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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 June 30, 2026
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) 866-8547
(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 July 31, 2026 was 159,847,403. This number does not include 28,331,779 shares of common stock issuable upon the exercise of pre-funded warrants outstanding as of July 31, 2026 (which are immediately exercisable at an exercise price of $0.01 per share of common stock, subject to beneficial ownership limitations). See Note 11 — Common Stock to the registrant's condensed consolidated financial statements.

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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)

	June 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 201,530	$ 205,326
Short-term marketable securities	508,941	662,553
Accounts receivable, net	3,927	—
Inventory	4,139	—
Prepaid expenses and other current assets	35,390	32,779
Total current assets	753,927	900,658
Long-term marketable securities	229,534	98,322
Property and equipment, net	49,926	52,402
Finance lease right-of-use asset	46,700	48,531
Operating lease right-of-use asset	16,793	19,002
Intangible asset, net	35,250	—
Other non-current assets	25,825	25,939
Total assets	$ 1,157,955	$ 1,144,854
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 11,807	$ 505
Other accrued costs and current liabilities	78,276	97,846
Total current liabilities	90,083	98,351
Operating lease liability, less current portion	22,026	27,210
Finance lease liability, less current portion	5,479	5,532
Liability related to the revenue participation right agreement	205,189	—
Total liabilities	322,777	131,093
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Convertible preferred stock, $0.01 par value; 40,000,000 shares authorized as of June 30, 2026 and December 31, 2025; 0 shares issued and outstanding as of June 30, 2026 and December 31, 2025	—	—
Common stock, $0.01 par value; 400,000,000 shares authorized as of June 30, 2026 and December 31, 2025; 159,755,526 shares and 156,182,177 shares issued and outstanding as of June 30, 2026 and December 31, 2025, respectively	1,924	1,888
Additional paid-in capital	3,142,747	3,062,715
Accumulated other comprehensive income (loss)	(1,969)	682
Accumulated deficit	(2,307,524)	(2,051,524)
Total stockholders' equity	835,178	1,013,761
Total liabilities and stockholders' equity	$ 1,157,955	$ 1,144,854

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 June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Revenue:				
Product revenue, net	$ 3,604	$ —	$ 3,604	$ —
Total revenue	3,604	—	3,604	—
Operating expenses:				
Cost of goods sold	93	—	93	—
Research and development	97,019	102,696	200,865	218,923
Selling, general and administrative	36,283	32,267	69,794	61,620
Intangible asset amortization	750	—	750	—
Total operating expenses	134,145	134,963	271,502	280,543
Loss from operations	(130,541)	(134,963)	(267,898)	(280,543)
Interest and other income, net	2,988	10,844	11,898	23,454
Net loss	$ (127,553)	$ (124,119)	$ (256,000)	$ (257,089)
Other comprehensive loss:				
Net unrealized loss on marketable securities, net of tax	(1,287)	(1,098)	(2,651)	(1,081)
Comprehensive loss	$ (128,840)	$ (125,217)	$ (258,651)	$ (258,170)
Net loss per share, basic and diluted	$ (0.68)	$ (0.72)	$ (1.37)	$ (1.50)
Weighted average number of shares outstanding, basic and diluted	187,314,501	171,449,847	186,977,612	171,336,568

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, 2025	156,182,177	$ 1,888	$ 3,062,715	$ 682	$ (2,051,524)	$ 1,013,761
Issuance of common stock, net of issuance cost of $45	746,468	8	12,358	—	—	12,366
Issuances under equity incentive plans	1,484,925	14	21,686	—	—	21,700
Vesting of restricted stock units	1,341,956	14	(14)	—	—	—
Stock-based compensation	—	—	46,002	—	—	46,002
Net loss	—	—	—	—	(256,000)	(256,000)
Other comprehensive loss	—	—	—	(2,651)	—	(2,651)
June 30, 2026	159,755,526	$ 1,924	$ 3,142,747	$ (1,969)	$ (2,307,524)	$ 835,178
Balance at March 31, 2026	158,656,318	$ 1,913	$ 3,104,838	$ (682)	$ (2,179,971)	$ 926,098
Issuances under equity incentive plans	948,205	9	14,996	—	—	15,005
Vesting of restricted stock units	151,003	2	(2)	—	—	—
Stock-based compensation	—	—	22,915	—	—	22,915
Net loss	—	—	—	—	(127,553)	(127,553)
Other comprehensive loss	—	—	—	(1,287)	—	(1,287)
June 30, 2026	159,755,526	$ 1,924	$ 3,142,747	$ (1,969)	$ (2,307,524)	$ 835,178
Balance at December 31, 2024	144,220,986	$ 1,768	$ 2,764,880	$ 2,020	$ (1,538,984)	$ 1,229,684
Issuances under equity incentive plans	455,335	5	4,647	—	—	4,652
Vesting of restricted stock units	1,009,121	10	(10)	—	—	—
Stock-based compensation	—	—	50,887	—	—	50,887
Net loss	—	—	—	—	(257,089)	(257,089)
Other comprehensive loss	—	—	—	(1,081)	—	(1,081)
Balance at June 30, 2025	145,685,442	$ 1,783	$ 2,820,404	$ 939	$ (1,796,073)	$ 1,027,053
Balance at March 31, 2025	145,251,258	$ 1,778	$ 2,790,825	$ 2,037	$ (1,671,954)	$ 1,122,686
Issuances under equity incentive plans	341,543	4	4,053	—	—	4,057
Vesting of restricted stock units	92,641	1	(1)	—	—	—
Stock-based compensation	—	—	25,527	—	—	25,527
Net loss	—	—	—	—	(124,119)	(124,119)
Other comprehensive loss	—	—	—	(1,098)	—	(1,098)
Balance at June 30, 2025	145,685,442	$ 1,783	$ 2,820,404	$ 939	$ (1,796,073)	$ 1,027,053

See accompanying notes to unaudited condensed consolidated financial statements.

Denali Therapeutics Inc.

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

	Six Months Ended June 30,	
	2026	**2025**
Operating activities		
Net loss	$ (256,000)	$ (257,089)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	6,414	5,370
Stock–based compensation expense	46,002	50,547
Net accretion of discounts on marketable securities	(2,704)	(6,585)
Non-cash adjustment to operating lease expense	(2,353)	(2,161)
Right-of-use asset amortization for finance lease	1,831	1,798
Non-cash interest expense related to revenue participation right liability	5,941	—
Other non-cash items	(223)	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(3,927)	—
Inventory	(4,139)	—
Prepaid expenses and other current assets	(2,613)	(3,650)
Other non-current assets	(304)	3,022
Accounts payable	4,102	(43)
Accruals and other current liabilities	(19,107)	(14,151)
Deferred research and development funding liability	(1,126)	16,176
Net cash used in operating activities	(228,206)	(206,766)
Investing activities		
Purchases of marketable securