordance with Section 2.3 (Option Exercise), then notwithstanding any provision to the contrary set forth in this Agreement, the Parties shall negotiate in good faith one or more amendments to this Agreement modifying the terms set forth in this Agreement with respect to the Option TV Program to contemplate each Party granting the other Party Co-Co Rights with respect to such Option Products, (a "**Co-Co Amendment**"). If the Parties are unable to enter into a Co-Co Amendment within [***] following Biogen's delivery of an Option Exercise Notice for the Option TV Program to Denali, then unless the Parties otherwise agree [***], Biogen and Denali will not grant each other Co-Co Rights with respect to such Option Products, and the Parties will not so amend or modify this Agreement to contemplate the foregoing.

(b) **[***]**

(i) **[***]**

(ii) **[***]**

(iii) **[***]**

(iv) **[***]**

2.4.3 **Incomplete Option Data Package**. Following receipt of an Option Data Package for an Option Program, Biogen will have the one-time right (subject to the remainder of this Section 2.4.3 (Incomplete Option Data Package)) to promptly (but in any event, within [***] of its receipt of such Option Data Package) notify Denali if such Option Data Package is missing information corresponding to any of the [***] required to be provided in such Option Data Package. Denali shall provide Biogen with [***]. If, following any such request from Biogen, Denali does provide [***], then the Option Exercise Period with respect to such Option Program will be extended to end [***]. If Denali does not provide [***] within such [***] period and does not otherwise confirm in writing to Biogen that [***], then Biogen will have the right to request [***] from Denali again in accordance with this Section 2.4.3 (Incomplete Option Data Package) and the terms of this Section 2.4.3 (Incomplete Option Data Package) shall again apply. For clarity, Denali will not be obligated to perform or reperform any Development activities or any other analysis or investigation with respect to any Option Program to provide to Biogen any missing information pursuant to this Section 2.4.3 (Incomplete Option Data Package).

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

2.5 **Due Diligence**. During the Option Exercise Period for a given Option Program, to assist Biogen in conducting thorough due diligence to decide whether to exercise the Option for such Option Program, once every Calendar Quarter, Denali will present to Biogen an Option Update Report for such Option Program (*provided* that every other such presentation shall be made at a meeting of the JSC), and Denali will afford to Biogen and its representatives an opportunity to discuss such activities with Denali personnel during such presentation. In addition, during the Option Exercise Period following delivery to Biogen of the Option Data Package or Partial Option Data Package for an Option Program, as the case may be, upon Biogen's request, subject to customary and reasonable due diligence procedures to preserve the confidential nature of any such information, Denali will, upon Biogen's request, (a) afford to Biogen and its representatives reasonable access during normal business hours to Denali's and its Affiliates' personnel, records and data, offices, and laboratories, in each case, as Biogen may reasonably request related to such Option Program to conduct customary and reasonable due diligence of such Option Program and (b) promptly provide to Biogen through an electronic data room copies of (i) any documents reasonably requested by Biogen, (ii) any patent or regulatory information, and (iii) any results of preclinical activities relating to such Option Program, in each case ((i) – (iii)), then available to Denali or its Affiliates, to the extent that such information has not been previously provided by or on behalf of Denali to Biogen and pertains to such Option Program.

2.6 **Denali Restrictions; Acquisitions of Alternative Option Products during the Option Term**. During the Option Term for a given Option Program:

2.6.1 other than with the prior written consent of Biogen, Denali will not grant to any Third Party any right to Develop, Manufacture, perform Medical Affairs with respect to, or Commercialize any such Option Proteins or Option Products in a manner that would conflict with the Option granted to Biogen hereunder with respect to such Option Program or the rights granted to Biogen if Biogen were to exercise such Option; and

2.6.2 if Denali or any of its Affiliates [***] with respect to such Option Program, then Denali shall promptly so notify Biogen. Following such notice, the Parties will [***] under such Option Program, and if Biogen [***]. If Biogen [***]. If Denali [***].

2.7 **Subcontractors**. Notwithstanding Section 2.1.2 (Reserved Targets) and Section 2.6 (Denali Restrictions; Acquisitions of Alternative Option Products during the Option Term), nothing in those Sections shall restrict Denali's ability to grant non-exclusive licenses under the Option IP to Subcontractors to Develop or Manufacture Option Proteins or Option Products, provided that each such non-exclusive license will be granted pursuant to a written agreement that provides Denali with [***]. Denali shall remain liable under this Agreement for the performance of all its obligations under this Agreement and shall be responsible for and liable for compliance by all such Subcontractors with the applicable provisions of this Agreement.

2.8 **Termination of Option**. If Biogen does not provide an Option Exercise Notice in respect of a given Option Program prior to the expiration of the Option Exercise Period for such Option Program, then all of Biogen's rights with respect to such Option Program shall terminate and Denali shall have no further obligations to Biogen with respect to such Option Program and this Agreement will terminate with respect to such Option Program.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

ARTICLE 3 ROFN

3.1 **ROFN Program; Procedures**.

3.1.1 **Grant of ROFN.**

(a) **ROFN Interest Notice Period**. During the ROFN Term, if with respect to a given ROFN Program, Denali or its Affiliates intends to enter into material negotiations with any Third Party to grant to such Third Party the right (or any option or other contingent rights) to Commercialize ROFN Products that are the subject of such ROFN Program, whether by license, sale of assets, or otherwise, then Denali will provide to Biogen [***] ([***]. Subject to the time periods described in Section 3.1.2 (Failure to Enter into ROFN Definitive Agreement) below, Biogen will have an exclusive right of first negotiation ("**ROFN**") to negotiate the terms and conditions of a definitive agreement pursuant to which Denali would grant exclusive or co-exclusive (with Denali) rights to Biogen to Develop, Commercialize, or otherwise Exploit ROFN Products that are the subject of the applicable ROFN Program ("**ROFN Definitive Agreement**"). Biogen may exercise the ROFN with respect to the applicable ROFN Program by notifying Denali in writing (a "**ROFN Interest Notice**") no later than [***] following its receipt of [***] for a given ROFN Program (such [***] period, the "**ROFN Interest Notice Period**"), *provided* that, for clarity, Biogen may not provide ROFN Interest Notices to Denali for more than two (2) ROFN Programs.

(b) **ROFN Term Sheet Period**. If Biogen so provides a ROFN Interest Notice to Denali with respect to the applicable ROFN Program during the applicable ROFN Interest Notice Period, then from the period commencing upon Biogen's delivery to Denali of such ROFN Interest Notice and ending [***] thereafter (the "**ROFN Term Sheet Period**"), the Parties will exclusively negotiate in good faith with one another the terms of a non-binding term sheet in respect of a ROFN Definitive Agreement for such ROFN Program.

(c) **ROFN Definitive Agreement Period**. If the Parties agree on the terms of a non-binding term sheet for a ROFN Definitive Agreement in respect of a given ROFN Program during the applicable ROFN Term Sheet Period in accordance with Section 3.1.1(b) (ROFN Term Sheet Period), then for the [***] period following the expiration of such ROFN Term Sheet Period (the "**ROFN Definitive Agreement Period**"), the Parties will exclusively negotiate in good faith with one another the terms of a definitive ROFN Definitive Agreement for such ROFN Program.

(d) **Denali Restrictions**. Until the expiration of (i) the ROFN Interest Notice Period (if Biogen does not issue a ROFN Interest Notice within the applicable ROFN Interest Notice Period), (ii) the ROFN Term Sheet Period (if Biogen issues a ROFN Interest Notice within the applicable ROFN Interest Notice Period), and (iii) the ROFN Definitive Agreement Period (if the Parties agree on the terms of a non-binding term sheet for a ROFN Definitive Agreement within the applicable ROFN Term Sheet Period), in each case ((i) – (iii)), for a given ROFN Program, Denali and its Affiliates will not enter into negotiations or any agreement with any Third Party, in each case, relating to any license, sale, or other transfer of rights to Commercialize ROFN Products that are the subject of such ROFN Program.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

3.1.2 **Failure to Enter into ROFN Definitive Agreement**. If, with respect to a ROFN Program, (a) Biogen does not provide a ROFN Interest Notice for such ROFN Program to Denali within the applicable ROFN Interest Notice Period, (b) the Parties do not agree on the terms of a non-binding term sheet in respect of a ROFN Definitive Agreement for such ROFN Program within the applicable ROFN Term Sheet Period, or (c) the Parties have agreed on such terms of a non-binding term sheet for such ROFN Program within the applicable ROFN Term Sheet Period, but have not executed a ROFN Definitive Agreement in respect of such ROFN Program within the applicable ROFN Definitive Agreement Period, then, in each case ((a), (b), or (c)), Denali and its Affiliates shall be free to grant to any Third Party any rights to such ROFN Program without further obligations to Biogen, and on any terms that Denali and such Third Party considers appropriate [***].

3.1.3 **Consequences of Delivering a ROFN Interest Notice**. Upon Biogen providing a ROFN Interest Notice for two (2) ROFN Programs, (a) the ROFN shall apply solely with respect to those two (2) ROFN Programs, subject to the procedures set forth in this Section 3.1 (ROFN Program; Procedures) and only for so long as Biogen's rights persist under this Section 3.1 (ROFN Program; Procedures) with respect to each such ROFN Program for which Biogen provided a ROFN Interest Notice, (b) the ROFN shall not apply with respect to any other ROFN Program and Denali shall have no further obligations to provide [***] with respect to any other ROFN Program, nor otherwise to comply with the procedures set forth in this Section 3.1 (ROFN Program; Procedures) with respect to any other ROFN Program, and (c) Denali and its Affiliates shall be free to grant to any Third Party any rights to any such other ROFN Programs, without any obligations to Biogen.

3.2 **Additional ROFN Details**.

3.2.1 **Due Diligence**. During the ROFN Interest Notice Period, the ROFN Term Sheet Period and the ROFN Definitive Agreement Period, in each case, to the extent applicable with respect to a given ROFN Program with respect to which Denali has issued a ROFN Interest Notice and for which Biogen's rights hereunder have not terminated, and subject to customary and reasonable due diligence procedures to preserve the confidential nature of any such information, Denali will, upon Biogen's request, (i) afford to Biogen and its representatives reasonable access during normal business hours to Denali's and its Affiliates' personnel, records and data, offices, and laboratories, in each case, as Biogen may reasonably request related to such ROFN Program to conduct customary and reasonable due diligence and (ii) promptly provide through an electronic data room copies of (A) any documents reasonably requested by Biogen, (B) any patent or regulatory information, and (C) any results of preclinical activities relating to such ROFN Program, in each case ((A) – (C)), then available to Denali or its Affiliates, to the extent that such information pertains to such ROFN Program and has not been previously provided by or on behalf of Denali to Biogen.

3.2.2 **[***] Updates**. Without limiting Section 3.1.1 (Grant of ROFN) above, once every [***] during the ROFN Term, Denali shall provide a ROFN Update Report for all ROFN Programs that are subject to the ROFN at such time.

3.2.3 **Indications**. [***]

3.2.4 **[***]**

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

3.2.5 **ROFN Requirements**. It is understood and agreed that certain product(s) included in a ROFN Program may or may not be discovered or reduced to practice to any particular degree or at all at the time of delivery of [***] and that further modification or variations of products in any ROFN Program may be developed after the date of [***]. Accordingly, following delivery of [***], then, subject to the second to last sentence of Section 3.1.2 (Failure to Enter into ROFN Definitive Agreement), the requirements of the ROFN shall be deemed satisfied with respect to any and all products that are the subject of such ROFN Program or otherwise directed to the applicable Target (and mutants or variants thereof), whether developed or reduced to practice before or after the date of [***]. Further, the Parties acknowledge and agree that Denali will provide to Biogen [***] prior to the commencement of material negotiations with Third Parties with respect to such ROFN Program, in accordance with Section 3.1.1(a) (ROFN Interest Notice Period). Accordingly, if Denali subsequently enters into negotiations with a Third Party to grant such Third Party rights to Commercialize [***], then Denali and its Affiliates shall be deemed to have satisfied its obligations to Biogen under Section 3.1.1(a) (ROFN Interest Notice Period) with respect to the applicable ROFN Program, regardless of the scope of the rights actually negotiated with, or granted to, a Third Party. In addition, Denali need only provide one [***] with respect to such ROFN Program before engaging in such material negotiations with the first Third Party for a particular ROFN Program, even if Denali subsequently engages in discussions with more than one Third Party [***].

3.2.6 **Contingent Rights**. Additionally, if Denali or its Affiliates enters into a transaction with a Third Party as permitted under the ROFN provisions above (following the expiration of the applicable time periods set forth Section 3.1.2 (Failure to Enter into ROFN Definitive Agreement)) that includes the grant by Denali or its Affiliates of an option or other contingent right to acquire the right to Commercialize products that are the subject of a ROFN Program (each such option or right being referred to as a "**Contingent Right**"), then the Third Party's subsequent exercise of such Contingent Right shall not be subject to the ROFN. Denali and its Affiliates are not obligated to provide to Biogen any particular information with respect to a ROFN Program other than as expressly stated in this Section 3.2 (Additional ROFN Details).

3.3 **Disclaimers Regarding ROFN and Option Terms**.

3.3.1 The only obligations of Biogen and Denali and their respective Affiliates with respect to the ROFN Programs and Options are as expressly set forth in this Agreement and there are no other implied obligations relating to the matters contemplated therein. [***].

3.3.2 It is further acknowledged and agreed that neither the ROFN(s) or Option(s) shall apply to, nor otherwise restrict, a transaction involving a Change of Control of Denali, *provided* that, [***]. Further in no event shall the terms of the ROFN apply to any program of any Third Party Acquiror of Denali (or any of such Third Party Acquiror's Affiliates) [***].

ARTICLE 4 LICENSE GRANTS; EXCLUSIVITY

4.1 **Licenses to Biogen**.

4.1.1 **Option IP and TV Platform IP**. On an Option Program-by-Option Program basis, subject to the terms and conditions of this Agreement (including Section 4.1.6 (Certain Restrictions)) and effective automatically upon Biogen's exercise of the Option with respect to a given Option Program in accordance with Section 2.3 (Option Exercise), Denali hereby grants and will to grant to Biogen and its Affiliates, with respect to such Option Program:

(a) an exclusive, worldwide, royalty-bearing license, with the right to sublicense through multiple tiers (subject to the provisions of Section 4.1.4 (Sublicensing by Biogen)), under the Option IP with respect to such Option Program (including Denali's interest in the Joint Program IP) to Develop, Manufacture, and use the Option Proteins and Option Products that are the subject of such Option Program and perform Medical Affairs activities with respect to, and Commercialize Option Products that are the subject of such Option Program in the Field in the Territory; and

(b) a non-exclusive, worldwide, royalty-bearing license, with the right to sublicense through multiple tiers (subject to the provisions of Section 4.1.4 (Sublicensing by Biogen)), under the TV Platform IP with respect to such Option Program to Develop, Manufacture, and use the Option Proteins and Option Products that are the subject of such Option Program and perform Medical Affairs activities with respect to, and Commercialize Option Products that are the subject of such Option Program in the Field in the Territory.

4.1.2 **Option Development Activities**. On an Option Program-by-Option Program basis, subject to the terms and conditions of this Agreement (including Section 4.1.6 (Certain Restrictions)) during the Option Term for a given Option Program, Denali hereby grants and will grant to Biogen and its Affiliates, with respect to such Option Program, a non-exclusive, worldwide, royalty-free license, with the right to sublicense solely as permitted under Section 4.1.4(b) (Option Development Activities), [***].

4.1.3 **[***]**

4.1.4 **Sublicensing by Biogen**.

(a) **Option IP and TV Platform IP**. On an Option Program-by-Option Program basis, following Biogen's exercise of the Option with respect a given Option Program and subject to Section 4.1.4(d) (Sublicense Requirements), [***], *provided* that [***].

(b) **Option Development Activities**. On an Option Program-by-Option Program basis, during the Option Term with respect a given Option Program and subject to Section 4.1.4(d) (Sublicense Requirements), [***], *provided* that [***].

(c) **[***]**

(d) **Sublicense Requirements**. Any sublicense granted or authorized under this Section 4.1.4 (Sublicensing by Biogen) will be [***]. For the avoidance of doubt, any sublicenses granted by a Sublicensee of Biogen or its Affiliates shall include [***]. Without limiting the foregoing, Biogen shall remain liable under this Agreement for the performance of all its obligations under this Agreement and shall be responsible for and liable for compliance by its Sublicensees ([***]) with the applicable provisions of this Agreement.

4.1.5 **Subcontracting**. Biogen, its Affiliates, and its Sublicensees may subcontract the performance of any of its activities with respect to an Option Program undertaken in accordance with this Agreement to one or more Subcontractors pursuant to an agreement that shall be consistent with the terms of this Agreement [***]. Notwithstanding the foregoing, Biogen shall remain liable under this Agreement for the performance of all its obligations under this Agreement and shall be responsible for and liable for compliance by all such Subcontractors with the applicable provisions of this Agreement.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

4.1.6 **Certain Restrictions**. Notwithstanding any other provision of this Agreement, the rights and licenses granted to Biogen and its Affiliates under the TV Platform IP or otherwise set forth in this Agreement shall not include, or be deemed to include, any rights to [***], and Biogen and its Affiliates agree not to practice [***] to conduct any such activities nor authorize any Third Party to conduct any such activities, except as otherwise expressly agreed in writing in advance by the Parties. In no event shall Biogen or its Affiliates use (or authorize the use of) any [***] except for the purposes of Developing and Manufacturing Option Proteins and Option Products and performing Medical Affairs activities with respect to and Commercializing Option Products, in each case, under and in accordance with this Agreement. For the avoidance of doubt, the exclusive rights granted by Denali to Biogen and its Affiliates under this Agreement will not prohibit Denali from Exploiting, and, subject to Section 4.4 (Exclusive Collaboration), Denali will retain all rights to Exploit for any purpose, [***].

4.1.7 **Sublicenses upon Termination**. Upon termination of this Agreement for any reason in its entirety or with respect to an Option Program (in its entirety of for a Region), all rights granted by Biogen or its Affiliates to any Sublicensee that pertain solely to the applicable Terminated Region, Terminated Proteins and Terminated Products shall be assigned to Denali to the extent Biogen has the right to do so and Denali so requests, and in the event such assignment is not so requested by Denali or Biogen does not have the right to do so, then the rights of any such Sublicensee with respect to the applicable Terminated Region(s), Terminated Products and Terminated Proteins shall terminate upon the termination of Biogen's rights with respect to the Terminated Region(s), Terminated Products and Terminated Proteins; [***]. Notwithstanding the foregoing, [***].

4.2 **Licenses to Denali**

4.2.1 **Collaboration License**. On an Option Program-by-Option Program basis, subject to the terms and conditions of this Agreement [***], Biogen will grant to Denali a royalty-free, non-exclusive, worldwide license, with the right to sublicense through multiple tiers (subject to the provisions of Section 4.2.3 (Sublicensing by Denali)), under the Biogen IP relevant to such Option Program solely for the purpose of performing Denali's other obligations under this Agreement with respect to such Option Program.

4.2.2 **Biogen Program Patent Rights**. On an Option Program-by-Option Program basis, subject to the terms and conditions of this Agreement [***], Biogen will grant to Denali a non-exclusive, worldwide, perpetual, irrevocable, fully-paid, royalty-free license, with the right to sublicense through multiple tiers (subject to the provisions of Section 4.2.3 (Sublicensing by Denali)), under any Biogen Program Patent Rights that [***], to Exploit [***].

4.2.3 **Sublicensing by Denali**.

(a) **Biogen IP**. Denali shall have the right to grant a sublicense under Section 4.2.1 (Collaboration License) to Denali's Affiliates and any of Denali's or its Affiliates' Subcontractors in accordance with Section 2.7 (Subcontractors). [***] Without limiting the foregoing, Denali shall remain liable under this Agreement for the performance of all its obligations under this Agreement and shall be responsible for and liable for compliance by sublicensees with the applicable provisions of this Agreement.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(b) **Biogen Program Patent Rights**. Denali and its Affiliates may grant sublicenses through multiple tiers under Section 4.2.2 (Biogen Program Patent Rights) to any Affiliate of Denali or Third Party, *provided* that [***]. [***] Without limiting the foregoing, Denali shall remain liable under this Agreement for the performance of all its obligations under this Agreement and shall be responsible for and liable for compliance by sublicensees with the applicable provisions of this Agreement.

4.3 **Third Party Intellectual Property.**

4.3.1 **Existing Third Party Agreements.** It is understood that the terms of those Existing Third Party Agreements set out on Schedule 4.3.1 (Existing Third Party Agreement Provisions) attached hereto require particular provisions to be incorporated into any sublicense granted under the [***] Controlled by Denali pursuant to such agreements. [***] Biogen agrees to comply with the provisions set out on Schedule 4.3.1 (Existing Third Party Agreement Provisions) to the extent applicable to Biogen in its capacity as a sublicensee under each such Existing Third Party Agreement and to the extent applicable to the Development, Commercialization, Manufacturing and other Exploitation activities conducted by or on behalf of Biogen with respect to such Option Program for so long as the applicable Existing Third Party Agreement is in full force and effect and thereafter with respect to [***], and, to the extent expressly specified on Schedule 4.3.1 (Existing Third Party Agreement Provisions) and required by any such Existing Third Party Agreement as of the Effective Date, the relevant Third Party licensor shall be deemed to be a third party beneficiary of this Agreement solely for the purposes of enforcing any of such Third Party licensor's rights against Biogen in its capacity as a sublicensee under such Existing Third Party Agreement. Notwithstanding any provision in this Agreement to the contrary, [***].

4.3.2 **New Third Party Intellectual Property**.

(a) **In-License Agreements Prior to Option Exercise.** During the Option Term with respect to a given Option Program, (i) Denali will have the sole right to obtain and maintain rights to use any and all Third Party Intellectual Property (whether through acquisition or license) that is [***] to Exploit any Option Protein or Option Product that is the subject of such Option Program and (ii) if either Party identifies any such Third Party Intellectual Property that would be [***] for Biogen to Exploit such Option Protein or Option Product (if Biogen were to exercise its Option with respect to such Option Program), then such Party will promptly notify the other Party of such Third Party Intellectual Property and the Parties shall discuss in good faith whether Denali will seek to obtain rights to such Third Party Intellectual Property by entering into an In-License Agreement. If Denali does enter into an In-License Agreement with respect to such Third Party Intellectual Property during such Option Term, then, except with respect to [***], Denali will [***]. Denali will [***].

(b) **[***] In-License Agreements After Option Exercise**. Following Biogen's exercise of the Option for a given Option Program in accordance with Section 2.3 (Option Exercise) [***], (i) Denali will be responsible for [***] and (ii) if either Party identifies any such [***], then such Party will promptly notify the other Party of [***] and the Parties shall discuss in good faith such [***]. Following such notification, Denali will, [***]. Denali will [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(c) **[***] Third Party IP Dispute**. If, pursuant to Section 4.3.2(b) ([***] In-License Agreements after Option Exercise), a Party disputes whether [***], then each Party may refer the matter to the Chief IP Counsel of Biogen and the Head of IP/Legal of Denali or their designees (the "**IP Counsels**"). The IP Counsels will meet promptly to discuss and resolve the matter within [***] after referral of such matter to such IP Counsels. If the IP Counsels cannot agree on a resolution to the matter within such [***] period, then either Party may refer such matter for resolution to an independent Third Party expert agreed upon by the Parties within [***] after the IP Counsels have failed to resolve such matter. Such independent Third Party expert will be an attorney who has practiced United States patent law for at least [***] (or who has such other similar credentials as agreed by the Parties), and unless otherwise agreed in writing by the Parties, must not be a current or former employee, contractor, agent, or consultant of either Party or its Affiliates. [***] Within [***] of the engagement of such expert by the disputing Party, such expert will deliver its written decision to the Parties with respect to whether [***], such decision will be binding on the Parties, and for clarity, if such expert does so determine that [***], then the terms of Section 4.3.2(b) ([***] In-License Agreements after Option Exercise) shall apply to [***].

4.4 **Exclusive Collaboration**

4.4.1 **Exclusivity**. Except in the performance of activities under this Agreement and subject to the remainder of this Section 4.4 (Exclusive Collaboration), on an Option Program-by-Option Program basis, following Biogen's exercise of the Option with respect to a given Option Program, neither Party will (and will not permit its Affiliates to), [***] (any such product, excluding: (i) any product that includes a viral vector (including adeno-associated virus), any oligonucleotide, or any small molecule, in each case, directed to an Option Target; and (ii) all Option Proteins and Option Products, an "**Alternative Option Product**"), *provided*, *however*, that nothing in this Section 4.4.1 (Exclusivity) shall restrict or prevent either Party from conducting activities with respect to ([***]Development, Manufacture, Commercialization, or other Exploitation of any product that includes a viral vector (including adeno-associated virus), any oligonucleotide, or any small molecule [***]. For avoidance of doubt, nothing in this Section 4.4.1 (Exclusivity) shall restrict or prevent [***].

4.4.2 **Acquisitions of Alternative Option Products**. If following Biogen's exercise of its Option with respect to a given Option Program, either Party licenses, acquires, or otherwise obtains rights to Develop or Commercialize any Alternative Option Product (such Party, the "**Acquiring Party**"), then such Acquiring Party shall promptly so notify the non-Acquiring Party. Within [***] from the closing date of such transaction pursuant to which the Acquiring Party obtained rights to such Alternative Option Product, as applicable, the Acquiring Party will notify the non-Acquiring Party in writing of its election to either (a) [***] or (b) [***].

4.4.3 **Acquisitions by a Third Party that Controls Alternative Option Products.** If a Party undergoes a Change of Control with a Third Party Acquiror that owns or Controls one or more Alternative Option Products and one or more products that are not Alternative Option Products, in each case, pursuant to programs that are in existence as of the effective date of such transaction (such Party, the "**Acquired Party**"), then such Acquired Party shall promptly so notify the non-Acquired Party. Such Third Party Acquiror may [***].

4.4.4 **Protective Provisions**. Without limiting anything set forth in Section 4.4.2 (Acquisitions of Alternative Option Products) or Section 4.4.3 (Acquisitions by a Third Party that Controls Alternative Option Products) each Acquiring Party and Acquired Party will ensure that (i) [***], and (ii) [***]. Notwithstanding the foregoing clause (ii) and without limiting the obligations under clause (i), the foregoing [***] obligation under clause (ii) will not apply to [***].

4.5 **Retained Rights**.

4.5.1 Except as expressly provided herein, Denali grants no other right or license, including any rights or licenses to the [***] not otherwise expressly granted herein, whether by implication, estoppel or otherwise. Notwithstanding any provision to the contrary set forth in this Agreement, Denali shall retain the right to (a) Exploit the [***], including the right to grant and authorize licenses under such [***] to the extent [***] for the purposes of [***] and (b) Exploit the [***], including the right to grant and authorize licenses under such [***], for the following purposes: [***].

4.5.2 Except as expressly provided herein, Biogen grants no other right or license, including any rights or licenses to the Biogen IP, or any other Intellectual Property or proprietary rights not otherwise expressly granted herein, whether by implication, estoppel or otherwise. [***]

ARTICLE 5 OPTION DEVELOPMENT ACTIVITIES

5.1 **Development and Manufacturing Activities during the Option Term**. During the Option Term for a given Option Program: (a) Denali will use Commercially Reasonable Efforts to [***]; and (b) other than with the prior written consent of Biogen, Denali will not Initiate IND-Enabling Studies for any Option Product that is the subject of any given Option Program until the expiration of the applicable Option Term without Biogen exercising the Option for such Option Program. In addition, during the Option Term for a given Option Program, Biogen shall be responsible for any pre-clinical research or other activities (such as assays) with respect to such Option Program that are (i) [***] (such activities, the "**Biogen Option Development Activities**," and together with the Denali Option Development Activities, the "**Option Development Activities**"), and, subject to Section 5.5 (Materials), Denali will provide Biogen or its Affiliates with Materials Controlled by Denali that are necessary to perform such Biogen Option Development Activities. At either Party's request (which may occur prior to exercise of the Option by Biogen with respect to the applicable Option Program) and subject to Section 8.2.3 (CMC Plan), the Parties shall discuss and agree upon a CMC Plan (including CMC Budget) directed to the Manufacture of research grade Option Product for use in IND-Enabling Studies and for the Manufacture of GMP grade Clinical Trial Materials, and the conduct of Denali Manufacturing Activities in connection therewith.

5.2 **Conduct of Option Development Activities**.

5.2.1 **By Denali**. Denali will conduct all Denali Option Development Activities and Denali Manufacturing Activities in good scientific manner, and in compliance with all Applicable Laws, including cGMP, GLP and GCP, as applicable. In addition, Denali will perform all Denali Option Development Activities and Denali Manufacturing Activities with reasonable care and skill in accordance with the terms and conditions of this Agreement. Denali will ensure that its personnel who perform Denali Option Development Activities or Denali Manufacturing Activities are suitably qualified and trained to be capable of carrying out such Denali Option Development Activities or Denali Manufacturing Activities (as applicable) in a professional workmanlike manner and will provide such personnel with all reasonably necessary materials and facilities therefor. Denali will be responsible for [***] .

5.2.2 **By Biogen**. Biogen will conduct all Biogen Option Development Activities in good scientific manner, and in compliance with all Applicable Laws, including cGMP, GLP, and GCP, as applicable. In addition, Biogen will perform all Biogen Option Development Activities with reasonable care and skill in accordance with the terms and conditions of this Agreement. Biogen will ensure that its personnel who perform Biogen Option Development Activities are suitably qualified and trained to be capable of carrying out such Biogen Option Development Activities in a professional workmanlike manner and will provide such personnel with all reasonably necessary materials and facilities therefor. Biogen will be responsible for [***].

5.3 **Records**. During the Option Term for a given Option Program and for [***] thereafter, each Party will maintain records of all of its respective Option Development Activities and all Denali Manufacturing Activities (in the case of Denali) in sufficient detail and in good scientific manner, appropriate for scientific, patent, and regulatory purposes, which records will be complete and properly reflect all work done and results achieved in the performance of all such Option Development Activities and Denali Manufacturing Activities (in the case of Denali).

5.4 **Copies and Inspection of Records**. On an Option Program-by-Option Program basis (other than with respect to any Option Program for which Biogen does not provide an Option Exercise Notice prior to expiration of the Option Exercise Period corresponding to such Option Program), no more than [***], during normal business hours and upon reasonable notice not less than [***], and without limiting Section 2.5 (Due Diligence), (a) Biogen will have the right to inspect all records of Denali or its authorized Third Party designees created in the performance of Denali Option Development Activities and Denali Manufacturing Activities with respect to a given Option Program solely for the purpose of verifying Denali's compliance with the terms and conditions of this Agreement, and (b) Biogen will also have the right to [***].

5.1 **Materials**. To facilitate the conduct of the Option Programs or the performance of other activities under this Agreement related to any Option Program, during the Option Term, either Party may provide to the other Party, if and as agreed by the Parties, certain compositions of matter, biological materials, or chemical compounds Controlled by the supplying Party for use by the other Party (such materials or compounds and any progeny and derivatives thereof, collectively, "**Materials**"). Except as otherwise set forth in this Agreement, all such Materials shall remain the sole property of the supplying Party, shall be used only in the fulfillment of obligations or exercise of rights under this Agreement related to the relevant Option Program or expressly in accordance with any other written agreement by the Parties as to the use thereof, subject to any limitations specified in writing by the supplying Party in connection with such provision, shall not be used or delivered to or for the benefit of any Third Party without the prior written consent of the supplying Party, and shall not be used in research or testing involving human subjects, unless expressly agreed by the supplying Party. Without limiting the foregoing, it is understood that if any Biogen Option Development Activities agreed upon by the Parties require Biogen or its Affiliates to utilize any Option Protein or Option Product included in such Option Program, Denali will provide such Option Protein or Option Product only pursuant to a form of material transfer agreement agreed by Parties ("**Option MTA**"). The Option MTA will include terms that are consistent with this Section 5.5 (Materials) and are otherwise reasonable and customary for the provision of Materials in similar circumstances, including that (i) any Program Know-How generated in the performance of Biogen Option Development Activities under such Option MTA will be promptly disclosed to Denali and, notwithstanding any other provision to the contrary set forth in this Agreement, will be considered Confidential Information of both Parties and (ii) [***]. Except as otherwise set forth in this Agreement, THE MATERIALS ARE PROVIDED "AS IS" AND WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF THE MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

ARTICLE 6 GOVERNANCE

6.1 **Alliance Management**.

6.1.1 **Alliance Managers**. Each Party will appoint a single individual who possesses sufficient alliance management experience and is otherwise suitably qualified and who has the requisite decision-making authority, in each case, to act as its alliance manager under this Agreement (the "**Alliance Manager**"). Each Party may change the person designated as its Alliance Manager upon written notice (including via email notification) to the other Party, *provided* that such new Alliance Manager possesses sufficient alliance management experience and otherwise meets the requirements set forth in this Section 6.1.1 (Alliance Managers).

6.1.2 **Roles and Responsibilities**. The Alliance Managers will be responsible for (a) facilitating the flow of information between the Parties as provided in this Agreement, and otherwise creating and maintaining effective communication between the Parties regarding (i) during the Option Term, the Option Development Activities and Denali Manufacturing Activities and (ii) following Biogen's exercise of the option for any Option Program pursuant to Section 2.3 (Option Exercise), activities relating to the Development, Manufacture, performance of Medical Affairs activities with respect to, and Commercialization of Option Proteins and Option Products included in such Option Program, (b) providing a single point of communication for seeking consensus both internally within the respective Party's organization and between the Parties regarding key strategy and planning issues, (c) assisting the integration of teams across functional areas, to the extent applicable, (d) preparing and disseminating agendas and presentations for the JSC meetings, (e) following Biogen's exercise of the option with respect to each Option Program pursuant to Section 2.3 (Option Exercise), [***], and (f) performing such other functions as specified in this Agreement, requested by the JSC or agreed by the Parties.

6.2 **Joint Steering Committee**.

6.2.1 **Formation**. As soon as practicable, but no later than [***] after the Effective Date, the Parties will establish a joint steering committee (the "**JSC**") to monitor the Option Development Activities and Denali Manufacturing Activities. The JSC will be comprised of [***] representatives of Biogen and [***] representatives of Denali, each of whom will have the appropriate experience and expertise to perform their responsibilities on the JSC. Each Party will provide notice to the other Party of its initial representatives to the JSC. Either Party may replace its representatives with similarly qualified individuals at any time upon prior written notice to the other Party. If agreed by the Parties on a case-by-case basis, the JSC may invite other non-members to participate in the discussions and meetings of the JSC, *provided* that such participants will have no voting authority at the JSC and that any such non-employee participants are bound by written obligations of non-use and confidentiality no less stringent than those set forth in Article 11 (Confidentiality). The Alliance Managers will be responsible, on behalf of the JSC, for setting the agenda for meetings of the JSC with input from each Parties' JSC representatives. Neither Alliance Manager will be a member of the JSC, but the Alliance Managers will attend all meetings of the JSC.

6.2.2 **Meetings**. The JSC will meet in person (alternating between a site in the United States designated by each of Denali and Biogen) or by videoconference or teleconference, as agreed by the Parties, at least [***], or with such other frequency as the Parties may agree. Specific meeting dates will be determined by agreement of the Parties. Either Party may also call a special meeting of the JSC (by videoconference or teleconference) upon at least [***] prior written notice to the other Party if such Party reasonably believes that a significant matter must be addressed before the next regularly scheduled JSC meeting, and such Party will provide the JSC materials reasonably adequate to enable an informed discussion by its members no later than [***] before the special meeting. Biogen will host the first meeting of the JSC at a mutually agreeable time no later than [***] after the Effective Date. Each Party will be responsible for its own expenses relating to attendance at or participation in JSC meetings. The Alliance Managers will prepare and disseminate agendas and presentations no later than [***] in advance of each JSC meeting unless otherwise agreed to by the Parties in writing. The Alliance Managers will jointly prepare and circulate minutes for each JSC meeting within [***] after each such meeting and will ensure that such minutes are reviewed and approved by their respective companies within [***] thereafter.

6.2.3 **Responsibilities**. The JSC will monitor the progress of the Option Development Activities. Within such scope the JSC will, subject to Section 6.2.4 (Limits on JSC Authority):

(a) [***], provide a forum for Denali to present an Option Update Report for each Option Program;

(b) consider and discuss any technical issues that arise under the Option Development Activities or the Denali Manufacturing Activities;

(c) [***]

(d) provide a forum for discussing any pre-clinical research or other activities that either Party proposes to become Biogen Option Development Activities, as described in Section 5.1 (Development and Manufacturing Activities during the Option Term);

(e) [***];

(f) form such other committees as the JSC may deem appropriate, including individual committees to monitor Option Development Activities and Denali Manufacturing Activities related to a particular Option Program, including manufacturing process development activities under each CMC Plan;

(g) provide a forum for discussing disagreements between the Parties with respect to the Option Development Activities or Denali Manufacturing Activities on an informal basis; and

(h) perform such other functions as expressly set forth in this Agreement or allocated to the JSC by the written agreement of the Parties.

6.2.4 **Limits on JSC Authority**. A quorum for a meeting of the JSC will require the presence of at least one representative from each Party. The JSC will facilitate the exchange of information, and discussion between the Parties, with respect to matters relating to the Option Development Activities and Denali Manufacturing Activities and such other matters as the Parties agree, but the JSC will have no decision-making authority.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

6.3 **Disbandment of the JSC**. The JSC will disband upon the earlier of (a) on an Option Program-by-Option Program basis, the expiration (or earlier termination) of the Option Term for such Option Program, except that if Biogen exercises the Option for a particular Option Program pursuant to Section 2.3 (Option Exercise), then the JSC shall continue for so long as Denali is conducting Denali Manufacturing Activities with respect to such Option Program, or (b) the termination of this Agreement. If the JSC disbands after Biogen has exercised the Option for a particular Option Program pursuant to Section 2.3 (Option Exercise), then upon the disbanding of the JSC, the JSC will have a final meeting thereafter to review the results of all Option Development Activities and Denali Manufacturing Activities with respect to a given Option Program and will thereafter have no further authority with respect to the activities hereunder.

ARTICLE 7 DEVELOPMENT, REGULATORY MATTERS, AND COMMERCIALIZATION

7.1 **Technology Transfer**. On an Option Program-by-Option Program basis: (a) within [***] (or such other period as the Parties agree) following the execution of an Option MTA with respect to such Biogen Option Development Activities, Denali disclose to Biogen [***]; (b) within [***] (or such other period as the Parties agree) following the date on which the Parties agree in writing on any additional Biogen Option Development Activities that are not set forth on Schedule 5.1 (Biogen Option Development Activities) and execute an Option MTA with respect to such Biogen Option Development Activities, Denali will disclose to Biogen [***]; and (c) within [***] (or such other period as the Parties agree) following Biogen's exercise of its Option with respect to a given Option Program in accordance with Section 2.3 (Option Exercise), [***]. In addition to disclosing copies of such [***] in accordance with this Section 7.1 (Technology Transfer), Denali will make its personnel reasonably available to Biogen so as to enable Biogen to practice under the [***]in connection with the Exploitation of such Option Proteins and Option Products; *provided* that [***]; *provided* [***]. Denali may [***]. Notwithstanding any provision to the contrary in this Agreement, Denali shall have no obligation to disclose or make available to Biogen any Know-How that constitutes [***].

7.2 **Development and Medical Affairs Activities.**

7.2.1 **Development and Medical Affairs Activities**. On an Option Program-by-Option Program basis, following Biogen's exercise of the Option with respect to a given Option Program in accordance with Section 2.3 (Option Exercise) and Biogen will [***] with respect to, the further Development of, and the performance of all Medical Affairs with respect to, all Option Proteins and Option Products that are the subject of such Option Program, including all pharmacovigilance activities. Biogen shall conduct all Development and Medical Affairs activities with respect to the Option Proteins and Option Products in good scientific manner and in compliance with all Applicable Laws, including cGMP, GLP and GCP. The Parties may elect to execute a safety transition agreement at such time as agreed by the Parties (if necessary).

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

7.2.2 **Development Reports**. On an Option Program-by-Option Program basis, following Biogen's exercise of the Option with respect to a given Option Program in accordance with Section 2.3 (Option Exercise), Biogen shall keep Denali reasonably informed as to the progress and results of its and its Affiliates' and Sublicensees' Development activities with respect to Option Proteins and Option Products that are the subject of such Option Program (including dates of achievements of Development Milestone Events), and shall provide to Denali, at least [***], a written report with respect to such matters (including a high-level overview of any anticipated material Development activities of with respect to Option Proteins and Option Products that are the subject of such Option Program). Any reports delivered under this Section 7.2.2 (Development Reports) will be Biogen's Confidential Information under this Agreement. Upon Denali's reasonable request and no more frequently than [***], the Parties will schedule either an in-person meeting, videoconference, or teleconference to discuss the status, progress and results of such Development activities, and during such meeting, videoconference or teleconference or promptly thereafter, Biogen shall promptly respond to Denali's reasonable questions or requests for additional information relating to such Development activities.

7.3 **Regulatory**.

7.3.1 **Regulatory Activities**. On an Option Program-by-Option Program basis, following Biogen's exercise of the Option with respect to a given Option Program in accordance with Section 2.3 (Option Exercise), Biogen will [***] the preparation and submission of all Regulatory Submissions for all Option Proteins and Option Products that are the subject of such Option Program at its own cost and expense, including all Drug Approval Applications, orphan drug designations, and applications for obtaining, supporting, and maintaining Regulatory Approvals and Reimbursement Approvals for all such Option Products. Biogen may file all such Regulatory Submissions in its own name (or in the name of its designee) and will own and control all such applications. Pursuant to Section 7.6 (Denali Support), Denali will use [***] to assist Biogen in its efforts to prepare and submit any Regulatory Submissions to obtain, support, or maintain Regulatory Approvals and Reimbursement Approvals for such Option Products, including by providing or facilitating access to Biogen, upon Biogen's reasonable request, all data, written reports, and other documentation, materials, and samples related to such Option Products included in the Option Know-How and that are required by Applicable Law or required or requested by a Regulatory Authority to obtain such Regulatory Approvals or Reimbursement Approvals.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

7.3.2 **Regulatory Submissions and Interactions**. Biogen shall keep Denali reasonably informed regarding regulatory activities with respect to Option Products and shall provide Denali with copies of any material Regulatory Submissions (including INDs and Drug Approval Applications) submitted by Biogen (or its Affiliates and Sublicensees) relating to any Option Product [***] prior to the submission thereof and in the event such Regulatory Submissions pertain to the TV Platform, Denali shall have a reasonable opportunity (and to the extent possible, at least [***]) to review and comment on such Regulatory Submissions, which comments Biogen shall consider in good faith. Biogen shall provide Denali with prompt prior written notice, to the extent Biogen has advance notice, of any action taken by a Regulatory Authority in a Major Market pertaining to any Regulatory Approval or Reimbursement Approval for an Option Protein or Option Product and any scheduled substantive meeting, conference or discussion with any Regulatory Authority in any Major Market that pertain to the TV Platform. [***] Denali shall have the right to have up to [***] of its employees attend such substantive meetings, conferences and discussions (or portion thereof) to the extent pertaining to the TV Platform as an observer. In addition, Biogen shall promptly notify Denali in writing of any decision by any Regulatory Authority in a Major Market regarding any Regulatory Approval or Reimbursement Approval for any Option Product. Further, Biogen shall promptly provide to Denali a copy of any material correspondence from or to a Regulatory Authority in a Major Market in the event such correspondence pertains to the TV Platform, including any reports with respect thereto (such as meeting minutes or finding issued by such a Regulatory Authority in connection with an audit conducted by such Regulatory Authority or otherwise).

7.4 **Commercialization**.

7.4.1 **Commercialization Activities**. On an Option Program-by-Option Program basis, following Biogen's exercise of the Option with respect to a given Option Program in accordance with Section 2.3 (Option Exercise), Biogen will [***], will bear all costs and expenses of, and will [***] the Commercialization of all Option Products that are the subject of such Option Program.

7.4.2 **Commercialization Reports**. On an Option Program-by-Option Program basis, following Biogen's exercise of the Option with respect to a given Option Program in accordance with Section 2.3 (Option Exercise), for so long as Biogen or its Affiliates or Sublicensees are Commercializing any Option Product that is the subject of such Option Program, Biogen shall keep Denali reasonably informed as to the progress and results of its and its Affiliates' and Sublicensees' Commercialization of such Option Products, and shall provide to Denali, on at least [***] basis a reasonably detailed summary regarding the status of the Commercialization activities of Biogen and its Affiliates and Sublicensees with respect to such Option Products (which reports shall be in addition to any royalty or other reports or notices provided to Denali pursuant to this Agreement). Any reports delivered under this Section 7.4.2 (Commercialization Reports) will be Biogen's Confidential Information under this Agreement. Upon Denali's reasonable request and no more frequently than [***], the Parties will schedule either an in person meeting, videoconference, or teleconference to discuss the status, progress and results of such Commercialization activities, and during such meeting, videoconference, or teleconference or promptly thereafter, Biogen shall promptly respond to Denali's reasonable questions or requests for additional information relating to such Commercialization activities.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

7.5 **Diligence Obligations**.

7.5.1 **Development Diligence Obligations**. On an Option Program-by-Option Program basis, following Biogen's exercise of the Option with respect to a given Option Program in accordance with Section 2.3 (Option Exercise), Biogen, by itself or through its Affiliates or Sublicensees, will use Commercially Reasonable Efforts to [***].

7.5.2 **Commercialization Diligence Obligations**. On an Option Program-by-Option Program basis, Biogen will use Commercially Reasonable Efforts to [***].

7.6 **Denali Support**. The Parties understand and agree that following Biogen's exercise of its Option with respect to a given Option Program in accordance with Section 2.3 (Option Exercise), in addition to the cooperation and assistance to be expressly provided under Section 7.1 (Technology Transfer), Section 7.3 (Regulatory), and Section 8.8 (Denali Manufacturing Support), from time to time it may be necessary for Biogen to seek assistance and cooperation from Denali in connection with the Exploitation of Option Proteins or Option Products that are the subject of such Option Program. Denali hereby agrees to use [***]; *provided* that [***], *provided* that [***]. [***]

ARTICLE 8 MANUFACTURE AND SUPPLY

8.1 **General Responsibilities**. Except as otherwise set forth in this Agreement (including Section 8.2 (Denali Supply Obligations) below), on an Option Program-by-Option Program basis, following Biogen's exercise of the Option with respect to a given Option Program in accordance with Section 2.3 (Option Exercise), Biogen will [***] with respect to, the Manufacture of Option Proteins and Option Products by itself or through one or more Affiliates or Third Parties selected by Biogen in its sole discretion.

8.2 **Denali Supply Obligations**.

8.2.1 **Supply Requirements**. Subject to the terms and conditions of this Agreement, on an Option Program-by-Option Program basis, following Biogen's exercise of the Option with respect to a given Option Program in accordance with Section 2.3 (Option Exercise), Denali shall, pursuant to and in accordance with the Supply Agreement, supply to Biogen any and all [***] of (a) [***], (b) [***], and (c) [***], in each case ((a)-(c)), (i) in a form as agreed to by the Parties and in accordance with the applicable specifications set forth in the applicable CMC Plan (the "**Specifications**") and (ii) including all product specification files or similar documentation required by applicable Regulatory Authorities, *provided*, *however*, that the foregoing supply obligations of Denali described in clauses (a)-(c) will expire upon the earliest of [***].

8.2.2 **Supply Agreement**. Promptly following Biogen's exercise of its Option with respect to a given Option Program in accordance with Section 2.3 (Option Exercise), the Parties shall negotiate in good faith and enter into a supply agreement for Manufacture and supply of the Option Products to be supplied by Denali to Biogen under Section 8.2.1 (Supply Requirements) (the "**Supply Agreement**"), which Supply Agreement shall be consistent with this Article 8 (Manufacture and Supply) and the Parties shall negotiate in good faith and enter into a quality agreement (the "**Quality Agreement**") that addresses the quality control and quality assurance terms and conditions related to the supply of Option Products pursuant to the Supply Agreement.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

8.2.3 **CMC Plan**. Subject to the terms and conditions of this Agreement, Denali shall also use [***] to perform all manufacture process development work required for Denali to Manufacture (or have Manufactured) the Option Products that Denali is obligated to supply under Section 8.2.1 (Supply Requirements). Denali shall perform such manufacture process development activities for each Option Program pursuant to, and contingent upon, a written manufacture process development plan [***] that sets forth all material process development work to be conducted for each Option Product, the timeline for performance thereof, and the Specifications (each, a "**CMC Plan**"). The CMC Plans shall include all process development activities required for the Manufacture of [***] for the first Option Product that is subject to each Option Program for which Biogen has exercised its Option. Each CMC Plan shall also set forth (a) a detailed budget for such process development work, including both internal costs (at the FTE Rate) and out-of-pocket costs (each, a "**CMC Budget**") and (b) the quantities of the applicable Option Product to be ordered by Biogen and the estimated delivery date for such Option Product, which shall be consistent with the forecast provided by Biogen in accordance with a forecasting schedule to be agreed by the Parties in the Supply Agreement. The Parties shall collaboratively prepare the CMC Plan (including the CMC Budget) for such Option Program in accordance with Section 5.1 (Development and Manufacturing Activities during the Option Term) and in any case no later than [***].

8.2.4 **CMOs**. Denali may perform its obligations set forth under this Section 8.2 (Denali Supply Obligations) (the "**Denali Manufacturing Activities**") itself or through a Third Party contract manufacturer ("**CMO**") approved in writing by Biogen (which approval shall not be unreasonably withheld, conditioned, or delayed). Such approved CMOs are those CMOs set forth in Schedule 8.2.4 (Approved CMOs).

8.3 **Product Delivery**. Denali shall deliver all Option Product supplied pursuant to Section 8.2 (Denali Supply Obligations) to Biogen or its designee [***] at Biogen's or its designee's designated facility. [***].

8.4 **Manufacture by CMO**. If Denali utilizes one or more CMOs to supply Option Product to Biogen, then as long as Denali uses [***] to perform its obligations and to exercise its rights under its applicable agreement(s) with such CMO, including seeking or exercising all remedies provided by such CMO under such agreement(s), then [***]. Unless otherwise agreed by the Parties, if Denali is performing the Denali Manufacturing Activities through one or more CMOs, then, in connection with the transition of any Manufacturing responsibilities to Biogen for a given Option Product, the Parties will discuss in good faith [***].

8.5 **Manufacturing Costs**. On an Option Program-by-Option Program basis, following Biogen's exercise of the Option with respect to a given Option Program in accordance with Section 2.3 (Option Exercise):

8.5.1 Biogen shall pay Denali [***];

8.5.2 Biogen shall pay Denali [***]; and

8.5.3 in addition to the amounts to be paid by Biogen pursuant to Section 8.5.1 and Section 8.5.2, Biogen shall reimburse Denali for [***]. Denali may invoice Biogen for such costs so incurred in accordance with this Section 8.5.3, and Biogen will pay the undisputed invoiced amounts within [***] after the date of such invoice.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

8.6 **Observation by Biogen**. Before the completion of the Manufacturing Technology Transfer with respect to Option Products under a given Option Program and subject to this Section 8.6 (Observation by Biogen) below, Denali will provide Biogen with the opportunity, upon Biogen's reasonable request during normal business hours and to the extent not unreasonably disruptive to the normal course of business, to observe the Manufacturing processes and procedures for such Option Products (e.g., review assays, batch records, and release processes and procedures) for the purpose of enabling Biogen (or a CMO designated by Biogen) to Manufacture such Option Products following the completion of such Manufacturing Technology Transfer pursuant to Section 8.7 (Manufacturing Technology Transfer). If Denali utilizes a CMO for the Manufacture of any Option Product, then [***], provided that [***]. Notwithstanding the foregoing, (a) [***] and (b) [***].

8.7 **Manufacturing Technology Transfer**.

8.7.1 In addition to the initial technology transfer set forth in Section 7.1 (Technology Transfer) and subject to the remainder of this Section 8.7 (Manufacturing Technology Transfer), upon Biogen's reasonable request with respect to an Option Product that Denali is Manufacturing pursuant to Section 8.2 (Denali Supply Obligations) at any time following Biogen's exercise of its Option with respect to a given Option Program in accordance with Section 2.3 (Option Exercise) and upon reasonable advance notice to Denali (but in no event less than [***] notice, or such other period as the Parties may agree), Denali will work with Biogen to disclose and make available to Biogen or one of its CMOs all [***], *provided* that in no event will Denali be required (x) to [***] or (y) to [***] (for each Option Product, the "**Manufacturing Technology Transfer**"). Each Manufacturing Technology Transfer will be conducted at (a) [***], or (b) [***].

8.7.2 Each such Manufacturing Technology Transfer will be conducted pursuant to and will be subject to a written plan agreed by the Parties in good faith prior to the anticipated commencement of such Manufacturing Technology Transfer, the purpose of which plan will be to provide for the complete and timely transfer of [***] to Biogen. Without limiting the foregoing, in connection with the development of each plan for a Manufacturing Technology Transfer, Denali will identify to Biogen any Third Party Intellectual Property or any Materials included in [***] and that would contain restrictions or conditions applicable to the use of such Third Party Materials or Intellectual Property by or on behalf of Biogen to Manufacture Option Products or Option Proteins included in the applicable Option Program under and in accordance with the terms and conditions of this Agreement ("**Existing Third Party Manufacturing IP**").

8.7.3 Upon Biogen's reasonable request, Denali shall [***].

8.7.4 After completion of Manufacturing Technology Transfer for an Option Product, Biogen shall [***] with respect to the Manufacture and supply of such Option Product.

8.8 **Denali Manufacturing Support**. Without limiting the generality of Section 7.6 (Denali Support), the Parties understand and agree following the Manufacturing Technology Transfer contemplated by Section 8.7 (Manufacturing Technology Transfer) it may be necessary for Biogen from time to time to seek assistance and cooperation from Denali in connection with the Manufacture of Option Products for which Biogen has exercised its Option, including with respect to scale-up activities. Denali will use [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

ARTICLE 9 PAYMENTS AND ROYALTIES

9.1 **Upfront Payment**. No later than [***] after the Effective Date, Biogen will pay to Denali a one-time upfront payment of one hundred sixty million Dollars ($160,000,000), payable by wire transfer of immediately available funds.

9.2 **Option Exercise Fee**. On an Option Program-by-Option Program basis, Biogen will pay to Denali a one-time payment of [***] (each, an "**Option Exercise Fee**") no later than [***] after its receipt of invoice for such Option Exercise Fee, which invoice Denali may not deliver until receipt by Denali of an Option Exercise Notice for such Option Program.

9.3 **Milestone Payments**.

9.3.1 **Development Milestones**. On an Option Program-by-Option Program basis, following Biogen's exercise of its Option with respect to a given Option Program in accordance with Section 2.3 (Option Exercise), Biogen will make one-time milestone payments (each, a "**Development Milestone Payment**") to Denali upon the first achievement by Biogen or its Affiliates or Sublicensees of each of the development milestone events (each, a "**Development Milestone Event**") set forth in TABLE 9.3.1(a) (in the case of [***]) or TABLE 9.3.1(b) (in the case of [***]) below for the first Option Product under [***] to achieve the applicable Development Milestone Event. For the avoidance of doubt, each Development Milestone Payment hereunder will be payable only once per Option Program upon the first achievement of the applicable Development Milestone Event by an Option Product that is the subject of such Option Program. No additional Development Milestone Payments will be made for any subsequent achievement of such Development Milestone Event by any other Option Product that is the subject of such Option Program. Biogen will notify Denali in writing of the achievement of a Development Milestone Event by Biogen or its Affiliates or Sublicensees no later than [***] after Biogen becomes aware of the achievement thereof. Thereafter, Denali will provide Biogen with an invoice for the corresponding Development Milestone Payment, and Biogen will pay to Denali such Development Milestone Payment no later than [***] after its receipt of invoice for such Development Milestone Payment. [***]

TABLE 9.3.1(a) – [***] Development Milestones

Development Milestone Event	Development Milestone Payment (US$)
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

TABLE 9.3.1(b) – [***] Development Milestones	
Development Milestone Event	**Development Milestone Payment (US$)**
[***]	**[***]**
[***]	**[***]**
[***]	**[***]**
[***]	**[***]**
[***]	**[***]**

[***]

9.3.2 **Commercial Milestones**. On an Option Program-by-Option Program basis, following Biogen's exercise of its Option with respect to a given Option Program in accordance with Section 2.3 (Option Exercise), Biogen will make one-time milestone payments (each, a "**Commercial Milestone Payment**") to Denali upon the first achievement by Biogen or its Affiliates or Sublicensees of each of the commercial milestone events (each, a "**Commercial Milestone Event**") set forth in TABLE 9.3.2(a) [***] or TABLE 9.3.2(b) [***] below for the first Option Product [***] to achieve the applicable Commercial Milestone Event. For the avoidance of doubt, each Commercial Milestone Payment hereunder will be payable only once per Option Program upon the first achievement of the applicable Commercial Milestone Event by an Option Product that is the subject of such Option Program. No additional Commercial Milestone Payments will be made for any subsequent achievement of such Commercial Milestone Event by any other Option Product that is the subject of such Option Program. Biogen will notify Denali in writing of the achievement of a Commercial Milestone Event by Biogen or its Affiliates or Sublicensees no later than [***] after Biogen becomes aware of the achievement thereof. Thereafter, Denali will provide Biogen with an invoice for the corresponding Commercial Milestone Payment, and Biogen will pay to Denali such Commercial Milestone Payment no later than [***] after its receipt of invoice for such Commercial Milestone Payment. [***]

TABLE 9.3.2(a) – [***] Commercial Milestones	
Commercial Milestone Event	***Commercial Milestone Payment (US$)***
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

TABLE 9.3.2(b) – [***] Commercial Milestones	
Commercial Milestone Event	***Commercial Milestone Payment (US$)***
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

A Commercial Milestone Event in a particular country shall be deemed to be achieved for an Indication if the relevant Regulatory Approval in a given country for an Option Product has a label for such Indication.

[***]

9.3.3 **Sales Milestones**. On an Option Program-by-Option Program basis, following Biogen's exercise of its Option with respect to a given Option Program in accordance with Section 2.3 (Option Exercise), Biogen will make one-time sales milestone payments (each, a "**Sales Milestone Payment**" and together with the Development Milestone Payments and Commercial Milestone Payments, the "**Milestone Payments**") to Denali upon the achievement by Biogen or its Affiliates or Sublicensees of each of the sales-based milestones events (each, a "**Sales Milestone Event**") set forth in TABLE 9.3.3(a) [***] or TABLE 9.3.3(b) [***] below with respect to aggregate annual Net Sales of Option Products under such Option Program. Each of the Sales Milestone Payments set forth below will be payable only one time, for the first Calendar Year in which the corresponding Sales Milestone Event is achieved. Biogen will notify Denali in writing of the achievement of a Sales Milestone Event by Biogen or its Affiliates or Sublicensees no later than [***] after the end of the Calendar Year in which such Sales Milestone Payment is payable pursuant to the preceding sentence. Thereafter, Denali will provide Biogen with an invoice for the corresponding Sales Milestone Payment, and Biogen will pay to Denali such Sales Milestone Payment no later than [***] after its receipt of invoice for such Sales Milestone Payment. [***]

TABLE 9.3.3(a) – [***] Sales Milestones	
Sales Milestone Event	***Sales Milestone Payment (US$)***
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

TABLE 9.3.3(b) – [***] Sales Milestones	
Sales Milestone Event	***Sales Milestone Payment (US$)***
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

9.4 **Royalties**.

9.4.1 **Royalty Payments**. Subject to the provisions of Section 9.4.4 (Royalty Reductions), on an Option Product-by-Option Product and country-by-country basis following Biogen's exercise of its Option with respect to a given Option Program in accordance with Section 2.3 (Option Exercise), Biogen will pay to Denali royalties in the amount of the marginal royalty rates set forth in TABLE 9.4.1(a) [***] or TABLE 9.4.1(b) [***] below of the aggregate Net Sales resulting from the sale of Option Products in the Territory during each Calendar Year of the applicable Royalty Term for each Option Product in each country (each, the "**Per Product Annual Net Sales**").

TABLE 9.4.1(a) – Marginal Royalty Rates for [***]	
Per Product Annual Net Sales	***Marginal Royalty Rate (% of Per Product Annual Net Sales)***
[***]	[***]
[***]	[***]
[***]	[***]

TABLE 9.4.1(b) – Marginal Royalty Rates for [***]	
Per Product Annual Net Sales	***Marginal Royalty Rate (% of Per Product Annual Net Sales)***
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

Each marginal royalty rate set forth in TABLE 9.4.1(a) and TABLE 9.4.1(b) above will apply only to that portion of the Net Sales of a given Option Product in the Territory during a given Calendar Year that falls within the indicated range. [***]

9.4.2 **Royalty Term**. On a country-by-country and Option Product-by-Option Product basis following Biogen's exercise of its Option with respect to a given Option Program in accordance with Section 2.3 (Option Exercise), Biogen will make royalty payments for each Option Product under such Option Program during the period commencing upon the First Commercial Sale of such Option Product in such country and continuing until the latest of: [***] (the "**Royalty Term**"), *provided*, *however*, that if at any time during the Royalty Term for an Option Product in a country [***], then the Royalty Term for such Option Product in such country [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

9.4.3 **Royalty Reports; Payments.**

(a) Within [***] following the end of each Calendar Quarter after the First Commercial Sale of an Option Product in the Territory, unless the Parties otherwise agree to alternate timing, Biogen shall provide to Denali a written report detailing the following information: (i) the amount of gross sales of the Option Products in the Calendar Quarter; and (ii) the amount of Net Sales in such Calendar Quarter.

(b) Within [***] following the end of each Calendar Quarter after the First Commercial Sale of an Option Product in the Territory, unless the Parties otherwise agree to alternate timing, Biogen shall provide Denali with a written report detailing the following information for the applicable Calendar Quarter and on an Option Product-by-Option Product and country-by-country basis (to the extent applicable): (i) the amount of gross sales of the Option Products in the relevant Calendar Quarter; (ii) Net Sales in the relevant Calendar Quarter; (iii) to the extent such Net Sales include sales not denoted in U.S. Dollars, a summary of the current exchange rate methodology then in use by Biogen; (iv) a calculation of any adjustments to such royalties under Section 9.4.4(a) (Loss of Patent Coverage) through Section 9.4.4(d) (Cumulative Adjustments) and (v) a calculation of the final royalty payment due on such Net Sales (such report, the "**Final Royalty Report**").

(c) In addition, (i) at Denali's request, Biogen shall provide to Denali with at least such information pertaining to Net Sales as may be necessary for Denali to comply with its external reporting requirements as determined by Applicable Law, and such information shall be provided by Biogen together with each Final Royalty Report (or within [***] following the applicable request by Denali, if a Final Royalty Report for the applicable Calendar Quarter has already been delivered), and (ii) without limiting subclause (i), to the extent raised by either Party, the Parties will discuss any questions regarding the deductions included in the Net Sales calculation in a given Calendar Quarter. Biogen shall pay all royalty payments due to Denali under this Section 9.4 (Royalties), within [***] after the end of each Calendar Quarter.

9.4.4 **Royalty Reductions.**

(a) **Loss of Patent Coverage**. On an Option Product-by-Option Product and country-by-country basis following Biogen's exercise of its Option with respect to a given Option Program in accordance with Section 2.3 (Option Exercise), if during the Royalty Term for an Option Product in [***], then the royalty due for such Option Product in such country will be reduced by [***], subject to Section 9.4.4(d) (Cumulative Adjustments).

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(b) **Biosimilar Competition**. If, on an Option Product-by-Option Product, Calendar Quarter-by-Calendar Quarter and country-by-country basis following Biogen's exercise of its Option with respect to a given Option Program in accordance with Section 2.3 (Option Exercise), [***], then the royalties payable by Biogen pursuant to Section 9.4.1 (Royalty Payments) for such Option Product in such country will be reduced by the applicable percentage described below for the remainder of the Royalty Term for such Option Product in such country:

[***]	**Royalty Reduction**
[***]	[***]
[***]	[***]
[***]	[***]

(c) **Third Party Payments**. If Biogen makes any payment to a Third Party in consideration for a license or other acquisition of rights under any Patent Right (or Know-How licensed or otherwise acquired with such Patent Rights) owned or controlled by such Third Party that are [***] for the Exploitation of an Option Product in a country in the Territory, then Biogen may deduct from [***] up to [***].

(d) **Cumulative Adjustments**. Notwithstanding the reductions set forth in Section 9.4.4(a) (Loss of Patent Coverage) and Section 9.4.4(b) (Biosimilar Competition), in no event shall the operation of such reductions, individually or in combination, reduce the royalty payments paid to Denali with respect to any Option Product in the Territory in any Calendar Quarter under Section 9.4 (Royalties) to less than [***].

9.5 **Payment Method**. All payments to be made between the Parties under this Agreement will be made in Dollars and may be paid by wire transfer in immediately available funds to a bank account designated by Denali; *provided* that in no event will Biogen be obligated to make payments under this Agreement to any Affiliate of Denali that is organized in any jurisdiction outside of the U.S. without Biogen's prior written consent. Except as expressly provided in this Agreement, all payments to be made between the Parties under this Agreement are non-refundable and non-creditable against future payments to be made by such Party to the other Party under this Agreement.

9.6 **Currency Exchange**. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than Dollars), in the case of any amounts designated in another currency, each Party shall convert such foreign currency into Dollars using its standard conversion method consistent with GAAP in a manner consistent with the respective Party's customary and usual conversion procedures used in preparing its audited financial reports applied on a consistent basis, *provided* that such procedures use a widely accepted source of published exchange rates.

9.7 **Late Payments**. If a Party does not receive payment of any undisputed sum due to it on or before the due date set forth under this Agreement, then [***] interest will thereafter accrue on the sum due to such Party from the due date until the date of payment at [***] rate [***] or the maximum rate allowable under Applicable Law, whichever is lower.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

9.8 **Payment Allocations**.

9.8.1 Subject to the remainder of this Section 9.8 (Payment Allocations), payments under this Agreement shall be paid by BIMA and BIG separately and in such proportions [***] and shall be invoiced separately by Denali; *provided* that [***].

9.8.2 With respect to the upfront payment set forth in Section 9.1 (Upfront Payment), BIG will pay a portion of such amount in consideration of the rights granted outside of the U.S. [***], and BIMA will pay a portion of such amount in consideration of the rights granted in the U.S. [***].

9.8.3 With respect to the Development Milestone Payments and Option Exercise Fees, BIG will pay a percentage of each such amount in consideration of the rights granted outside of the U.S. and BIMA will pay a percentage each such amount in consideration to the rights granted in the U.S., such percentages, in each case, to be determined by Biogen at the time at which such amounts are due.

9.8.4 BIG will pay the Commercial Milestone Payments that are achieved outside of the U.S. when such amounts become due and payable in accordance with Section 9.3.2 (Commercial Milestones). BIMA will pay the Commercial Milestone Payments that are achieved in the U.S. when such amounts become due and payable in accordance with Section 9.3.2 (Commercial Milestones).

9.8.5 BIMA will pay the portion of the Sales Milestone Payments and royalties hereunder based on the pro rata allocation of the Per Product Annual Net Sales attributable to sales of the applicable Option Product in the U.S., and BIG will pay the portion of the Sales Milestone Payments and royalties hereunder based on the pro rata allocation of the Per Product Annual Net Sales attributable to sales of the applicable Option Product outside of the U.S.

9.8.6 With respect to all milestone payments set forth in this Agreement that are not described in Section 9.8.2 through Section 9.8.5 above, BIG will pay a percentage of each such amount in consideration of the rights granted outside of the U.S. and BIMA will pay a percentage each such amount in consideration to the rights granted in the U.S., such percentages, in each case, to be determined by Biogen at the time in which such amounts are due.

9.8.7 For clarity, nothing in this Section 9.8 (Payment Allocations) is intended to limit Section 15.16.1 (Performance by BIMA and BIG).

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

9.9 **Taxes**.

9.9.1 Each Party will be responsible for all Taxes imposed on such Party's net income, or on net income allocated to such Party under Applicable Law. To the extent one Party pays Taxes imposed on net income of the other Party, the other Party shall reimburse the paying Party for any such Taxes paid. The amounts payable pursuant to this Agreement ("**Payments**") shall not be reduced on account of any Taxes unless required by Applicable Law. A payor Party shall deduct and withhold from the Payments any Taxes that it is required by Applicable Law to deduct or withhold including from subsequent Payments. Notwithstanding the foregoing, if the recipient Party is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, or recovery of, applicable withholding tax, it may deliver to the payor Party or the appropriate Governmental Authority the prescribed forms necessary to reduce the applicable rate of withholding or to relieve the payor Party of its obligation to withhold tax. In such case the payor Party shall apply the reduced rate of withholding, or not withhold, as the case may be, provided that the payor Party is in receipt of evidence, in a form reasonably satisfactory to the payor Party of the recipient Party's entitlement to a reduced or no withholding rate. If, in accordance with the foregoing, a payor Party withholds any amount, it shall pay to the recipient Party the balance when due, make timely payment to the proper taxing authority of the withheld amount, and send the recipient Party proof of such payment within [***] following that payment. The Parties shall use reasonable efforts to reduce any withholding required under Applicable Law. The Parties hereto agree that as of the date hereof, no U.S. or Swiss withholding taxes are required on the upfront payment described in Section 9.1 (Upfront Payment) under Applicable Law [***].

9.9.2 If a Party that owes a Payment assigns its rights and obligations to any person as permitted in accordance with Section 15.3 (Assignment) of this Agreement (or any successor provision) and if, solely as a result of such assignment, the withholding of taxes required by Applicable Law with respect to the Payments is increased, then any Payments shall be increased to take into account such withheld taxes so that, after making all required withholding tax (including withholding tax on amounts payable pursuant to Section 9.9.1), the recipient Party receives an amount equal to the sum it would have received had no such assignment been made.

9.9.3 All payments or amounts due under this Agreement, whether monetary or non-monetary are exclusive of VAT. Any Party receiving a supply under this Agreement or the Supply Agreement hereby covenants that it will pay any such VAT correctly charged in addition to any amounts due under this Agreement or the Supply Agreement. Where the prevailing legislation requires the recipient to self-account for VAT (for example, but not limited to, the VAT reverse charge mechanism), then the receiving Party covenants that it shall correctly account for VAT in respect of the services received. The supplying Party agrees that it will raise a tax invoice (or equivalent document) to support the charge to VAT.

9.9.4 For the purposes of VAT, the services, rights and licenses provided by Denali under this Agreement shall be considered to be taxed under by Art 44 of Council Directive 2006/112/EC or any equivalent provision in the country of performance if performed outside the European Union and as such will be considered to be taxed for VAT purposes in the country of the recipient. For the purposes of this clause, BIG warrants that it is established in Switzerland for the purposes of receiving any such services, rights or licenses.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

9.9.5 Any supply of goods under this Agreement or the Supply Agreement shall be taxed in accordance with the prevailing VAT legislation. All Parties agree that they will reasonably cooperate to ensure the use of any VAT exemptions, zero-ratings, reduced-ratings, suspensions or other reliefs.

9.9.6 In the event that the local competent tax authority determines that VAT is chargeable, Denali in the first instance shall undertake all reasonable steps to refute any such assertions by the local tax authority. Only once this process is completed should Denali raise valid tax invoices for the additional VAT liability.

9.9.7 The Parties shall take all reasonable steps to recover any additional VAT liability from the same local tax authorities by submitting regular claims (for example, through periodical VAT returns and discrete non-resident claims such as 8th Directive claims, 13th Directive claims and non-EU equivalents) and shall use commercially reasonable efforts to provide necessary assistance to facilitate the recovery of VAT. If the VAT cannot be recovered, then the supplying Party shall be entitled to invoice the receiving Party directly for these amounts.

9.9.8 Each Party shall be responsible for any penalties or interest accruing due to incorrect VAT treatment of the supplies of goods or services made by that Party or any failure to correctly account for VAT on any receipt of a supply of goods or services under this Agreement except where those penalties or interest arise as a result of the actions of the other Party, in which case that Party shall be liable to reimburse the value of the penalties and interest.

9.9.9 Each Party shall be responsible for reporting its own transactions to the local tax authorities if required for VAT purposes. There shall be no shared, mutual or otherwise collective VAT filings that may suggest that the Parties are anything other than separately operational entities for VAT purposes.

9.10 **Orphan Credit**. Denali shall cooperate with Biogen in seeking any tax exemption or credits that may be available to Biogen with respect to any Option Protein, including the tax credit available under section 45C of the Internal Revenue Code by reason of Biogen's research and development expenditures contributing to the any compound under this Agreement being granted Orphan Drug status by the FDA. Notwithstanding any provision to the contrary set forth in this Agreement, Denali accepts no responsibility for, and expressly disclaims all liability arising from, Biogen's failure to qualify for any tax exemptions or credits for any reason.

9.11 **[***]**

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

9.12 **Financial Audits**.

9.12.1 **Financial Records**. Each Party shall keep complete and accurate books and records pertaining to Net Sales of Option Products, Manufacturing Costs, and costs eligible for reimbursement by Biogen pursuant to Sections 7.1 (Technology Transfer), 7.6 (Denali Support), 8.7 (Manufacturing Technology Transfer), and 8.8 (Denali Manufacturing Support), in each case, with respect to the Option Proteins and Option Products, and Development of the Option Proteins or Option Products, including books and records of actual expenditures with respect to the CMC Budget, in sufficient detail to calculate all amounts payable hereunder and to verify compliance with its obligations under this Agreement. Such books and records shall be retained by such Party until the later of (a) [***] after the end of the period to which such books and records pertain, and (b) the expiration of the applicable tax statute of limitations (including any extensions thereof), or for such longer period as may be required by Applicable Law.

9.12.2 **Audit**. At the request of the other Party, each Party shall permit an independent public accounting firm of nationally recognized standing designated by the other Party and reasonably acceptable to the audited Party, at reasonable times during normal business hours and upon reasonable notice, to audit the books and records maintained pursuant to Section 9.12.1 (Financial Records) to ensure the accuracy of all financial reports and notices delivered and payments made hereunder. Such examinations may not (a) be conducted for any Calendar Year more than [***] after the end of such Calendar Year, (b) be conducted more than [***] or (c) be repeated for any audited period; except for cause. The accounting firm shall disclose to the auditing Party whether the reports are correct or not, and the details concerning any discrepancies sufficient for the auditing Party to understand any such discrepancies. Except as provided below, the cost of this audit shall be borne by the auditing Party, unless the audit reveals a variance of greater than [***] from the reported amounts for the inspected period, in which case the audited Party shall bear the cost of the audit. If such audit concludes that (i) additional amounts were owed by the audited Party, the audited Party shall pay the additional undisputed amounts, with interest from the date originally due as provided in Section 9.7 (Interest on Late Payments), or (ii) excess payments were made by the audited Party, the auditing Party shall, at its election, reimburse such undisputed excess payments or elect that such excess payments shall be offset against future payments due to the auditing Party under this Agreement, in either case ((i) or (ii)), within [***] after the date on which such audit is completed by the auditing Party. Any disputes with respect to the findings of such accounting firm may be referred by either Party to the dispute resolution procedure set forth in Section 15.6 (Dispute Resolution). The auditing Party will treat all financial information disclosed by its accounting firm pursuant to this Section 9.12.2 (Audit) as Confidential Information of the audited Party for purposes of Article 11 (Confidentiality) of this Agreement, and will cause its accounting firm to do the same.

ARTICLE 10 REPRESENTATIONS, WARRANTIES, AND COVENANTS

10.1 **Mutual Representations and Warranties of the Parties**. Each Party represents and warrants to the other Party as of the Effective Date as follows:

10.1.1 **Organization**. It is duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform its obligations under this Agreement.

10.1.2 **Authorization**. The execution and delivery of this Agreement and the performance by it of its obligations hereunder have been duly authorized by all necessary corporate action, and do not violate: (a) such Party's charter documents, bylaws or other organizational documents; (b) in any material respect, any agreement, instrument, or contractual obligation to which such Party is bound; (c) any requirement of any Applicable Law existing as of the Effective Date and applicable to such Party; or (d) any order, writ, judgment, injunction, decree, determination, or award of any court or Governmental Authority in effect as of the Effective Date and applicable to such Party.

10.1.3 **Binding Agreement**. This Agreement is a legal, valid, and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity).

10.1.4 **No Inconsistent Obligation**. It is not under any obligation, contractual or otherwise, to any person that conflicts with or is inconsistent in any material respect with the terms of this Agreement relating to the Development or Manufacturing activities contemplated by the Parties hereunder.

10.1.5 **No Consents**. No governmental authorization, consent, approval, license, exemption of or filing or registration with any court or Governmental Authority, domestic or foreign, under any Applicable Laws currently in effect, is or will be necessary for, on in connection with, the transaction contemplated by this Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of its obligations under this Agreement and such other agreements.

10.1.6 **Debarment**. Neither it nor any of its employees nor to its knowledge, any of the agents performing hereunder, has ever been, is currently, or is the subject of a proceeding that could lead to it or such employees or agents becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual. For purposes of this provision, the following definitions shall apply:

(a) A "**Debarred Individual**" is an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from providing services in any capacity to a person that has an approved or pending drug or biological product application.

(b) A "**Debarred Entity**" is a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or Affiliate of a Debarred Entity.

(c) An "**Excluded Individual**" or "**Excluded Entity**" is (A) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services, or (B) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA).

(d) A "**Convicted Individual**" or "**Convicted Entity**" is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §335a (a) or 42 U.S.C. §1320a – 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

10.2 **Additional Representations and Warranties of Denali**. Denali further represents and warrants to Biogen as of [***] as follows:

10.2.1 It has the full right, power and authority to grant all of the licenses and rights granted to Biogen under this Agreement;

10.2.2 No claim, suit, proceeding, settlement, arbitration, citation, summons, or subpoena of any nature, civil, criminal, regulatory or otherwise, in law or in equity, has been brought or obtained against Denali or any of its Affiliates relating to the ROFN IP or Option IP (collectively, the "**Denali IP**"). No claim, suit, proceeding, arbitration, citation, summons, or subpoena of any nature, civil, criminal, regulatory or otherwise, in law or in equity, to Denali's knowledge, has been threatened in writing by any person: [***].

10.2.3 To Denali's knowledge: [***].

10.2.4 (a) [***] that are owned or Controlled by Denali or any of its Affiliates that are [***] to Develop, Manufacture, Commercialize, or otherwise Exploit any Option Protein or Option Product, (b) [***]; and (c) [***].

10.2.5 [***].

10.2.6 To Denali's knowledge, the Denali Patent Rights for which Denali controls Prosecution and Maintenance are being Prosecuted and Maintained in the respective patent offices in the Territory in accordance with Applicable Law.

10.2.7 To Denali's knowledge, all fees required to be paid by Denali in any jurisdiction where a Denali Patent Right for which Denali controls Prosecution and Maintenance has issued in order to maintain such Denali Patent Right in such jurisdiction have been timely paid, and to Denali's knowledge, the Denali Patent Rights that have issued are subsisting, valid, and enforceable.

10.2.8 [***];

10.2.9 Denali has not previously assigned, transferred, conveyed, or granted any license or other rights under the Denali IP that would conflict with or limit the scope of any of the rights, options, or licenses granted to Biogen hereunder;

10.2.10 To Denali's knowledge, no person is infringing or threatening to infringe or misappropriating or threatening to misappropriate or otherwise violating or threatening to violate the Denali IP.

10.2.11 Denali's rights, title, and interests to all Denali IP are free of any lien or security interest.

10.2.12 No written claim has been filed, or to Denali's knowledge, threatened in writing, against it by any Third Party alleging that the conception, development, or reduction to practice of the Denali IP owned by Denali involve the misappropriation of trade secrets or other violation of the rights or property of any Person.

10.2.13 Denali has conducted, and to Denali's knowledge, its contractors and consultants have conducted, all Development and Manufacturing of the Option Proteins in accordance with Applicable Law.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

10.2.14 Denali has obtained, or caused its Affiliates, as applicable, to obtain, assignments from the inventors of any Denali IP who were employees of Denali or its Affiliates at the time of the invention, of all inventorship rights to such Denali IP, and, to Denali's knowledge, all such assignments are valid and enforceable.

10.2.15 Except for the Existing Third Party Agreements, there are no Third Party agreements pursuant to which Denali is granted an exclusive license under any Patent Rights or Know-How included in the Denali IP, and no Third Party has any rights, title, or interests in or to, or any license under, any such Denali IP that would conflict with the rights, options, and licenses granted to Biogen hereunder.

10.2.16 Denali has provided Biogen with a redacted copy of each Existing Third Party Agreement, and each such agreement is in full force and effect, and no written notice of default or termination has been received or given under any such agreement, and, to Denali's knowledge, there is no act or omission by Denali or its Affiliates that would provide a right to terminate any such agreement.

10.2.17 Denali and its Affiliates have taken commercially reasonable measures consistent with industry practices to protect the secrecy, confidentiality and value of all ROFN Know-How and Option Know-How (collectively, "**Denali Know-How**") that constitutes trade secrets under Applicable Law (including requiring all employees, consultants and independent contractors to execute binding and enforceable agreements requiring all such employees, consultants, and independent contractors to maintain the confidentiality of such Denali Know-How) and, to Denali's knowledge, such Denali Know-How has not been used or disclosed to any Third Party except pursuant to such confidentiality agreements, and to Denali's knowledge, there has not been a material breach by any party to such confidentiality agreements.

10.2.18 To Denali's knowledge, [***].

10.3 **Covenants of Denali**.

10.3.1 [***]

10.3.2 [***]

10.3.3 [***]

10.3.4 [***]; and

10.3.5 If Denali, or any of its employees (and to the extent Denali is aware of the situation, its agents performing hereunder), became, become or are the subject of a proceeding that could lead to a Person becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual, then Denali shall promptly notify Biogen, and Biogen shall have the option, at its sole discretion, to prohibit such Person from performing work under this Agreement.

10.4 **Covenants of Biogen.**

10.4.1 [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

10.4.2 If Biogen or its Affiliates, or any of its or their respective employees (and to the extent Biogen is aware of the situation, its or their respective agents performing hereunder), became, become or are the subject of a proceeding that could lead to a Person becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual, then Biogen shall promptly notify Denali, and Denali shall have the option, at its sole discretion, to prohibit such Person from performing work under this Agreement.

10.5 **DISCLAIMER OF WARRANTIES**. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENT RIGHTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY OF THIRD PARTIES.

10.6 **LIMITATION OF LIABILITY**. EXCEPT [***] NEITHER PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE FOR INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR CONSEQUENTIAL DAMAGES, INCLUDING LOSS OF PROFITS OR BUSINESS INTERRUPTION (TO THE EXTENT THE SAME ARE CONSEQUENTIAL DAMAGES), HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY, OR OTHERWISE IN CONNECTION WITH OR ARISING IN ANY WAY OUT OF THE TERMS OF THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THE USE OF AN OPTION COMPOUND OR OPTION PRODUCT, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

ARTICLE 11 CONFIDENTIALITY

11.1 **Confidential Information**. It is understood and agreed by the Parties that:

11.1.1 The terms and conditions of this Agreement, all royalty reports provided to Denali pursuant to Section 9.4.3 (Royalty Reports), and all reports provided to Denali pursuant to Section 7.2.2 (Development Reports) or Section 7.4.2 (Commercialization Reports) will be considered Confidential Information of both Parties and kept confidential by each of the Parties in accordance with this Article 11 (Confidentiality);

11.1.2 The Biogen IP and the identities of the Option Targets and Reserved Targets (in each case, as Targets under this Agreement), the Option Proteins, and the Option Products will each be considered the Confidential Information of Biogen; *provided*, *however*, that (a) on and after the date on which a TV Target Notice is provided, the identity of the Reserved Target that is not selected to be the Option TV Target in accordance with Section 2.1 (Selection of Option TV Target) shall cease to be Confidential Information of Biogen and shall instead be deemed Confidential Information of Denali and (b) with respect to an Option Program, on and after the earlier of (i) the date on which the Option Term for an Option Program expires without Biogen exercising its Option for such Option Program or (ii) the date on which this Agreement is terminated with respect to an Option Program, the identity of the Option Target, Option Proteins, and Option Products shall cease to be Confidential Information of Biogen; and

11.1.3 All Option IP, TV Platform IP, Assigned TV Platform IP, ROFN IP, all Option Update Reports, all ROFN Update Reports, all Option Data Packages, [***] will each be considered the Confidential Information of Denali.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

11.2 **Non-Disclosure and Non-Use Obligation**. Except as otherwise expressly set forth herein, each Party (the "**Receiving Party**") will, during the Term and for a period of [***] thereafter, keep the Confidential Information of the other Party (the "**Disclosing Party**") confidential using at least the same degree of care with which the Receiving Party holds its own confidential information (but in no event less than a reasonable degree of care) and will not (a) disclose such Confidential Information to any Person without the prior written approval of the Disclosing Party, except, solely to the extent necessary to exercise its rights or perform its obligations under this Agreement, to its employees, Affiliates, Sublicensees, and Subcontractors, consultants, or agents who have a need to know such Confidential Information, all of whom will be similarly bound by confidentiality, non-disclosure, and non-use provisions at least as restrictive or protective of the Parties as those set forth in this Agreement and for whom the Disclosing Party will be responsible, or (b) use such Confidential Information for any purpose other than for the purposes contemplated by this Agreement. The Receiving Party will use diligent efforts to cause the foregoing Persons to comply with the restrictions on use and disclosure set forth in this Section 11.2 (Non-Disclosure and Non-Use Obligation), and will be responsible for ensuring that such Persons maintain the Disclosing Party's Confidential Information in accordance with this Article 11 (Confidentiality). Each Party will promptly notify the other Party of any misuse or unauthorized disclosure of the other Party's Confidential Information.

11.3 **Exemptions**. Information of a Disclosing Party will not be Confidential Information of such Disclosing Party to the extent that the Receiving Party can demonstrate through competent evidence that such information: (a) is already in the possession of the Receiving Party at the time of its receipt from the Disclosing Party and not through a prior disclosure by or on behalf of the Disclosing Party, as evidenced by contemporaneous written records, (b) is generally available to the public before its receipt from the Disclosing Party, (c) became generally available to the public or otherwise part of the public domain after its disclosure by the Disclosing Party and other than through any act or omission of the Receiving Party or any of its Affiliates or discloses in breach of this Agreement, including pursuant to Section 11.7.2 (Publication Rights), (d) is subsequently disclosed to the Receiving Party or any of its Affiliates without obligation of confidentiality by a Third Party who may rightfully do so and is not under a conflicting obligation of confidentiality to the Disclosing Party, or (e) is developed independently by employees, subcontractors, consultants or agents of the Receiving Party or any of its Affiliates without use of or reliance upon the Disclosing Party's Confidential Information, as evidenced by contemporaneous written records. No combination of features or disclosures will be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the Receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party.

11.4 **Permitted Disclosures**. In addition to the exceptions contained in Sections 11.2 (Non-Disclosure and Non-Use Obligation) and 11.3 (Exemptions), the Receiving Party may disclose Confidential Information of the Disclosing Party to the extent (and solely to the extent) that such disclosure is reasonably necessary in the following instances:

11.4.1 Subject to Section 12.4.1(a) (Biogen's Rights), (a) [***]; or (b) Regulatory Submissions and other filings with Governmental Authorities (including Regulatory Authorities), as necessary for the Exploitation of an Option Protein or Option Product;

11.4.2 [***];

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

11.4.3 to comply with Applicable Law (whether generally or in pursuit of an application for listing of securities) including the United States Securities and Exchange Commission or equivalent foreign agency or regulatory body, or otherwise required by judicial or administrative process, provided that the Receiving Party shall, unless otherwise prohibited, first have given advanced written notice (and to the extent possible, at least [***] notice) to the Disclosing Party and (other than with regard to disclosures to securities regulators or to comply with Applicable Law, which disclosures are covered in Section 11.7.1 (Public Announcements)) give the Disclosing Party a reasonable opportunity to take whatever action it deems necessary to protect its Confidential Information. In the event that no such protective order or other remedy is obtained, or the Disclosing Party waives compliance with the terms of this Agreement, the Receiving Party shall furnish only that portion of Confidential Information which the Receiving Party is advised by counsel is legally required to be disclosed;

11.4.4 to prosecute or defend litigation so long as there is [***] prior written notice given by the Receiving Party before filing, and to enforce Patent Rights in connection with the Receiving Party's rights and obligations pursuant to this Agreement; and

11.4.5 [***].

11.5 **Use of Name and Logo**. Except as expressly provided in this Agreement, neither Party shall mention or otherwise use the name, logo or trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material, website or other form of publicity, without the prior written approval of such other Party. Notwithstanding the foregoing, the restrictions imposed by this Section 11.5 (Use of Name and Logo) shall not prohibit either Party from using the name, logo or trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any disclosure: (a) identifying the other Party that, in the opinion of the disclosing Party's counsel, is required by Applicable Law (including stock exchange rules); *provided* that such Party shall submit the proposed disclosure identifying the other Party in writing to the other Party as far in advance as reasonably practicable (and in no event less than [***] prior to the anticipated date of disclosure unless such proposed disclosure is required under Applicable Law, or the rules of an applicable securities exchange, in each case to be made in [***] or less) so as to provide a reasonable opportunity to comment thereon; (b) in connection with a disclosure permitted pursuant to Section 11.4 (Permitted Disclosures) or (c) following a press release or other announcement issued pursuant to Section 11.7.1 (Public Announcements), using such name, logo or trademark included in such press release or other announcement in connection with a general description of the arrangement between the Parties or any other subsequent announcement specified as not requiring the other Party's approval under Section 11.7.1 (Public Announcements).

11.6 **[***]**

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

11.7 **Publications**.

11.7.1 **Public Announcements**. The Parties have agreed upon the content of a press release to announce the collaboration, which press release shall be issued by Denali substantially in the form attached hereto as Schedule 11.7.1 (Press Release) upon execution of this Agreement. In addition, each Party may issue a press release upon exercise of an Option with respect to an Option Program, disclosing such exercise and the Option Target covered by such Option Program, *provided*, *however*, that any such press release shall be subject to the last sentence of this Section 11.7.1 (Public Announcements). Each Party may each disclose to Third Parties the information contained in such press release or any other announcement previously approved by the other Party without the need for further approval by the other Party. Neither Party shall issue any other public announcement, press release or other public disclosure regarding this Agreement or the Parties' activities hereunder without the other Party's prior written consent (which shall not be unreasonably withheld, delayed or conditioned), except for any such disclosure (a) regarding the [***] or (b) any other disclosure that is, in the opinion of the disclosing Party's counsel, required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed, or (c) is otherwise expressly permitted in accordance with the provisions of this Article 11 (Confidentiality). In the event a Party desires to make such a public announcement regarding (i) the [***] or (ii) any other disclosure that is, in the opinion of its counsel, required by Applicable Law or the rules of a stock exchange on which its securities are listed, in each case, such Party shall submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable (and in no event less than [***] prior to the anticipated date of disclosure, unless such proposed disclosure is required under Applicable Law, or the rules of an applicable securities exchange, in each case, to be made in [***] or less) so as to provide a reasonable opportunity to comment thereon.

11.7.2 **Publication Rights**.

(a) **During the Option Term**. On an Option Program-by-Option Program basis, during the Option Term with respect to a given Option Program, unless otherwise agreed by the Parties, [***].

(b) **After the Option Term**. On an Option Program-by-Option Program basis, following Biogen's exercise of its Option with respect to a given Option Program in accordance with Section 2.3 (Option Exercise), [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(c) **Publication Review and Comment**. Notwithstanding any provision in this Agreement to the contrary, any Party seeking to publish peer reviewed manuscripts, or give other forms of public disclosure such as abstracts and presentations, with respect to any Option Proteins and Option Products shall provide the other Party the opportunity to review and comment on any such proposed publication at least [***] prior to its intended submission for publication. The other Party shall provide the Party seeking publication with its comments in writing, if any, within [***] after receipt of such proposed publication. The Party seeking publication shall consider in good faith any comments thereto provided by the other Party and shall comply with the other Party's request to remove any and all of such other Party's Confidential Information from the proposed publication. In addition, the Party seeking publication shall delay the submission for a period up to [***] in the event that the other Party can demonstrate reasonable need for such delay, including the preparation and filing of a patent application. If the other Party fails to provide its comments to the Party seeking publication within such [***] period, such other Party shall be deemed to not have any comments, and the Party seeking publication shall be free to publish to the extent otherwise permitted under this Section 11.7.2 (Publication Rights) after the [***] period has elapsed. The Party seeking publication shall provide the other Party a copy of the manuscript at the time of the submission. Each Party agrees to acknowledge the contributions of the other Party and its employees in all publications as scientifically appropriate. [***]

11.8 **Prior Confidentiality**. Any information disclosed by a Party or its Affiliate to the other Party or its Affiliate prior to the Effective Date under the Confidentiality Agreement or the Provisional Agreement, to the extent related to Option Proteins, Option Products, Option Programs, ROFN Proteins, ROFN Products or ROFN Programs shall be deemed to have been disclosed under this Agreement, and subject to the provisions of this Article 11 (Confidentiality).

ARTICLE 12 INTELLECTUAL PROPERTY

12.1 **Ownership**.

12.1.1 **Inventions**. Except as expressly set forth in this Agreement, as between the Parties:[***]

12.1.2 **Disclosure**. [***]

12.2 **Assignments**.

12.2.1 **[***]**

12.2.2 **[***]**

12.3 **Joint Program IP**. [***]

12.4 **Patent Prosecution and Maintenance**.

12.4.1 **Right to File and Prosecute**. As between the Parties:

(a) **Biogen's Rights**. [***]

(i) [***].

(ii) [***].

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(iii) [***].

(b) **Denali's Rights**. [***]

(i) [***].

(ii) [***].

(iii) [***].

12.4.2 **Step-In Rights**.

(a) **[***]**

(b) **[***]**

12.4.3 **[***]**

12.4.4 **[***]**.

12.5 **Patent Enforcement**.

12.5.1 **[***]**

12.5.2 **Infringement Actions**.

(a) **[***]**

(i) [***].

(ii) [***].

(A) [***].

(B) [***].

(b) **[***]**

(c) **[***]**, *provided* that [***].

(d) **[***]**.

12.6 **[***]**.

12.7 **[***]**.

12.8 **[***]**.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

ARTICLE 13 INDEMNIFICATION

13.1 **Indemnification by Denali**. Denali will indemnify, defend, and hold harmless Biogen, each of its Affiliates and each of its and its Affiliates' respective employees, officers, directors, and agents (each, a "**Biogen Indemnified Party**") from and against any and all liabilities, losses, damages, expenses (including reasonable attorneys' fees and expenses), and costs (collectively, a "**Liability**") that the Biogen Indemnified Party may be required to pay to one or more Third Parties (a "**Third Party Claim**") resulting from or arising out of:

13.1.1 the Development of Option Proteins or Option Products by or under the authority of Denali (other than by or under the authority of Biogen or the Biogen Indemnified Parties), including by or under the authority of Denali [***];

13.1.2 the gross negligence, reckless conduct, or willful misconduct on the part of any Denali Indemnified Party in performing its or their obligations under this Agreement; or

13.1.3 any breach by Denali of this Agreement, including any breach of any representation, warranty, or covenant by Denali under this Agreement,

except, in each case, to the extent such claims fall within the scope of Biogen's indemnification obligations under Section 13.2 (Indemnification by Biogen).

13.2 **Indemnification by Biogen**. Biogen will indemnify, defend, and hold harmless Denali, each of its Affiliates, and each of its and its Affiliates' employees, officers, directors, and agents (each, a "**Denali Indemnified Party**") from and against any and all Liabilities that the Denali Indemnified Party may be required to pay to one or more Third Parties resulting from or arising out of:

13.2.1 the Development of Option Proteins or Option Products by or under the authority of Biogen (other than by or under the authority of Denali or the Denali Indemnified Parties) [***];

13.2.2 the gross negligence, reckless conduct, or willful misconduct on the part of any Biogen Indemnified Party in performing its or their obligations under this Agreement; or

13.2.3 any breach by Biogen of this Agreement, including any breach of any representation, warranty, or covenant by Biogen under this Agreement,

except, in each case, to the extent such claims fall within the scope of Denali's indemnification obligations under Section 13.1 (Indemnification by Denali).

13.3 **Procedure**.

13.3.1 **Notice of Claim**. All indemnification claims in respect of a Party, its Affiliates, or their respective directors, officers, employees and agents shall be made solely by such Party to this Agreement ("**Indemnified Party**"). The Indemnified Party shall give the indemnifying Party prompt written notice (an "**Indemnification Claim Notice**") of any Liabilities or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under this Article 13 (Indemnification), but in no event shall the indemnifying Party be liable for any Liabilities to the extent such Liabilities arise from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Liability (to the extent that the nature and amount of such Liability is known at such time). The Indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Liabilities and Third Party Claims.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

13.3.2 **Control of Defense**.

(a) **In General**. Subject to the provisions of Section 12.5 (Patent Enforcement) and Section 12.6 (Defense of Claims) above, at its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within [***] after the indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgment that the indemnifying Party is liable to indemnify the Indemnified Party in respect of the Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. Upon assuming the defense of a Third Party Claim pursuant to this Section 13.3.2(a) (In General), the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party that must be reasonably acceptable to the Indemnified Party. In the event the indemnifying Party assumes the defense of such a Third Party Claim, the Indemnified Party shall immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with such Third Party Claim. Should the indemnifying Party assume the defense of such a Third Party Claim, except as provided in Section 13.3.2(b) (Right to Participate in Defense), the indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim unless specifically requested in writing by the indemnifying Party. In the event that it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against such Third Party Claim, the Indemnified Party shall reimburse the indemnifying Party for any Liabilities incurred by the indemnifying Party in its defense of such Third Party Claim.

(b) **Right to Participate in Defense**. Without limiting Section 13.3.2(a) (In General), any Indemnified Party shall be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; *provided* that such employment shall be at the Indemnified Party's own expense unless: (i) the employment thereof, and the assumption by the indemnifying Party of such expense, has been specifically authorized by the indemnifying Party in writing; (ii) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 13.3.2(a) (In General) (in which case the Indemnified Party shall control the defense); or (iii) the interests of the Indemnified Party and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under Applicable Law, ethical rules or equitable principles.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(c) **Settlement**. With respect to any Liabilities relating solely to the payment of money damages in connection with a Third Party Claim and that shall not result in the Indemnified Party's becoming subject to injunctive or other relief or otherwise adversely affect the business of the Indemnified Party in any manner, and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Liability, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Liabilities in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 13.3.2(a) (In General), the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Liability; *provided* that it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, delayed or conditioned). If the indemnifying Party does not assume and conduct the defense of a Third Party Claim as provided above, then the Indemnified Party may defend against such Third Party Claim. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnified Party shall admit any liability with respect to, or settle, compromise or dispose of, any Third Party Claim in a manner that would have a material adverse effect on the Indemnified Party or admit wrongdoing on behalf of the Indemnified Party without the prior written consent of the indemnifying Party.

(d) **Cooperation**. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall, and shall cause each indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making Indemnified Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the indemnifying Party shall reimburse the Indemnified Party for all its reasonable out-of-pocket costs in connection therewith.

13.4 **Insurance**. Each Party shall procure and maintain, during the Term, commercial general liability insurance, including product liability insurance, with minimum "A-" Best rated insurance carriers to cover its indemnification obligations under Section 13.1 (Indemnification by Denali) or Section 13.2 (Indemnification by Biogen), as applicable, in each case with limits of not less than [***] per occurrence and in the aggregate. Each Party shall provide the other Party with evidence of such insurance by furnishing a certificate of insurance upon request. Product liability policies will be maintained for [***]. It is understood that such insurance shall not be construed to create a limit of either Party's liability, including with respect to its indemnification obligations under this Article 13 (Indemnification). Notwithstanding the foregoing, Biogen may self-insure to the extent that it self-insures for its other activities; *provided* that Biogen is and continues to be investment grade determined by reputable and accepted financial rating agencies.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

ARTICLE 14 TERM AND TERMINATION

14.1 **Term**. This Agreement will commence upon the Effective Date and unless terminated earlier, will continue in effect on an Option Program-by-Option Program basis and for all ROFN Programs until (a) in the case of an Option Program, either (i) the date of expiration of the Option Term for such Option Program (if Biogen does not exercise an Option for such Option Program in accordance with Section 2.3 (Option Exercise)) or (ii) the date on which the Royalty Term has expired in each country in the Territory for all Option Products that are the subject of such Option Program (if Biogen does exercise an Option for such Option Program in accordance with Section 2.3 (Option Exercise)), and (b) in the case of all ROFN Programs, the earlier of (i) the date on which the Parties enter into a ROFN Definitive Agreement with respect to two (2) ROFN Programs, (ii) the date on which Biogen may not provide to Denali any additional ROFN Interest Notices in accordance with the procedures set forth in Section 3.1 (ROFN Program; Procedures), and (iii) the expiration of the ROFN Term (the "**Term**"). Upon expiration of the Royalty Term for an Option Product in a country that is the subject of any Option Program for which Biogen has exercised an Option in accordance with Section 2.3 (Option Exercise), the licenses granted by Denali to Biogen under this Agreement with respect to such Option Product in such country will become fully-paid (other than with respect to any Sales Milestone Payments), irrevocable, and perpetual.

14.2 **Termination for Convenience**. On not less than [***] prior written notice to Denali, Biogen will have the right, at its sole discretion, to terminate this Agreement for convenience (a) in its entirety or (b) with respect to any Option Program: (i) for any Region or (ii) in its entirety.

14.3 **Termination for Material Breach**.

14.3.1 **Breach Notice**. Either Party (the "**Non-Breaching Party**") shall have the right to terminate this Agreement in the case of a material breach of this Agreement by the other Party (the "**Breaching Party**") if such material breach remains uncured after [***] (or if applicable, the cure period specified in this Section 14.3.1 (Breach Notice) below) following delivery by the Non-Breaching Party of written notice of such material breach to the Breaching Party (a "**Breach Notice**"), *provided* that if such material breach is with respect to an Option Program only, then such Non-Breaching Party shall have the right to terminate this Agreement solely with respect to such Option Program. The Breaching Party shall have [***] from its receipt of such Breach Notice to cure such material breach (subject to the dispute resolution procedures set forth in Section 14.3.2 (Disputes Regarding Material Breach) below). Notwithstanding any provision in this Agreement to the contrary, [***].

14.3.2 **Disputes Regarding Material Breach**. Notwithstanding any provision in this Agreement to the contrary, during the [***] cure period described in Section 14.3.1 (Breach Notice) above, the Breaching Party may dispute that it has committed such material breach. If the Breaching Party disputes the applicable Breach Notice within such cure period, then such cure period shall be tolled until the dispute is resolved pursuant to the dispute resolution procedures set forth in Section 15.6 (Dispute Resolution), and this Agreement will remain in full force and effect during the pendency of any such dispute. If, as a result of the application of such dispute resolution procedures, the Breaching Party is determined in accordance with Section 15.6 (Dispute Resolution) to be in material breach of this Agreement (an "**Adverse Ruling**") and the Breaching Party fails to complete the actions specified by the Adverse Ruling to cure such material breach within the applicable remainder of such cure period after such ruling is issued (or such longer period as the may be determined appropriate in accordance with Section 15.6 (Dispute Resolution)), then the Non-Breaching Party may terminate this Agreement in its entirety, or with respect to the applicable Option Program as described in Section 14.3.1 (Breach Notice) above, upon written notice to the Breaching Party.

14.4 **Termination for Insolvency**.

14.4.1 To the extent permitted by Applicable Law, either Party may terminate this Agreement upon the filing or institution of bankruptcy, reorganization, liquidation, or receivership proceedings, upon the appointment of a receiver or trustee over all or substantially all property, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided, however, that in the case of any involuntary bankruptcy proceeding such right to terminate will only become effective if the Party consents to the involuntary bankruptcy or such proceeding is not dismissed within [***] after the filing thereof.

14.4.2 All rights and licenses now or hereafter granted by one Party to the other Party under or pursuant to this Agreement are, for all purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined in the U.S. Bankruptcy Code. Upon the filing or institution of bankruptcy, reorganization, liquidation, or receivership proceedings, upon the appointment of a receiver or trustee over all or substantially all property, or upon an assignment of a substantial portion of the assets for the benefit of creditors by a Party, such Party agrees that the other Party, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. Each Party will, during the Term, create and maintain current copies or, if not amenable to copying, other appropriate embodiments, to the extent feasible, of all intellectual property rights licensed under this Agreement. Each Party acknowledges and agrees that "embodiments" of intellectual property rights within the meaning of Section 365(n) include laboratory notebooks, cell lines, product samples, and inventory, research studies and data, all Regulatory Approvals (and all applications for Regulatory Approval) and rights of reference therein, in each case, to the extent licensed by a Party to the other Party hereunder, as well as the Denali IP and the Biogen IP (as the case may be), and all information related to the Denali IP and the Biogen IP (as the case may be). If (i) a case under the U.S. Bankruptcy Code is commenced by or against the debtor Party, (ii) this Agreement is rejected as provided in the U.S. Bankruptcy Code, and (iii) the non-debtor Party elects to retain its rights hereunder as provided in Section 365(n) of the U.S. Bankruptcy Code, then the debtor Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) will:

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(a) provide the non-debtor Party with all such intellectual property rights (including all embodiments thereof) licensed hereunder and held by the debtor Party and such successors and assigns, or otherwise available to them, immediately upon the non-debtor Party's written request. Whenever the debtor Party or any of its successors or assigns provides to the non-debtor Party any of the intellectual property rights licensed hereunder (or any embodiment thereof) pursuant to this Section 14.4 (Termination for Insolvency), the non-debtor Party will have the right to perform the debtor Party's obligations hereunder with respect to such intellectual property rights, but neither such provision nor such performance by the non-debtor Party will release the debtor Party's from liability resulting from rejection of the license or the failure to perform such obligations; and

(b) not interfere with the non-debtor Party's rights under this Agreement, or any agreement supplemental hereto, with respect to such intellectual property rights (including such embodiments), including any right to obtain such intellectual property rights (or such embodiments) from another entity, to the extent provided in Section 365(n) of the U.S. Bankruptcy Code.

14.4.3 All rights, powers, and remedies of the non-debtor Party provided in this Section 14.4 (Termination for Insolvency) are in addition to and not in substitution for any other rights, powers, and remedies now or hereafter existing at law or in equity (including the U.S. Bankruptcy Code) in the event of the commencement of a case under the U.S. Bankruptcy Code with respect to the debtor Party. The Parties intend the following rights to extend to the maximum extent permitted by Applicable Law, and to be enforceable under U.S. Bankruptcy Code Section 365(n):

(a) the right of access to any intellectual property rights (and all embodiments thereof) of the debtor Party licensed hereunder, or any Third Party with whom the debtor Party contracts to perform any obligation of the debtor Party under this Agreement, and, in the case of any such Third Party, that is necessary for the Exploitation of Option Products or ROFN Products and licensed hereunder; and

(b) the right to contract directly with any Third Party to complete the contracted work.

14.5 **[***]**

14.6 **Effects of Termination**.

14.6.1 **Effects of Termination of an Option Program**. In the event of termination of an Option Program, whether by termination of this Agreement in its entirety or with respect to an Option Program (in its entirety or for a Region), the following terms shall apply with respect to such Option Program:

(a) **Terminating Rights and Obligations**. Any terminated Option Program will be referred to herein as a "**Terminated Program**". All Option Products that are the subject of any Terminated Program will be referred to herein as "**Terminated Products**", all Option Proteins that are the subject of any Terminated Program will be referred to herein as "**Terminated Proteins**" and any Region with respect to which this Agreement is terminated will be referred to herein as a "**Terminated Region**". If this Agreement is terminated in its entirety or with respect to all Option Programs, then all Option Programs will become Terminated Programs, all Option Products will become Terminated Products, all Option Proteins will become Terminated Proteins and all Regions in the Territory will become Terminated Regions.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(b) **[***]**

(c) **[***]**

(i) **[***]**

(A) **[***]**

(B) **[***]**

(C) **[***]**

(D) **[***]**

(ii) **[***]**

14.6.2 **Effects of Termination of all ROFN Programs**. In the event of termination of this Agreement in its entirety or with respect to all ROFN Programs, the following terms shall apply:

(a) **Terminating Rights and Obligations**. Article 3 (ROFN) shall terminate and shall have no further effect. Biogen shall have no rights, and Denali shall have no obligations, with respect to any ROFN Program on and after the effective date of such termination.

(b) **Confidentiality**. Except as otherwise provided herein, within [***] after any termination of this Agreement or with respect to all ROFN Programs, Biogen shall destroy or return to Denali (at Denali's discretion) all tangible items bearing, containing, or contained in, any of the Confidential Information of Denali that is solely related to the ROFN Programs, *provided*, however, copies may be retained and stored solely for the purpose of determining its obligations under this Agreement, subject to the non-disclosure and non-use obligation under Article 11 (Confidentiality). In addition, Biogen will not be required to return or destroy Confidential Information contained in any computer system back-up records made in the ordinary course of business; *provided* that such Confidential Information may not be accessed without Denali's prior written consent or as required by Applicable Law. If any such material is destroyed, then Biogen shall provide Denali written certification of such destruction.

14.7 **Rights Accruing Prior to Expiration or Termination**. Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination. Any expiration or termination of this Agreement will be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to expiration or termination, including any payment obligation that accrued prior to the effective date of such expiration or termination.

14.8 **Remedies.** Except as otherwise expressly provided herein, termination of this Agreement (either in its entirety, with respect to a Terminated Program, with respect to a Terminated Region or with respect to all ROFN Programs) in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

14.9 **Survival**.

14.9.1 All rights and obligations of the Parties shall terminate on termination or expiration of this Agreement, except that the following provisions will survive termination or expiration of this Agreement for any reason: [***].

14.9.2 If an Option Program is terminated with respect to a Terminated Region but not in its entirety, then following such termination, the foregoing provisions set forth in Section 14.9.1 of this Agreement shall remain in effect with respect to the Terminated Region (to the extent such provisions would survive and apply in the event this Agreement expires or is terminated in its entirety), and all provisions not surviving in accordance with the foregoing shall terminate upon termination of this Agreement with respect to the Terminated Region (other than Biogen's obligations under Section 4.4 (Exclusive Collaboration), which shall continue to apply worldwide with respect to the applicable Option Program until termination of this Agreement in its entirety) and be of no further force and effect (and, for purposes of clarity, all provisions of this Agreement shall remain in effect with respect to any Region that is not a Terminated Region).

ARTICLE 15 MISCELLANEOUS

15.1 **Force Majeure**. Neither Party will be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay performing any obligation under this Agreement to the extent that such failure or delay is caused by or results from acts of God, embargoes, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotions, strikes, lockouts, or other labor disturbances (other than strikes, lockouts, or labor disturbances involving a Party's own employees), government actions, fire, earthquakes, floods, [***] ("**Force Majeure**") beyond such Party's reasonable control, and renders the performance impossible or illegal. [***] The affected Party will notify the other Party in writing of any Force Majeure circumstances that may so affect its performance under this Agreement as soon as reasonably practical (but in any event within [***] after such Force Majeure occurrence), will provide a good faith estimate of the period for which its failure or delay in performance under this Agreement is expected to continue based on currently available information, and will undertake reasonable efforts necessary to mitigate and overcome such Force Majeure circumstances and resume normal performance of its obligations hereunder as soon as reasonably practicable under the circumstances. If the Force Majeure circumstance continues, then the affected Party will update such notice to the other Party on a weekly basis to provide updated summaries of its mitigation efforts and its estimates of when normal performance under the Agreement will be able to resume.

15.2 **Export Control**. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity in accordance with Applicable Law.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

15.3 **Assignment**. Without the prior written consent of the other Party, neither Party shall sell, transfer, assign, delegate (except as expressly permitted under this Agreement), pledge, or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; *provided*, that (a) either Party may make such an assignment without the other Party's consent to: (i) [***] or (ii) [***] and (b) [***]. [***] Any attempted assignment or delegation in violation of this Section 15.3 (Assignment) shall be void and of no effect. All validly assigned and delegated rights and obligations of the Parties hereunder shall be binding upon and inure to the benefit of and be enforceable by and against the successors and permitted assigns of Denali or Biogen, as the case may be. The permitted assignee or transferee shall assume all obligations of its assignor or transferor under this Agreement. Without limiting the foregoing, the grant of rights set forth in this Agreement shall be binding upon any successor or permitted assignee of a Party, and the obligations of the other Party, including the payment obligations, shall run in favor of any such successor or permitted assignee of such Party's benefits under this Agreement.

15.4 **Severability**. If any provision of this Agreement is held to be illegal, invalid, or unenforceable under any present or future law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, then: (a) such provision shall be fully severable; (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof; (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom; and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties. In the event a Party seeks to avoid a provision of this Agreement by asserting that such provision is invalid, illegal or otherwise unenforceable, the other Party shall have the right to terminate this Agreement upon [***] prior written notice, unless such assertion is eliminated and its effect is cured within such [***] period. Any such termination in accordance with this Section 15.4 (Severability) with respect to as assertion by a Party shall be deemed a termination for breach by such Party pursuant to Section 14.3 (Termination for Material Breach). To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid, or unenforceable in any respect.

15.5 **Governing Law and Service**.

15.5.1 **Governing Law**. This Agreement or the performance, enforcement, breach or termination hereof shall be interpreted, governed by and construed in accordance with the laws of the [***], United States, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction; *provided*, that all questions concerning: (a) determination of whether Know-How and inventions are conceived, discovered, developed or otherwise made by a Party for the purpose of allocating proprietary rights (including Patent Right, copyright or other Intellectual Property) therein, shall, for purposes of this Agreement, be made in accordance with Applicable Law in the United States; and (b) the construction or effect of Patent Rights shall be determined in accordance with the laws of the country or other jurisdiction in which the particular Patent Right has been filed or granted, as the case may be. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

15.5.2 Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 15.7 (Notices) shall be effective service of process for any action, suit, or proceeding brought against it under this Agreement in any such court.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

15.6 **Dispute Resolution**. Except as otherwise expressly provided herein with respect to particular disputes arising in connection with this Agreement (including any dispute that is expressly subject to resolution in accordance with Schedule 15.6.4 (Expert Arbitration)), if a dispute arises between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith or the breach, termination, enforcement, interpretation or validity hereof (a "**Dispute**"), then it shall be resolved pursuant to this Section 15.6 (Dispute Resolution). For the avoidance of doubt, [***].

15.6.1 **General**. Any Dispute shall first be referred to the Chief Executive Officer of Biogen (or his/her executive-level designee) and the Chief Executive Officer of Denali (or his/her executive-level designee) (the "**Chief Executive Officers**"), who shall confer in good faith on the resolution of the Dispute. Any final decision agreed to by the Chief Executive Officers shall be conclusive and binding on the Parties. If the Chief Executive Officers are not able to agree on the resolution of any such Dispute within [***] (or such other period of time as mutually agreed by the Chief Executive Officers) after such Dispute was first referred to them, then except as set forth in Section 15.6.2 (Intellectual Property Disputes) or Section 15.6.4 (Expert Arbitration), either Party may, by written notice to the other Party, elect to initiate a proceeding pursuant to the procedures set forth in Section 15.6.3 (Jurisdiction) for purposes of having the Dispute settled.

15.6.2 **Intellectual Property Disputes**. In the event that a Dispute arises with respect to the validity, scope, enforceability, inventorship or ownership of any Patent Right or other Intellectual Property, and such dispute cannot be resolved in accordance with Section 15.6.1 (General), either Party may initiate litigation in a court of competent jurisdiction, notwithstanding Section 15.5 (Governing Law and Service), in any country or other jurisdiction in which such rights apply.

15.6.3 **Jurisdiction**. Each of the Parties hereby submits to the jurisdiction [***] in any proceeding arising out of or relating to this Agreement, agrees not to commence any suit, action or proceeding relating thereto except in such court, and waives, to the fullest extent permitted by Applicable Law, the right to move or dismiss or transfer any action brought in such court on the basis of any objection to personal jurisdiction, venue or inconvenient jurisdiction. Any rights to trial by jury with respect to any suit, action, proceeding or claim (whether based upon contract, tort or otherwise), directly or indirectly, arising out of or relating to this Agreement hereunder are expressly and irrevocably waived by each of the Parties.

15.6.4 **Expert Arbitration**. Any dispute expressly stated in this Agreement to be resolved pursuant to this Section 15.6.4 (Expert Arbitration) shall take place pursuant to procedures described in Schedule 15.6.4 (Expert Arbitration).

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

15.7 **Notices**.

15.7.1 **Notice Requirements**. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if: (a) delivered by hand; (b) sent by facsimile or other reliable electronic transmission (with complete transmission confirmed); or (c) sent by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 15.7.2 (Address for Notice) or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 15.7.1 (Notice Requirements). Such notice shall be deemed to have been given as of the date delivered by hand or transmitted by facsimile or other electronic transmission (with complete transmission confirmed) or on [***] (at the place of delivery) after deposit with an internationally recognized overnight delivery service. Any notice delivered by facsimile or other electronic transmission shall be confirmed by a hard copy delivered as soon as practicable thereafter by the method described in clause (c) above. This Section 15.7.1 (Notice Requirements) is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

15.7.2 **Address for Notice**.

If to Denali:

Denali Therapeutics Inc.
161 Oyster Point Blvd
South San Francisco, CA 94080
[***]

With a copy (which shall not constitute notice) to:

Wilson Sonsini Goodrich and Rosati P.C.
12235 El Camino Real, Suite 200
San Diego, CA 92130
[***]

If to Biogen:

Biogen MA, Inc.
225 Binney Street
Cambridge, MA 02142
[***]

With a copy to:

Ropes & Gray LLP
Prudential Tower
800 Boylston Street
Boston, MA 02199-3600
[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

15.8 **Entire Agreement; Amendments**. This Agreement, together with the Schedules attached hereto, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises, and representations, whether written or oral, with respect thereto are superseded hereby (including the Confidentiality Agreement and the aspects of the Provisional Agreement pertaining to Option Proteins, Option Products, ROFN Proteins and ROFN Products). Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement. Except for amendments and modifications to the CMC Plan in accordance with Section 8.2.3 (CMC Plan), no amendment, modification, release, or discharge shall be binding upon the Parties, unless in writing and duly executed by authorized representatives of both Parties.

15.9 **English Language**. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

15.10 **Equitable Relief**. Notwithstanding any provision herein to the contrary, nothing in Section 15.6 (Dispute Resolution) shall preclude either Party from seeking interim or provisional relief, including a temporary restraining order, preliminary injunction or other interim equitable relief concerning a Dispute, if necessary to protect the interests of such Party. This Section 15.10 (Equitable Relief) shall be specifically enforceable. Additionally, each Party acknowledges and agrees that the restrictions set forth in Section 4.4 (Exclusive Collaboration), Section 14.6 (Effects of Termination) through Section 14.9 (Survival) and Article 11 (Confidentiality) are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered into this Agreement in the absence of such restrictions, and that any breach or threatened breach of any provision of such Section or Articles may result in irreparable injury to such other Party for which there may be no adequate remedy at law. In the event of an actual or threatened breach of any provision of such Sections or Article, or other default or non-performance with respect to such Section or Article, the aggrieved Party may seek equitable relief (including restraining orders, specific performance or other injunctive relief) in any court or other forum, without first submitting to the dispute resolution procedures set forth in Section 15.6 (Dispute Resolution). Nothing in this Section 15.10 (Equitable Relief) is intended, or should be construed, to limit either Party's right to equitable relief or any other remedy for a breach of any other provision of this Agreement.

15.11 **Waiver and Non-Exclusion of Remedies**. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

15.12 **No Benefit to Third Parties**. Except as provided in Article 13 (Indemnification) and Section 4.3.1 (Existing Third Party Agreements), covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and successors and permitted assigns of the Parties, and shall not be construed as conferring any rights on any other Persons.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

15.13 **Further Assurance**. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

15.14 **Relationship of the Parties**. Unless otherwise required by applicable tax law, this Agreement shall not constitute a partnership or a joint venture in whole or in part between any of BIG, BIMA or Denali. Except to the extent expressly stated in this Agreement, neither Denali, on the one hand, nor Biogen, on the other hand, shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

15.15 **Performance by Affiliates**. Without limiting Section 15.16.1 (Performance by BIMA and BIG), each Party recognizes that the other Party may perform some or all of its obligations under this Agreement through Affiliates to the extent permitted under this Agreement; *provided*, *however*, that, in such case, (a) [***] and (b) [***].

15.16 **Performance by Biogen**.

15.16.1 **Performance by BIMA and BIG**. [***]

15.16.2 **Coordination between BIMA and BIG**. [***]

15.17 **Counterparts; Execution**. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. Counterparts may be delivered via electronic mail, including Adobe™ Portable Document Format (PDF) or any electronic signature complying with the U.S. Federal ESIGN Act of 2000, and any counterpart so delivered will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Agreement.

15.18 **References**. Unless otherwise specified: (a) references in this Agreement to any Article, Section or Schedule shall mean references to such Article, Section or Schedule of this Agreement; (b) references in any Section to any clause are references to such clause of such Section; and (c) references to any agreement, instrument, or other document in this Agreement refer to such agreement, instrument, or other document as originally executed or, if subsequently amended, replaced, or supplemented from time to time, as so amended, replaced, or supplemented and in effect at the relevant time of reference thereto.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

15.19 **Construction**. Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (b) the words "include", "includes" and "including" will be deemed to be followed by the phrase "without limitation," (c) the word "will" will be construed to have the same meaning and effect as the word "shall," (d) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person or entity will be construed to include the person's or entity's successors and assigns, (f) the words "herein," "hereof" and "hereunder", and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement, (h) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent," or "approve" or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (i) references to any specific law, rule or regulation, or article, section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, (j) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or," (k) references to any Sections include Sections and subsections that are part of the related Section (e.g., a section numbered "Section 2.2" would be part of "Section 2", and references to "Section 2.2" would also refer to material contained in the subsection described as "Section 2.2(a)") and (l) neither Party or its Affiliates or Sublicensees shall be deemed acting "on behalf of" or "under the authority of" the other Party. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions. All amounts (including payment amounts and calculation thereof) are stated in U.S. Dollars unless another currency is specified. To the extent there exists any discrepancy between any internal, alphabetical or numerical cross-reference to a Section, Article or Schedule of this Agreement and the parenthetical immediately following such cross-reference, the parenthetical shall govern.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized officers.

Denali Therapeutics Inc.
By: /s/ Ryan J. Watts
Name: Ryan Watts, Ph.D.
Title: President and CEO

Biogen MA, Inc.
By: /s/ Alfred W. Sandrock, Jr.
Name: Alfred W. Sandrock, Jr.
Title: EVP, R&D

Biogen International GmbH
By: /s/ Frederick Lawson
Name: Frederick Lawson
Title: Senior Director

SCHEDULE 1.105

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

SCHEDULE 1.162

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

SCHEDULE 1.197

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

SCHEDULE 1.202

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

SCHEDULE 1.244

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

SCHEDULE 4.3.1

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

SCHEDULE 5.1

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

SCHEDULE 8.2.4

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

SCHEDULE 11.7.1

PRESS RELEASE

Denali Therapeutics Announces Closing of Collaboration and Share Purchase Agreements with Biogen

SOUTH SAN FRANCISCO, Calif., Oct 7, 2020 — Denali Therapeutics Inc. (NASDAQ: DNLI), a biopharmaceutical company developing a broad portfolio of product candidates engineered to cross the blood-brain barrier (BBB) for neurodegenerative diseases, today announced the signing of a Definitive LRRK2 Collaboration and License Agreement and a Right of First Negotiation, Option and License Agreement with Biogen, in connection with its previously announced binding provisional collaboration and license agreement for neurodegenerative diseases with Biogen, and the closing of the related common stock purchase agreement.

In connection with the signing of the agreements with Biogen, Denali will receive a $560 million upfront payment. In addition, on September 22, 2020, in a private placement transaction, Biogen made an equity investment of $465 million in Denali through the purchase of 13,310,243 newly issued shares of Denali common stock at approximately $34.94 per share in connection with its previously announced stock purchase agreement.

Under the terms of the Definitive LRRK2 Collaboration and License Agreement, the companies will co-develop Denali's small molecule inhibitors of leucine-rich repeat kinase 2 (LRRK2) for Parkinson's disease, and will co-commercialize Denali's LRRK2 products in the United States and China, with shared responsibility for worldwide development costs (60 percent Biogen; 40 percent Denali), as well as profits and losses for commercialization in the United States (50 percent Biogen; 50 percent Denali) and China (60 percent Biogen; 40 percent Denali). Outside the United States and China, Biogen will be responsible for commercialization and will pay Denali tiered royalties. Should the LRRK2 program achieve certain development and commercial milestones, Denali will be eligible to receive up to $1.125 billion in potential milestone payments.

Mutations in LRRK2 can cause Parkinson's disease. LRRK2 is a regulator of lysosomal function, which is impaired in Parkinson's disease and may contribute to neurodegeneration. As previously announced, Denali's small molecule inhibitor of LRRK2, DNL151, has been selected to progress into late-stage clinical studies, which are expected to commence in 2021.

Under the terms of the Right of First Negotiation, Option and License Agreement with Biogen, Biogen has exclusive option rights to two programs for neurodegenerative diseases using Denali's BBB-crossing transport vehicle (TV) technology platform, including for amyloid beta, plus right of first negotiation for two additional unnamed TV platform programs should Denali decide to seek a collaboration for such programs. These rights are limited to certain modalities and indications and are also exercisable during a limited time period. Denali's proprietary TV technology is designed to effectively deliver large therapeutic molecules such as antibodies, enzymes, proteins and oligonucleotides across the BBB after intravenous administration.

The closing of the common stock purchase agreement and the definitive collaboration agreements were subject to the satisfaction of customary closing conditions, including the expiration of the waiting period under the Hart-Scott-Rodino (HSR) Antitrust Improvements Act of 1976. Additional details regarding the financial terms can be found in Denali's Form 8-K filed with the Securities and Exchange Commission on October 7, 2020.

About Denali's LRRK2 DNL151 Program

DNL151 is a small molecule inhibitor of LRRK2 invented at Denali which has completed dosing of 162 healthy volunteers in an ongoing Phase 1 clinical study and completed dosing in 25 Parkinson's patients in a Phase 1b clinical study. Denali is currently completing further dose escalation cohorts in an expanded Phase 1 and an additional cohort in the Phase 1b study to define the full therapeutic window of the molecule. Based on the clinical data to date that has been generated in Europe, DNL151 appears to have an acceptable safety and tolerability profile and has met desired target engagement goals. An Investigational New Drug application for DNL151 was cleared by the U.S. Food and Drug Administration in July 2020 and enables expansion of Denali clinical trials for DNL151 globally.

About Denali Therapeutics

Denali Therapeutics is a biopharmaceutical company developing a broad portfolio of product candidates engineered to cross the blood-brain barrier (BBB) for neurodegenerative diseases. Denali pursues new treatments by rigorously assessing genetically validated targets, engineering delivery across the BBB and guiding development through biomarkers that demonstrate target and pathway engagement. Denali is based in South San Francisco. For additional information, please visit www.denalitherapeutics.com.

Cautionary Note Regarding Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements expressed or implied in this press release include, but are not limited to, plans, timelines and expectations related to DNL151 and other LRRK2 inhibitor molecules, Denali's TV technology platform and TV programs; LRRK2 inhibitors as modifying therapy for Parkinson's disease; the ability of the TV technology to effectively deliver large therapeutic molecules across the BBB; expectations regarding the collaboration with Biogen, including financial aspects of the collaboration; the potential benefits and results of the transaction with Biogen; expectations regarding the commencement of clinical trials; expectations regarding ongoing clinical trials; and plans to conduct development and commercialization activities.

Actual results are subject to risks and uncertainties and may differ materially from those indicated by these forward-looking statements as a result of these risks and uncertainties, including but not limited to: any and all risks to Denali's business and operations caused directly or indirectly by the evolving COVID-19 pandemic; the risk of the occurrence of any event, change or other circumstance that could give rise to the termination of the agreements with Biogen; risks related to the effect of the announcement of the transaction on Denali's business relationships, operating results, stock price and business generally; Denali's early stages of clinical drug development; Denali's and its partners' ability to complete the development and, if approved, commercialization of its product candidates; Denali's and its partners' ability to enroll patients in clinical trials; Denali's reliance on third parties for the manufacture and supply of its product candidates for clinical trials; Denali's dependence on successful development of its BBB platform technology and whether the platform technology effectively delivers large therapeutic molecules across the BBB; Denali's and its partners' ability to conduct or complete clinical trials on expected timelines; the risk that preclinical profiles and results of early clinical trials of Denali's product candidates, such as DNL151, may not translate in later clinical trials; the risk that DNL151 and Denali's other LRRK2 inhibitors may not sufficiently modify Parkinson's disease; the uncertainty that product candidates will receive regulatory approval necessary to be commercialized; Denali's ability to continue to create a pipeline of product candidates or develop commercially successful products; developments relating to Denali's competitors and its industry, including competing product candidates and therapies; Denali's ability to obtain, maintain or protect intellectual property rights related to its product candidates; implementation of Denali's strategic plans for its business, product candidates and BBB platform technology; Denali's ability to obtain additional capital to finance its operations, as needed; Denali's ability to accurately forecast future financial results in the current environment; general economic and market conditions; and other risks and uncertainties, including those described in Denali's most recent Annual Report on Form 10-K, most recent Quarterly Report on Form 10-Q and Denali's future reports to be filed with the SEC. The forward-looking statements in this press release are based on information available to Denali as of the date hereof. Denali disclaims any obligation to update any forward-looking statements, except as required by law.

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[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

SCHEDULE 15.6.4

[***]

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

DENALI THERAPEUTICS INC.
KEY EXECUTIVE CHANGE IN CONTROL AND SEVERANCE PLAN
(Effective November 10, 2017)

1. **Introduction**. This Denali Therapeutics Inc. Key Executive Change in Control and Severance Plan (the "**Plan**") has been established by Denali Therapeutics Inc., a Delaware corporation, for the benefit of a select group of management or highly compensated employees of the Employer, in order to provide them with assurances of specified benefits if they (a) incur qualifying terminations of employment, and (b) abide by the terms and conditions of participation in, and receipt of such benefits, as set forth in the Plan. The Plan also provides certain Participants with specified benefits in the event of a Change in Control.

2. **Important Terms**. The following capitalized words and phrases will have the meanings set forth in this Section 2, unless a different meaning is plainly required by the context:

2.1. **"Administrator"** means the Company, acting through the Compensation Committee of the Board or another duly constituted committee of members of the Board, or any person to whom the Administrator or the Board has delegated any authority or responsibility with respect to the Plan pursuant to Section 13, but only to the extent of such delegation.

2.2. **"Board"** means the Board of Directors of the Company.

2.3. **"Cause"** means (a) a Participant's conviction of, or plea of guilty or nolo contendere to, any crime involving dishonesty or moral turpitude or any felony; or (b) a Participant's (i) engagement in material dishonesty, willful misconduct or gross negligence in each case in connection with the Participant's position at the Company, (ii) breach of any confidentiality, invention assignment, non-disclosure, or non-solicitation agreement entered into between the Company and the Participant, (iii) material violation of a written Company policy or procedure that has been provided to the Participant causing substantial injury to the Company, and/or (iv) willful refusal to perform the Participant's assigned duties to the Company, following written notice of such refusal by the Company and a period of fifteen (15) days to cure the same and the Participant's failure to cure during such time period. No act or omission shall be considered "willful" if such act or omission was done, or not done, in the reasonable, good-faith belief that such act or omission was in the best interests of the Company or upon the advice of counsel to the Company.

2.4. **"Change in Control"** means the occurrence of any of the following events:

(a) a change in the ownership of the Company which occurs on the date that any one person, or more than one person acting as a group ("**Person**"), acquires ownership of the stock of the Company that, together with the stock held by such Person, constitutes more than fifty percent (50%) of the total voting power of the stock of the Company; provided, however, that for purposes of this subsection, the acquisition of additional stock by any one Person, who is considered to own more than fifty percent (50%) of the total voting power of the stock of the Company will not be considered a Change in Control. Further, if the stockholders of the Company immediately before such change in ownership continue to retain immediately after the change in ownership, in substantially the same proportions as their ownership of shares of the Company's voting stock immediately prior to the change in ownership, direct or indirect beneficial ownership of fifty percent (50%) or more of the total voting power of the stock of the Company or of the ultimate parent entity of the Company, such event shall not be considered a Change in Control under this subsection (a). For this purpose, indirect beneficial ownership shall include, without limitation, an interest resulting from ownership of the voting securities of one or more corporations or other business entities which own the Company, as the case may be, either directly or through one or more subsidiary corporations or other business entities; or

(b) a change in the effective control of the Company which occurs on the date that a majority of members of the Board is replaced during any twelve (12) month period by members of the Board whose appointment or election is not endorsed by a majority of the members of the Board prior to the date of the appointment or election. For purposes of this subsection (b), if any Person is considered to be in effective control of the Company, the acquisition of additional control of the Company by the same Person will not be considered a Change in Control; or

(c) a change in the ownership of a substantial portion of the Company's assets which occurs on the date that any Person acquires (or has acquired during the twelve (12) month period ending on the date of the most recent acquisition by such person or persons) assets from the Company that have a total gross fair market value equal to or more than fifty percent (50%) of the total gross fair market value of all of the assets of the Company immediately prior to such acquisition or acquisitions; provided, however, that for purposes of this subsection (c), the following will not constitute a change in the ownership of a substantial portion of the Company's assets: (i) a transfer to an entity that is controlled by the Company's stockholders immediately after the transfer, or (ii) a transfer of assets by the Company to: (A) a stockholder of the Company (immediately before the asset transfer) in exchange for or with respect to the Company's stock, (B) an entity, fifty percent (50%) or more of the total value or voting power of which is owned, directly or indirectly, by the Company, (C) a Person, that owns, directly or indirectly, fifty percent (50%) or more of the total value or voting power of all the outstanding stock of the Company, or (D) an entity, at least fifty percent (50%) of the total value or voting power of which is owned, directly or indirectly, by a Person described in this subsection (c). For purposes of this subsection (c), gross fair market value means the value of the assets of the Company, or the value of the assets being disposed of, determined without regard to any liabilities associated with such assets.

For purposes of this Section 2.4, persons will be considered to be acting as a group if they are owners of a corporation that enters into a merger, consolidation, purchase or acquisition of stock, or similar business transaction with the Company.

Notwithstanding the preceding, no transaction will be a Change in Control under this definition unless it is also a "change in control event" within the meaning of Treasury Regulation Section 1.409A-3(i)(5).

Further and for the avoidance of doubt, a transaction will not constitute a Change in Control if: (a) its sole purpose is to change the state of the Company's incorporation, or (ii) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction.

2.5. **"Change in Control Period"** means the time period beginning on the consummation of the first Change in Control to occur on or after the Effective Date and ending on the date that is twelve (12) months following the consummation of such Change in Control.

2.6. **"Code"** means the U.S. Internal Revenue Code of 1986, as amended. Reference to a specific section of the Code includes such section, any valid regulation or other Treasury Department or Internal Revenue Service guidance promulgated thereunder, and any comparable provision of any future legislation amending, supplementing or superseding such section.

2.7. **"Company"** means Denali Therapeutics Inc., a Delaware corporation, and any successor that assumes the obligations of the Company under the Plan, by way of merger, acquisition, consolidation or other transaction.

2.8. **"Deferred Payments"** means any Severance Benefits to be paid or provided to a Participant pursuant to this Plan and any other severance payments or separation benefits to be paid or provided to such Participant, that in each case, when considered together, are considered deferred compensation under Section 409A.

2.9. **"Disability"** means "permanent and total disability" within the meaning of Section 22(e)(3) of the Code. The Administrator will determine whether a Participant has incurred a Disability based on such evidence as the Administrator deems necessary or advisable.

2.10. **"Effective Date"** means November 10, 2017.

2.11. **"Eligible Employee"** means a member of a "select group of management or highly compensated employees" (within the meaning of Sections 201(2), 301(a)(3) and 401(a)(1) of ERISA) of an Employer who has been designated by the Administrator as being eligible to participate in the Plan and has been provided a Participation Agreement by the Administrator.

2.12. **"Employer"** means, with respect to an Eligible Employee, the Company or the parent or subsidiary of the Company that directly employs the Eligible Employee.

2.13. **"ERISA"** means the U.S. Employee Retirement Income Security Act of 1974, as amended. Reference to a specific section of ERISA includes such section, any valid regulation or other Department of Labor guidance promulgated thereunder, and any comparable provision of any future legislation amending, supplementing or superseding such section.

2.14. **"Good Reason"** means the occurrence of one or more of the following without a Participant's written consent: (a) a change in the Participant's principal work location resulting in a new one-way commute that is more than thirty-five (35) miles greater than the Participant's one-way commute prior to the change in the Participant's principal work location, regardless of whether Participant receives an offer of relocation benefits, (b) a material reduction in the Participant's authority, duties and/or responsibilities as compared to the Participant's authority, duties and/or responsibilities in effect immediately prior to the occurrence of the event, or (c) a material reduction in the Participant's base compensation as compared to the Participant's base compensation in effect immediately prior to the occurrence of the event; provided, however, that no such occurrence will constitute Good Reason unless (i) the Participant gives the Employer a written notice of termination for Good Reason not more than ninety (90) days after the initial existence of the condition, (ii) the grounds for termination (if susceptible to correction) are not corrected by the Employer within thirty (30) days of its receipt of such notice, and (iii) the Participant's Involuntary Termination occurs within ninety (90) days following the Employer's receipt of such notice.

2.15. **"Grandfathered Award"** means a Time-Based Equity Award, if any, granted to an applicable Participant before the Effective Date.

2.16. **"Involuntary Termination"** means a Non-CIC Involuntary Termination or a CIC Involuntary Termination, in each case, under the circumstances described in Section 4 or Section 5, respectively.

2.17. **"Participant"** means an Eligible Employee who has timely and properly executed and delivered his or her Participation Agreement to the Administrator, as set forth therein. A Participant's Severance Benefit levels will be determined by the Administrator, in its sole discretion, and reflected in the Participation Agreement.

2.18. **"Participation Agreement"** means the individual agreement (as will be provided by separate cover as Appendix A) provided by the Administrator to an Eligible Employee designating him or her as such; provided, however, that, after a Participation Agreement has been entered into between a Participant and the Employer, it may be modified only by a supplemental written agreement executed by both Participant and the Employer.

2.19. **"Section 409A"** means Section 409A of the Code.

2.20. **"Section 409A Limit"** means two (2) times the lesser of: (a) the Participant's annualized compensation based upon the annual rate of pay paid to the Participant during the Participant's taxable year preceding the Participant's taxable year of the Participant's termination of employment as determined under, and with such adjustments as are set forth in, Treasury Regulation Section 1.409A-1(b)(9)(iii)(A)(1) and any Internal Revenue Service guidance issued with respect thereto; or (b) the maximum amount that may be taken into account under a qualified plan pursuant to Section 401(a)(17) of the Code for the year in which the Participant's employment is terminated.

2.21. **"Severance Benefits"** means the compensation and other benefits that a Participant will be provided under the Plan in the circumstances described in Section 4 or Section 5, as applicable.

2.22. **"Time-Based Equity Award**" means any Company equity compensation award (including, but not limited to, stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares, performance stock units) granted to an applicable Participant that, as of the applicable date, is scheduled to vest based solely on the Participant's continued service with the Employer through the scheduled date(s) of vesting. For the avoidance of doubt, an outstanding equity compensation award (or portion thereof) granted to a Participant for which, as of the applicable date, any performance-based vesting requirements have been fully achieved or waived, and which remains subject solely to vesting requirements based solely on the Participant's continued service with the Employer through the scheduled date(s) of vesting, is considered a "Time-Based Equity Award" as of the applicable date.

3. **Eligibility for Severance Benefits**. A Participant is eligible for Severance Benefits, as described in Section 4 or Section 5, as applicable, only if he or she is an Eligible Employee on the date he or she experiences an Involuntary Termination and otherwise satisfies the requirements of the Plan.

4. **Involuntary Termination Outside the Change in Control Period**. If, outside of the Change in Control Period, (a) a Participant terminates his or her employment with the Employer for Good Reason, or (b) the Employer terminates the Participant's employment for a reason other than (x) Cause, (y) the Participant's death, or (z) the Participant's Disability (in each case of (a) or (b), a "**Non-CIC Involuntary Termination**"), then subject to Sections 8 through 12 and the Participant's compliance with Section 7, the Participant will receive the following Severance Benefits:

4.1. **Cash Severance Payments**. Payments of cash severance for the period and in the amounts set forth in the Participant's Participation Agreement; and

4.2. **In-lieu of COBRA Benefit**. If, on the day immediately before the Participant's Non-CIC Involuntary Termination, the Participant and any qualifying spouse and/or other dependents of the Participant ("**Family Members**"), have coverage under a group health plan sponsored by the Company or any parent or subsidiary of the Company ("**Qualifying Health Coverage**"), a lump sum cash payment in an aggregate amount equal to a specified number of months of the Monthly COBRA Premium Amount (as defined below), as set forth in the Participant's Participation Agreement. "**Monthly COBRA Premium Amount**" for purposes of the Plan means the applicable monthly premium cost that a Participant otherwise would be required to pay to continue Qualifying Health Coverage pursuant to the federal Consolidated Omnibus Budget Reconciliation Act of 1986, as amended ("**COBRA**"), which amount will be determined based on the premium otherwise payable for the first month of such COBRA continuation coverage, including the two-percent (2%) administrative charge, if applicable. For the avoidance of doubt, any such payment will be made regardless of whether the Participant (and/or any Family Members) actually elect COBRA continuation coverage. Notwithstanding anything to the contrary in the Plan or any Participation Agreement, if at any time the Company determines in its sole discretion that the payment contemplated by this Section 4.2 cannot be provided to a Participant without violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), such Participant will not receive such payment or any benefits or payments in lieu thereof.

5. **Involuntary Termination During the Change in Control Period**. If, during the Change in Control Period, (a) a Participant terminates his or her employment with the Employer for Good Reason, or (b) the Employer terminates the Participant's employment for a reason other than (x) Cause, (y) the Participant's death, or (z) the Participant's Disability (in each case of (a) or (b), a "**CIC Involuntary Termination**"), then, subject to Sections 8 through 12 and the Participant's compliance with Section 7, the Participant will receive the following Severance Benefits:

5.1. **Cash Severance Payments**. Payments of cash severance for the period and in the amounts set forth in the Participant's Participation Agreement;

5.2. **Time-Based Equity Award Vesting Acceleration Benefit**. The Participant's Time-Based Equity Awards, if any, which are outstanding and unvested as of the date of the Participant's CIC Involuntary Termination, will accelerate and vest as to the amount(s) set forth in the Participant's Participation Agreement, as applicable; and

5.3. **In-Lieu of COBRA Benefit**. If, on the day immediately before the Participant's CIC Involuntary Termination, the Participant and any Family Members have Qualifying Health Coverage , a lump sum cash payment in an aggregate amount equal to a specified number of months of the Monthly COBRA Premium Amount, as set forth in the Participant's Participation Agreement. For the avoidance of doubt, any such payment will be made regardless of whether the Participant (and/or any Family Members) actually elect COBRA continuation coverage. Notwithstanding anything to the contrary in the Plan or any Participation Agreement, if at any time the Company determines in its sole discretion that the payments contemplated by this Section 4.2 cannot be provided to a Participant without violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), such Participant will not receive such payment or any benefits or payments in lieu thereof.

6. **Grandfathered Award Vesting Acceleration Benefit Upon a Change in Control.** In the event of a Change in Control, a Participant's Grandfathered Awards, if any, which are then outstanding and unvested will accelerate and vest as to the amount(s) set forth in the Participant's Participation Agreement, as applicable.

7. **Limitation on Payments**. In the event that the severance and other benefits provided for in this Plan or otherwise ("**280G Payments**") payable to a Participant (i) constitute "parachute payments" within the meaning of Section 280G of the Code ("**Section 280G**"), and (ii) but for this Section 7, would be subject to the excise tax imposed by Section 4999 of the Code ("**Section 4999**"), then the 280G Payments will be either:

(a) delivered in full, or

(b) delivered as to such lesser extent which would result in no portion of such benefits being subject to excise tax under Section 4999,

whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the excise tax imposed by Section 4999, results in the receipt by the Participant on an after-tax basis, of the greatest amount of benefits, notwithstanding that all or some portion of such benefits may be taxable under Section 4999. If a reduction in severance and/or other benefits constituting "parachute payments" is necessary so that benefits are delivered to a lesser extent, reduction will occur in the following order: (i) cancellation of awards granted "contingent on a change in ownership or control" (within the meaning of Section 280G), which will occur in the reverse order of the date of grant for such awards (i.e., the most recently granted awards will be reduced first); (ii) reduction of cash payments, which will occur in reverse chronological order such that the cash payment owed on the latest date following the occurrence of the event triggering such excise tax will be the first cash payment to be reduced, (iii) reduction of acceleration of vesting of equity awards, which will occur in the reverse order of the date of grant for such awards (i.e., the vesting of the most recently granted equity awards will be reduced first), (iv) reduction of other benefits paid or provided to the Participant, which will occur in reverse chronological order such that the benefit owed on the latest date following the occurrence of the event triggering such excise tax will be the first benefit to be reduced. If more than one equity award was made to the Participant on the same date of grant, all such awards will have their acceleration of vesting reduced pro rata. Notwithstanding the foregoing, to the extent the Company submits any payment or benefit payable to the Participant under this Plan or otherwise to the Company's stockholders for approval in accordance with Treasury Regulation Section 1.280G-1 Q&A 7, the foregoing provisions shall not apply following such submission and such payments and benefits will be treated in accordance with the results of such vote, except that any reduction in, or waiver of, such payments or benefits required by such vote will be applied without any application of discretion by the Participant and in the order prescribed by this Section 7 . In no event will a Participant have any discretion with respect to the ordering of payment reductions.

Unless the Participant and the Company otherwise agree in writing, any determination required under this Section 7 will be made in writing by a nationally recognized firm of independent public accountants or valuation firm selected by the Company or such other person or entity to which the parties mutually agree (the "**Firm**"), whose determination will be conclusive and binding upon the Participant and the Company. For purposes of making the calculations required by this Section 7 the Firm may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999. The Participant and the Company will furnish to the Firm such information and documents as the Firm may reasonably request in order to make a determination under this Section 7. The Company will bear all costs the Firm may reasonably incur in connection with any calculations contemplated by this Section 7.

8. **Conditions to Receipt of Severance Benefits**.

8.1. **Release Agreement**. Notwithstanding any contrary Plan provision, as a condition to receiving any Severance Benefits, a Participant (or, after a Participant's death, an authorized representative of the Participant's estate) will be required to sign and not revoke a separation and release of claims agreement in a form reasonably satisfactory to the Company (the "**Release**"). In all cases, the Release must become effective and irrevocable no later than the sixtieth (60th) day following the Participant's Involuntary Termination (the "**Release Deadline Date**"). If the Release does not become effective and irrevocable by the Release Deadline Date, the Participant will forfeit any right to any Severance Benefits. In no event will any Severance Benefits be paid or provided to the Participant until the Release becomes effective and irrevocable.

8.2. **Other Requirements**. A Participant's receipt of Severance Benefits will be subject to the Participant continuing to comply with the provisions of the Participant's Release and the terms of any confidentiality, proprietary information and inventions agreement and any other written agreement or agreements between the Participant and the Employer under which the Participant has a material duty or obligation to the Employer. Any Severance Benefits will terminate immediately for a Participant if the Participant, at any time, violates any such agreement and/or his or her Release, and Participant will be obligated to repay all Severance Benefits paid or provided to the Participant.

9. **Timing of Severance Benefits**. Except as otherwise provided in a Participant's Participation Agreement and subject to Section 11, any Severance Benefits that are payable to a Participant in cash will be paid (or in the case of Severance Benefits scheduled to be paid in installments, will commence) on the first Employer payroll date following the Release Deadline Date (such payment date, the "**Severance Start Date**"), with any payments due thereafter to be made as provided in this Plan or the applicable Participation Agreement.

10. **Exclusive Benefit.** The benefits, if any, provided under this Plan will be the exclusive benefits for a Participant related to his or her termination of employment with the Employer and/or a change in control of the Company and will supersede and replace any severance and/or change in control benefits set forth in any offer letter, employment or severance agreement and/or other agreement between the Participant and the Employer. For the avoidance of doubt, if a Participant was otherwise eligible to participate in any other Employer severance and/or change in control plan (whether or not subject to ERISA), then participation in this Plan will supersede and replace eligibility in such other plan.

11. **Section 409A**. Notwithstanding anything to the contrary in this Plan or any Participation Agreement:

(a) No Deferred Payments, if any, will be paid or provided until the Participant has a "separation from service" within the meaning of Section 409A (a "Separation from Service"). Similarly, no Severance Benefits payable to a Participant, if any, which otherwise would be exempt from Section 409A pursuant to Treasury Regulation Section 1.409A-1(b)(9), will be payable until the Participant has a Separation from Service.

(b) It is intended that none of the Severance Benefits will constitute Deferred Payments but rather will be exempt from Section 409A as a payment that would fall within the "short-term deferral period" as described in subsection (c) below or resulting from an involuntary separation from service as described in subsection (d) below. In no event will a Participant have discretion to determine the taxable year of payment of any Deferred Payment.

(c) If a Participant is a "specified employee" within the meaning of Section 409A at the time of the Participant's Separation from Service (other than due to death), then the Deferred Payments, if any, that are payable within the first six (6) months following the Participant's Separation from Service, will become payable on the date six (6) months and one (1) day following the date of the Participant's Separation from Service. All subsequent Deferred Payments, if any, will be payable in accordance with the payment schedule applicable to each payment or benefit. However, in the event of the Participant's death following the Participant's Separation from Service, but before the six (6)-month anniversary of the Separation from Service, then any payments delayed in accordance with this subsection (c) will be payable in a lump sum as soon as administratively practicable after the date of the Participant's death and all other Deferred Payments will be payable in accordance with the payment schedule applicable to each payment or benefit. Each payment and benefit payable under this Plan is intended to constitute a separate payment under Section 1.409A-2(b)(2) of the Treasury Regulations.

(d) Any amount paid under this Plan that satisfies the requirements of the "short-term deferral" rule set forth in Section 1.409A-1(b)(4) of the Treasury Regulations will not constitute Deferred Payments for purposes of this Section 11.

(e) Any amount paid under this Plan that qualifies as a payment made as a result of an involuntary separation from service pursuant to Section 1.409A-1(b)(9)(iii) of the Treasury Regulations that does not exceed the Section 409A Limit will not constitute Deferred Payments for purposes of this Section 11. All amounts paid under this Plan will be paid to the applicable Participant as provided under the Plan and the Participant's Participation Agreement, but in no event later than the last day of the second taxable year of the Participant following the taxable year of the Participant in which his or her Separation from Service occurs.

(f) The foregoing provisions are intended to comply with or be exempt from the requirements of Section 409A so that none of the payments and benefits to be provided under the Plan will be subject to the additional tax imposed under Section 409A, and any ambiguities herein will be interpreted to so comply or be exempt. Notwithstanding anything to the contrary in the Plan, including but not limited to Sections 13 and 15, the Company reserves the right to amend the Plan as it deems necessary or advisable, in its sole discretion and without the consent of the Participants, to comply with Section 409A or to avoid income recognition under Section 409A prior to the actual payment of benefits under the Plan or imposition of any additional tax. In no event will the Company or any other Employer reimburse a Participant for any taxes that may be imposed on the Participant as result of Section 409A.

12. **Withholdings**. Notwithstanding anything to the contrary in the Plan or any Participation Agreement, the Employer will withhold from any Severance Benefits all applicable U.S. federal, state, local and non-U.S. taxes required to be withheld and any other required payroll deductions.

13. **Administration**. The Company is the administrator of the Plan (within the meaning of Section 3(16)(A) of ERISA). The Plan will be administered, interpreted and operated by the Administrator (in its sole discretion). The Administrator will have the exclusive right and full discretion (a) to interpret the Plan, (b) to designate the management or highly compensated employees of the Employer who are eligible to participate in the Plan and to provide Participation Agreements to any such Eligible Employees, (c) to decide any and all matters arising under the Plan or any Participation Agreement (including the right to remedy possible ambiguities, inconsistencies, or omissions), (d) to make, amend and rescind such rules as it deems necessary or appropriate for the proper administration of the Plan, and (e) to make all other determinations and resolve all questions of fact necessary or advisable for the administration of the Plan, including eligibility for any benefit or payment under the Plan. In accordance with Section 2.1, the Administrator may, in its sole discretion and on such terms and conditions as it may provide, delegate in writing to one or more officers of the Company all or any portion of its authority or responsibility with respect to the Plan All decisions, interpretations and/or other actions of the Administrator and its authorized delegates (including with respect to whether an Involuntary Termination or a Change in Control has occurred) will be final, conclusive and binding on all persons and will be given the maximum possible deference permitted by law. The Administrator is the appropriate named fiduciary of the Plan solely for purposes of the Plan's claims and appeal procedures set forth in Section 16.

14. **Eligibility to Participate**. To the extent that the Administrator has delegated administrative authority or responsibility to one or more officers of the Company in accordance with Sections 2.1 and 13, each such officer will not be excluded from participating in the Plan if otherwise eligible, but he or she is not entitled to act upon or make determinations regarding any matters pertaining specifically to his or her own benefit or eligibility under the Plan. The Administrator will act upon and make determinations regarding any matters pertaining specifically to the benefit or eligibility of each such officer under the Plan.

15. **Amendment or Termination**. The Company, by action of the Board or the Administrator, reserves the right to amend or terminate the Plan at any time, without advance notice to any Participant and without regard to the effect of the amendment or termination on any Participant or on any other individual. Any amendment or termination of the Plan must be in writing. In addition, and notwithstanding the preceding, the Company may not, without a Participant's written consent, amend or terminate the Plan in any way, nor take any other action, that (a) prevents that Participant from becoming eligible for Severance Benefits under the Plan, or (b) reduces or alters to the detriment of the Participant the Severance Benefits payable, or potentially payable, to a Participant under the Plan (including, without limitation, imposing additional conditions).

16. **Claims and Appeal Procedures**.

16.1. **Claims Procedure**. Any Participant who believes he or she is entitled to but has not received a benefit or payment under the Plan or disagrees with the determination of the amount of any Plan benefit or payment or any other decision regarding his or her interest under the Plan (or his or her authorized legal representative) (the "**Claimant**") must submit such claim for (the "**Claim**") in writing to the Administrator at the following address within ninety (90) calendar days after the date the Claimant first knew or should have known of the facts on which the Claim is based, unless the Administrator consents otherwise in writing: Denali Therapeutics Inc., Attn: Administrator of the Change in Control and Severance Plan, 151 Oyster Point Blvd., 2nd Floor, South San Francisco, CA 94080.

16.1.1. **Non-Disability Benefit Claim**. If a Non-Disability Benefit Claim (as defined below) is denied (in full or in part), the Claimant will be provided a written notice of such denial within ninety (90) days after such Claim is received by Administrator in accordance with Section 16.1, unless special circumstances require an extension of time (up to ninety (90) days), in which case written notice of the extension will be given to the Claimant within the initial ninety (90)-day review period. This notice of extension will indicate the special circumstances requiring the extension of time and the date by which the Administrator expects to render its decision on the Non-Disability Benefit Claim. The denial notice will include: (a) the specific reason(s) for the denial; (b) references to the specific Plan provision(s) on which the denial was based; (c) a description of any additional material or information that is necessary to perfect the Claim; (d) a description of the Plan's procedures for appealing the denial and the time limits applicable to such procedures; and (e) any other information required by ERISA. A "**Non-Disability Benefit Claim**" means a Claim that does not involve any determination of Disability by the Administrator.

16.1.2. **Disability Benefit Claim**. If a Disability Benefit Claim (as defined below) is denied (in full or in part), the Claimant will be provided a written notice of such denial within forty-five (45) days after such Claim is received by the Administrator in accordance with Section 16.1. However, the forty-five (45)-day time period may be extended for up to two (2) thirty (30)-day periods for matters beyond the control of the Administrator, in which case the Claimant will be notified in writing of the extension within the initial forty-five (45)-day or thirty (30)-day review period, as applicable, the circumstances requiring the extension and the date by which the Administrator expects to render its decision. Any notice of extension also will explain the standards on which the entitlement to a Plan benefit is based, the unresolved issues that prevent a decision on the Disability Benefit Claim and the additional information needed to resolve those issues, and notice that the Claimant will be afforded at least forty-five (45) calendar days within which to provide the specified information, in which case the period for making the determination on such Claim will be tolled from the date the notification of extension was provided until the Claimant responds to the request for additional information. No additional extensions may be made, except with the Claimant's voluntary consent. The denial notice will include: (a) the specific reason(s) for the denial; (b) references to the specific Plan provision(s) on which the denial was based; (c) a description of any additional material or information that is necessary to perfect such Claim; (d) a copy of any internal rule, guideline, protocol or other similar criteria relied on in denying such Claim or a statement that such rule, guideline, protocol or other similar criteria was relied on in denying such Claim and that a copy of it will be provided without charge upon request; (e) a description of the Plan's procedures for appealing the denial; and (f) any other information required by ERISA. A "**Disability Benefit Claim**" means a Claim that involves a determination of Disability by the Administrator.

16.2. **Appeal Procedur**e. A Claimant may appeal any denied Claim by filing a request for review of such denial in writing with the Administrator at the address noted in Section 16.1. Such request must be made within sixty (60) days following the date the Claimant received the written notice of denial (or, in the case of a Disability Benefit Claim, within one hundred and eighty (180) days following receipt of the denial). The Claimant then has the right to review and obtain copies of all documents and other information relevant to the Claim, upon request and at no charge, and to submit comments, documents and other information relating to the Claim in writing. The Administrator will provide written notice of its decision on review (whether or not adverse) within sixty (60) days after it receives a timely review request (or in the case of a Disability Benefit Claim, within forty-five (45) days after receipt of a timely review request), unless special circumstances require a longer period of time, in which case a decision will be rendered as soon as possible, but not later than one hundred and twenty (120) days after receipt of the timely review request (or, in the case of a Disability Benefit Claim, not later than ninety (90) days after the timely review request). The Claimant will be given written notice of any such extension before the end of the original 60-day review period (or 45-day review period in the case of a Disability Benefit Claim), as well as the special circumstances requiring the extension of time and the date by which the Administrator expects to render its decision. In the case of a Disability Benefit Claim, the review of the appealed Claim will be conducted by the Administrator (who will not be the individual who decided the initial Claim nor the subordinate of such individual). In deciding an appeal of any denied Disability Benefit Claim that is based in full or in part on a medical judgment, the Administrator will consult with a health care professional (who will neither be an individual who was consulted in connection with the initial Claim nor the subordinate of such individual) who has appropriate training and experience in the field of medicine involved in the medical judgment. Any medical or vocational experts whose advice was obtained on behalf of the Administrator in connection with such denied Claim will be identified, regardless of whether the advice was relied upon in denying the Claim.

If the Administrator denies the appealed Claim, the notice of denial will include: (a) the specific reason(s) for the denial; (b) references to the specific provision(s) of the Plan on which the denial was based; (c) a statement that the Claimant will be provided, upon request and free of charge, reasonable access to, and copies of, all documents and other information relevant to the Claim; (d) in the case of a Disability Benefit Claim, a copy of any internal rule, guideline, protocol or other similar criteria relied on in denying the appeal or a statement that such rule, guideline, protocol or other similar criteria was relied on in denying the appeal and that a copy of it will be provided without charge upon request; (e) a statement regarding the claimant's right to bring an action under Section 502(a) of ERISA following the denial on review; and (f) any other information required by ERISA.

16.3. **Exhaustion of Plan's Claims and Appeal Procedure Required; Limitations on any Legal Actions; Venue**. Exhaustion of the Plan's applicable claims and appeal procedure set forth in this Section 16 is mandatory for resolving any Claim under the Plan before initiating any legal action relating to the Claim. Any legal action with respect to a Claim, if permitted, must be brought (a) no later than one (1) year after the Administrator's denial of such Claim on appeal, regardless of any state or federal statutes establishing provisions relating to limitations on actions, and (b) in the U.S. District Court for the Northern District of California. In any such action, all determinations made by the Administrator (and its authorized delegates) in connection with its review of the Claim will be afforded the maximum possible deference permitted by law.

17. **Attorneys' Fees**. The parties shall each bear their own expenses, legal fees and other fees incurred in connection with this Plan. Notwithstanding the foregoing, in the event that a Participant is required to incur attorneys' fees in order to obtain any Severance Benefit, and the Participant prevails on at least one material issue related to his or her Claim for such benefit, then the Company will reimburse the reasonable attorneys' fees so incurred by the Participant.

18. **Source of Payments**. The Plan will be maintained at all times in a manner to be considered "unfunded" for purposes of ERISA. All payments under the Plan will be paid from the general funds of the Company; no separate fund will be established under the Plan, and the Plan will have no assets. No right of any person to receive any payment under the Plan will be any greater than the right of any other general unsecured creditor of the Company or other Employer.

19. **Inalienability**. In no event may any current or former employee of the Employer sell, transfer, anticipate, assign or otherwise dispose of any right or interest he or she may have under the Plan. At no time will any such right or interest be subject to the claims of creditors nor liable to attachment, execution or other legal process. If any Severance Benefit is payable to a Participant who is unable to care for his or her affairs, payment may be made directly to his or her legal guardian or personal representative.

20. **Death**. Notwithstanding anything to the contrary in the Plan, if a Participant dies after his or her Involuntary Termination and after the Participant (or the authorized representative of the Participant's estate) have timely executed and returned the applicable Release to the Administrator (without having timely revoked it) but before receiving all of the Severance Benefits otherwise payable to him or her, such benefits instead will be paid to the executor of the Participant's estate, on behalf of the estate, at the time(s) and in the form(s) applicable to such Severance Benefits under the Plan.

21. **No Enlargement of Employment Rights**. Neither the establishment or maintenance or amendment of the Plan, nor the making of any benefit payment hereunder, will be construed to confer upon any individual any right to continue to be an employee of the Employer. The Employer expressly reserves the right to discharge any of its employees at any time, with or without cause or notice, as permitted by applicable law.

22. **Successors**. Any successor to the Company of all or substantially all of the Company's business and/or assets (whether direct or indirect and whether by purchase, merger, consolidation, liquidation or other transaction) will assume the obligations under the Plan and agree expressly to perform the obligations under the Plan in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. For all purposes under the Plan, the term "Company" will include any successor to the Company's business and/or assets which become bound by the terms of the Plan by operation of law, or otherwise.

23. **Applicable Law**. The Plan is intended to be an unfunded deferred compensation plan within the meaning of U.S. Department of Labor Regulation Section 2520.104-23 and will be construed, administered and enforced as such in accordance with ERISA. To the extent applicable, the internal substantive laws of the state of California (but not its conflict of laws provisions) will apply.

24. **Severability**. If any provision of the Plan is held invalid or unenforceable, its invalidity or unenforceability will not affect any other provision of the Plan, and the Plan will be construed and enforced as if such provision had not been included.

25. **Headings**. Headings in this Plan document are for purposes of reference only and will not limit or otherwise affect the meaning, construction or interpretation of the Plan's provisions.

26. **Indemnification**. The Company hereby agrees to indemnify and hold harmless the officers and employees of the Company, and the members of its Board, from all losses, claims, costs or other liabilities arising from their acts or omissions in connection with the administration, amendment or termination of the Plan, to the maximum extent permitted by applicable law. This indemnity will cover all such liabilities, including judgments, settlements and costs of defense. The Company will provide this indemnity from its own funds to the extent that insurance does not cover such liabilities. This indemnity is in addition to and not in lieu of any other indemnity provided to such person by the Company.

27. **No Guarantee of Tax Consequences**. Neither the Administrator, the Board, the Company nor any other Employer makes any guarantees regarding the tax treatment to any person of any benefits or payments provided under the Plan.

CEO ***[To the extent designated for such benefit levels by the Administrator]***

Appendix A

Denali Therapeutics Inc. Key Executive Change in Control and Severance Plan [Amended and Restated] Participation Agreement

Denali Therapeutics Inc. (the "**Company**") is pleased to inform you that you are eligible to participate in the Denali Therapeutics Inc. Key Executive Change in Control and Severance Plan (the "**Plan**"). [This Amended and Restated Participation Agreement (this "**Participation Agreement**") replaces and supersedes in full all participation agreements under the Plan previously signed by you, including the participation agreement signed by you on [DATE].]

A copy of the Plan has been delivered to you with this Participation Agreement. Your participation in the Plan is subject to all of the terms and conditions of the Plan, including this Participation Agreement. The capitalized terms used but not defined herein will have the meanings ascribed to them in the Plan.

In order to actually become a Participant in the Plan, you must complete and sign this Participation Agreement, and return it to [INSERT APPLICABLE INFO]. We ask that you do so as soon as practicable.

If you are a Participant, then subject to the terms and conditions of the Plan, you will receive the following benefits or payments under the Plan, as applicable:

[Applicable only to Participant who serves as CEO as of the Initial Adoption of the Plan: **I. Change in Control**

In the event of a Change in Control, the vesting schedule of any then-outstanding and unvested Grandfathered Awards held by you will be accelerated in part so that the number of shares, if any, subject to each such Grandfathered Award that would otherwise have first become vested in the period between the date of consummation of the Change in Control and the date on which all but the unvested shares subject to each such Grandfathered Award that would have vested in the final twelve (12) months of the vesting period will have first become vested will immediately become vested and exercisable, as applicable. The remaining number of shares subject to each such Grandfathered Award representing the last twelve (12) months of vesting will continue to be eligible to vest in accordance with the original vesting schedule within the next twelve (12) months set forth in the applicable award agreements for such awards, if any. By way of illustration, if, on the date of consummation of a Change in Control, you hold an unvested Grandfathered Award in the form of stock options that vest over a remaining period of thirty-six (36) months, then the shares subject to such stock option that would have vested over the next twenty-four (24) months will accelerate in full, and shares subject to such stock option that would have vested over the remaining twelve (12) months would continue to vest from and after the Change in Control over the twelve (12) months following the Change in Control, subject to the provisions of Paragraph III.3. of this Participation Agreement. ***]***

II. Non-CIC Involuntary Termination

If, outside of the Change in Control Period, you incur a Non-CIC Involuntary Termination, then subject to the terms and conditions of the Plan, you will receive the following Severance Benefits:

1. **Cash Severance Benefits**.

a. **Base Salary**. One hundred percent (100%) of your annual base salary (as in effect as of the date of your Non-CIC Involuntary Termination or, if your Non-CIC Involuntary Termination is pursuant to clause (iii) of the Good Reason definition, as in effect as of immediately prior to the reduction triggering your grounds for Good Reason) paid ratably over a period of twelve (12) months, beginning on the Severance Start Date.

b. ***[Applicable only to Participant who serves as CEO as of the Initial Adoption of the Plan:*** **Pro-Rated Bonus**. A lump sum payment equal to the annual target bonus you would otherwise be eligible to receive from the Employer for the fiscal year in which the Non-CIC Involuntary Termination occurs, assuming the achievement of all annual targets at one hundred percent (100%), pro-rated for the portion of such year during which you were employed by the Employer. Any such payment will be paid on the Severance Start Date. **]**

2. **In-Lieu of COBRA Benefit**. If, on the day immediately before the Non-CIC Involuntary Termination occurs, you and any Family Members have Qualifying Health Coverage, a lump sum payment in an aggregate amount equal to twelve (12) months of the Monthly COBRA Premium Amount. Any such payment will be paid on the Severance Start Date. Notwithstanding anything to the contrary in the Plan or this Participation Agreement, if at any time the Company determines in its sole discretion that the payments contemplated by this Paragraph II.2. of this Participation Agreement cannot be provided to you without violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), you will not receive such payment or any benefits or payments in lieu thereof.

III. CIC Involuntary Termination

If, during the Change in Control Period, you incur a CIC Involuntary Termination, then subject to the terms and conditions of the Plan, you will receive the following Severance Benefits:

1. **Cash Severance Benefits**.

a. **Base Salary**. Two hundred percent (200%) of your annual base salary (as in effect immediately prior to your CIC Involuntary Termination or, if your Non-CIC Involuntary Termination is pursuant to clause (iii) of the Good Reason definition, as in effect as of immediately prior to the reduction triggering your grounds for Good Reason), paid ratably over a period of twenty-four (24) months, in accordance with the Employer's normal payroll policies and practices. The severance payments pursuant to the prior sentence shall commence on the Severance Start Date.

a. **Target Bonus**. A lump sum payment equal to two hundred percent (200%) of the annual target bonus you would otherwise be eligible to receive from the Employer for the fiscal year in which the CIC Involuntary Termination occurs, assuming the achievement of all annual targets at one hundred percent (100%). Any such payment will be paid on the Severance Start Date.

2. **In-Lieu of COBRA Benefit**. If, on the day immediately before the CIC Involuntary Termination occurs, you and any Family Members have Qualifying Health Coverage, a lump sum payment in an aggregate amount equal to twenty-four (24) months of the Monthly COBRA Premium Amount. Any such payment will be paid on the Severance Start Date. Notwithstanding anything to the contrary in the Plan or this Participation Agreement, if at any time the Company determines in its sole discretion that the payments contemplated by this Paragraph III.2. of this Participation Agreement cannot be provided to you without violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), you will not receive such payment or any benefits or payments in lieu thereof.

3. **Time-Based Equity Award Vesting Acceleration**. One hundred percent (100%) of your then outstanding and unvested Time-Based Equity Awards automatically will become vested in full and, if applicable, exercisable (each, an "**Accelerated Award**"). The period over which an Accelerated Award may be exercised, if applicable, will be governed by the applicable provisions of the Company's equity compensation plan under which such award had been granted and the related award agreement. Any Accelerated Awards that are restricted stock units, performance units or similar awards will be paid to you on the Release Deadline Date; the acceleration of an Accelerated Award that is a stock option or shares of restricted stock shall be effective immediately upon the timely effectiveness of the Release.

For the avoidance of doubt, no Company equity compensation award held by you that is outstanding as of the Effective Date and is subject to performance-based vesting will be subject to any "single trigger" or similar acceleration of vesting upon a Change in Control, change of control or similar event (but will vest upon achievement of the relevant performance metrics in connection with such event to the extent provided under the equity award's terms), and no such award will be subject to acceleration of vesting in connection with a termination of your employment upon or following a Change in Control, change of control or similar event, in each case, unless determined otherwise by the Board or the Compensation Committee of the Board following the date hereof; in the event any such performance-metrics have not been achieved in connection with the Change in Control, change of control or similar event, such performance-based equity awards will be treated in accordance with the terms of Section 9 of the 2015 Stock Incentive Plan.

In order to receive any Severance Benefits for which you otherwise become eligible under the Plan, you must sign and deliver to the Administrator the Release, as set forth therein, which must become effective and irrevocable within the requisite period set forth in the Release and is subject to the Release timing requirements specified in the Plan. Also, as set forth in the Plan, any benefits or payments for which you otherwise become eligible under the Plan will be reduced if necessary to avoid such benefits from becoming subject to "golden parachute" excise taxes under the Code.

Please note that the Employer will withhold from any Plan benefits or payments all applicable U.S. federal, state and local, and non-U.S. taxes required to be withheld and any other required payroll deductions. All Severance Benefits are subject to the terms and conditions of the Plan, including but not limited to Section 11 of the Plan.

By your signature below, you and the Company agree that your participation in the Plan is governed by this Participation Agreement and the provisions of the Plan. Your signature below confirms that: (1) you have received a copy of the Plan; (2) you have carefully read this Participation Agreement and the Plan, including, but not limited to, the terms and conditions of participation in, and receipt of any benefits or payments, under the Plan; (3) you agree that the decisions and determinations of the Administrator under the Plan (and its authorized delegates) will be final and binding on you and your successors, and will be given the maximum possible deference permitted by law; and (4) you agree that your participation in the Plan and this Participation Agreement replaces in its entirety any severance and/or change in control provisions set forth in any offer letter, employment agreement, severance and/or change in control agreement, or other agreement between you and the Company, including, but not limited to, your offer letter with the Company dated February 1, 2015, as amended.

DENALI THERAPEUTICS INC.	**PARTICIPANT**
Signature	Signature
Name	Printed Name
Title	Date

Attachment: Denali Therapeutics Inc. Key Executive Change in Control and Severance Plan

[Signature Page to the Participation Agreement]

C-Level Executives ***[To the extent designated for such benefit levels by the Administrator]***

Appendix A

Denali Therapeutics Inc. Key Executive Change in Control and Severance Plan [Amended and Restated] Participation Agreement

Denali Therapeutics Inc. (the "**Company**") is pleased to inform you that you are eligible to participate in the Denali Therapeutics Inc. Key Executive Change in Control and Severance Plan (the "**Plan**"). [This Amended and Restated Participation Agreement (this "**Participation Agreement**") replaces and supersedes in full all participation agreements under the Plan previously signed by you, including the participation agreement signed by you on [DATE].]

A copy of the Plan has been delivered to you with this Participation Agreement. Your participation in the Plan is subject to all of the terms and conditions of the Plan, including this Participation Agreement. The capitalized terms used but not defined herein will have the meanings ascribed to them in the Plan.

In order to actually become a Participant in the Plan, you must complete and sign this Participation Agreement, and return it to: [INSERT APPLICABLE INFO]. We ask that you do so as soon as practicable.

If you are a Participant, then subject to the terms and conditions of the Plan, you will receive the following benefits or payments under the Plan, as applicable:

[Applicable only to Participants who are C-Level Executives as of the Initial Adoption of the Plan: **I. Change in Control**

In the event of a Change in Control, the vesting schedule of any then-outstanding and unvested Grandfathered Awards held by you will be accelerated in part so that the number of shares, if any, subject to each such Grandfathered Award that would otherwise have first become vested in the period between the date of consummation of the Change in Control and the date on which all but the unvested shares subject to each such Grandfathered Award that would have vested in the final twelve (12) months of the vesting period will have first become vested will immediately become vested and exercisable, as applicable. The remaining number of shares subject to each such Grandfathered Award representing the last twelve (12) months of vesting will continue to be eligible to vest in accordance with the original vesting schedule within the next twelve (12) months set forth in the applicable award agreements for such awards, if any. By way of illustration, if, on the date of consummation of a Change in Control, you hold an unvested Grandfathered Award in the form of stock options that vest over a remaining period of thirty-six (36) months, then the shares subject to such stock option that would have vested over the next twenty-four (24) months will accelerate in full, and the shares subject to such stock option that would have vested over the remaining twelve (12) months would continue to vest from and after the Change in Control over the twelve (12) months following the Change in Control, subject to the provisions of Paragraph III.3. of this Participation Agreement. ***]***

II. Non-CIC Involuntary Termination

If, outside of the Change in Control Period, you incur a Non-CIC Involuntary Termination, then subject to the terms and conditions of the Plan, you will receive the following Severance Benefits:

1. **Cash Severance Benefits**.

a. **Base Salary**. Seventy five percent (75%) of your annual base salary (as in effect as of the date of your Non-CIC Involuntary Termination or, if your Non-CIC Involuntary Termination is pursuant to clause (iii) of the Good Reason definition, as in effect as of immediately prior to the base compensation reduction triggering your grounds for Good Reason) paid ratably over a period of nine (9) months beginning on the Severance Start Date, in accordance with the Employer's normal payroll policies and practices.

b. **[*Applicable only to Participants who are C-Level Executives as of the Initial Adoption of the Plan*: Pro-Rated Bonus**. A lump sum payment equal to the annual target bonus you would otherwise be eligible to receive from the Employer for the fiscal year in which the Non-CIC Involuntary Termination occurs, assuming the achievement of all annual targets at one hundred percent (100%), pro-rated for the portion of such year during which you were employed by the Employer. Any such payment will be made on the Severance Start Date.]

2. **In-Lieu of COBRA Benefit**. If, on the day immediately before your Non-CIC Involuntary Termination occurs, you and any Family Members have Qualifying Health Coverage, a lump sum payment in an aggregate amount equal to nine (9) months of the Monthly COBRA Premium Amount. Any such payment will be paid on the Severance Start Date. Notwithstanding anything to the contrary in the Plan or this Participation Agreement, if at any time the Company determines in its sole discretion that the payments contemplated by this Paragraph II.2. of this Participation Agreement cannot be provided to you without violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), you will not receive such payment or any benefits or payments in lieu thereof.

III. CIC Involuntary Termination

If, during the Change in Control Period, you incur a CIC Involuntary Termination, then subject to the terms and conditions of the Plan, you will receive the following Severance Benefits:

1. **Cash Severance Benefits**.

a. **Base Salary**. One hundred percent (100%) of your base salary (as in effect immediately prior to your CIC Involuntary Termination or, if your Non-CIC Involuntary Termination is pursuant to clause (iii) of the Good Reason definition, as in effect as of immediately prior to the base compensation reduction triggering your grounds for Good Reason), paid ratably over a period of twelve (12) months beginning on the Severance Start Date, in accordance with the Employer's normal payroll practices.

b. **Target Bonus**. A lump-sum payment equal to one hundred percent (100%) of the annual target bonus you would otherwise be eligible to receive from the Employer for the fiscal year in which your CIC Involuntary Termination occurs, assuming the achievement of all annual targets at one hundred percent (100%). Any such payment will be paid on the Severance Start Date.

2. **In-Lieu of COBRA Benefit**. If, on the day immediately before your CIC Involuntary Termination occurs, you and any Family Members have Qualifying Health Coverage, a lump sum payment in an aggregate amount equal to twelve (12) months of the Monthly COBRA Premium Amount. Any such payment will be paid on the Severance Start Date. Notwithstanding anything to the contrary in the Plan or this Participation Agreement, if at any time the Company determines in its sole discretion that the payments contemplated by this Paragraph III.2. of this Participation Agreement cannot be provided to you without violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), you will not receive such payment or any benefits or payments in lieu thereof.

3. **Time-Based Equity Award Vesting Acceleration**. One hundred percent (100%) of your then-outstanding and unvested Time-Based Equity Awards automatically will become vested in full and, if applicable, exercisable (each, an "**Accelerated Award**"). The period over which an Accelerated Award may be exercised, if applicable, will be governed by the applicable provisions of the Company's equity compensation plan under which such award had been granted and the related award agreement. Any Accelerated Awards that are restricted stock units, performance units or similar awards will be paid to you on the Release Deadline Date; the acceleration of an Accelerated Award that is a stock option or shares of restricted stock shall be effective immediately upon the timely effectiveness of the Release.

For the avoidance of doubt, no Company equity compensation award held by you that is outstanding as of the Effective Date and is subject to performance-based vesting will be subject to any "single trigger" or similar acceleration of vesting upon a Change in Control, change of control or similar event (but will vest upon achievement of the relevant performance metrics in connection with such event to the extent provided under the equity award's terms), and no such award will be subject to acceleration of vesting in connection with a termination of your employment upon or following a Change in Control, change of control or similar event, in each case, unless determined otherwise by the Board or the Compensation Committee of the Board following the date hereof; in the event any such performance-metrics have not been achieved in connection with the Change in Control, change of control or similar event, such performance-based equity awards will be treated in accordance with the terms of Section 9 of the 2015 Stock Incentive Plan.

In order to receive any Severance Benefits for which you otherwise become eligible under the Plan, you must sign and deliver to the Administrator the Release, as set forth therein, which must become effective and irrevocable within the requisite period set forth in the Release and is subject to the Release timing requirements specified in the Plan. Also, as set forth in the Plan, any benefits or payments for which you otherwise become eligible under the Plan will be reduced if necessary to avoid such benefits from becoming subject to "golden parachute" excise taxes under the Code.

Please note that the Employer will withhold from any Plan benefits or payments all applicable U.S. federal, state and local, and non-U.S. taxes required to be withheld and any other required payroll deductions. All Severance Benefits are subject to the terms and conditions of the Plan, including but not limited to Section 11 of the Plan.

By your signature below, you and the Company agree that your participation in the Plan is governed by this Participation Agreement and the provisions of the Plan. Your signature below confirms that: (1) you have received a copy of the Plan; (2) you have carefully read this Participation Agreement and the Plan; (3) you agree that the decisions and determinations of the Administrator under the Plan (and its authorized delegates) will be final and binding on you and your successors, and will be given the maximum possible deference permitted by law; and (4) you agree that your participation in the Plan and this Participation Agreement replaces in its entirety any severance and/or change in control provisions set forth in any offer letter, employment agreement, severance and/or change in control agreement, and/or other agreement between you and the Employer, including, but not limited to, your [_____].

DENALI THERAPEUTICS INC.	**PARTICIPANT**
Signature	Signature
Name	Printed Name
Title	Date

Attachment: Denali Therapeutics Inc. Key Executive Change in Control and Severance Plan

[Signature Page to the Participation Agreement]

VP Level Executives ***[To the extent designated for such benefit levels by the Administrator]***

Appendix A

Denali Therapeutics Inc. Key Executive Change in Control and Severance Plan [Amended and Restated] Participation Agreement

Denali Therapeutics Inc. (the "**Company**") is pleased to inform you that you are eligible to participate in the Company's Key Executive Change in Control and Severance Plan (the "**Plan**"). [This Amended and Restated Participation Agreement (this "**Participation Agreement**") replaces and supersedes in full all participation agreements under the Plan previously signed by you, including the participation agreement signed by you on [DATE].]

A copy of the Plan has been delivered to you with this Participation Agreement. Your participation in the Plan is subject to all of the terms and conditions of the Plan, including this Participation Agreement. The capitalized terms used but not defined herein will have the meanings ascribed to them in the Plan.

In order to actually become a Participant in the Plan, you must complete and sign this Participation Agreement, and return it to: [INSERT APPLICABLE INFO]. We ask that you do so as soon as practicable.

I. Non-CIC Involuntary Termination

If, outside of the Change in Control Period, you incur a Non-CIC Involuntary Termination, then subject to the terms and conditions of the Plan, you will receive the following Severance Benefits:

1. **Cash Severance Benefits**. Fifty percent (50%) of your annual base salary (as in effect as of the date of your Non-CIC Involuntary Termination or, if your Non-CIC Involuntary Termination is pursuant to clause (iii) of the Good Reason definition, as in effect as of immediately prior to the base compensation reduction triggering your grounds for Good Reason) paid ratably over a period of six (6) months beginning on the Severance Start Date, in accordance with the Employer's normal payroll policies and practices.

2. **In-Lieu of COBRA Benefit**. If, on the day immediately before the Non-CIC Involuntary Termination occurs, you and any Family Members have Qualifying Health Coverage, a lump sum payment in an aggregate amount equal to six (6) months of the Monthly COBRA Premium Amount. Any such payment will be paid on the Severance Start Date. Notwithstanding anything to the contrary in the Plan or this Participation Agreement, if at any time the Company determines in its sole discretion that the payments contemplated by this Paragraph I.2. of this Participation Agreement cannot be provided to you without violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), you will not receive such payment or any benefits or payments in lieu thereof

II. CIC Involuntary Termination

If, during the Change in Control Period, you incur a CIC Involuntary Termination, then subject to the terms and conditions of the Plan, you will receive the following Severance Benefits:

1. **Cash Severance Benefits**.

a. **Base Salary**. Seventy five percent (75%) of your annual base salary (as in effect immediately prior to your CIC Involuntary Termination or, if your Non-CIC Involuntary Termination is pursuant to clause (iii) of the Good Reason definition, as in effect as of immediately prior to the base compensation reduction triggering your grounds for Good Reason), paid ratably over a period of nine (9) months beginning on the Severance Start Date, in accordance with the Employer's normal payroll policies and practices.

b. **Target Bonus**. A lump sum payment equal to one hundred percent (100%) of the annual target bonus you would otherwise be eligible to receive from the Employer for the fiscal year in which your CIC Involuntary Termination occurs, assuming the achievement of all annual targets at one hundred percent (100%). Any such payment will be paid on the Severance Start Date.

2. **In-Lieu of COBRA Benefit**. If, on the day immediately before your CIC Involuntary Termination occurs, you and any Family Members have Qualifying Health Coverage, a lump sum payment in an aggregate amount equal to nine (9) months of the Monthly COBRA Premium Amount. Any such payment will be paid on the Severance Start Date. Notwithstanding anything to the contrary in the Plan or this Participation Agreement, if at any time the Company determines in its sole discretion that the payments contemplated by this Paragraph II.2. of this Participation Agreement cannot be provided to you without violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), you will not receive such payment or any benefits or payments in lieu thereof.

3. **Time-Based Equity Award Vesting Acceleration**. One hundred percent (100%) of your then-outstanding and unvested Time-Based Equity Awards automatically will become vested in full and, if applicable, exercisable (each, an "**Accelerated Award**"). The period over which an Accelerated Award may be exercised, if applicable, will be governed by the applicable provisions of the Company's equity compensation plan under which such award had been granted and the related award agreement. (For the avoidance of doubt, no outstanding Company equity compensation award held by you that is subject to performance-based vesting will be accelerated, other than as provided in the related award agreement or plan under which the award was granted.) Any Accelerated Awards that are restricted stock units, performance units or similar awards will be paid to you on the Release Deadline Date; the acceleration of an Accelerated Award that is a stock option or shares of restricted stock shall be effective immediately upon the timely effectiveness of the Release.

In order to receive any Severance Benefits for which you otherwise become eligible under the Plan, you must sign and deliver to the Administrator the Release, as set forth therein, which must become effective and irrevocable within the requisite period set forth in the Release and is subject to the Release timing requirements specified in the Plan. Also, as set forth in the Plan, any benefits or payments for which you otherwise become eligible under the Plan will be reduced if necessary to avoid such benefits from becoming subject to "golden parachute" excise taxes under the Code.

Please note that the Employer will withhold from any Plan benefits or payments all applicable U.S. federal, state and local, and non-U.S. taxes required to be withheld and any other required payroll deductions. All Severance Benefits are subject to the terms and conditions of the Plan, including but not limited to Section 11 of the Plan.

By your signature below, you and the Company agree that your participation in the Plan is governed by this Participation Agreement and the provisions of the Plan. Your signature below confirms that: (1) you have received a copy of the Plan; (2) you have carefully read this Participation Agreement and the Plan; (3) you agree that the decisions and determinations of the Administrator under the Plan (and its authorized delegates) will be final and binding on you and your successors, and will be given the maximum possible deference permitted by law; and (4) you agree that your participation in the Plan and this Participation Agreement replaces in its entirety any severance and/or change in control provisions set forth in any offer letter, employment agreement, severance and/or change in control agreement, and/or other agreement between you and the Employer.

[Signature page follows.]

DENALI THERAPEUTICS INC.	**PARTICIPANT**
Signature	Signature
Name	Printed Name
Title	Date

Attachment: Denali Therapeutics Inc. Key Executive Change in Control and Severance Plan

[Signature Page to the Participation Agreement]

Exhibit 31.1

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ryan J. Watts, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Denali Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 5, 2020

/s/ Ryan J. Watts
Ryan J. Watts, Ph.D.
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Steve E. Krognes, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Denali Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 5, 2020

/s/ Steve E. Krognes

Steve E. Krognes
Chief Financial Officer and Treasurer

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, Ryan J. Watts, Ph.D., President and Chief Executive Officer of Denali Therapeutics Inc. (the "Company"), hereby certify that:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2020, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 5, 2020

By:	/s/ Ryan J. Watts
Name:	Ryan J. Watts, Ph.D.
Title:	President and Chief Executive Officer

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, Steve E. Krognes, Chief Financial Officer and Treasurer of Denali Therapeutics Inc. (the "Company"), hereby certify that:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2020, to which this Certification is attached as Exhibit 32.2 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 5, 2020

By: /s/ Steve E. Krognes
Name: Steve E. Krognes
Title: Chief Financial Officer and Treasurer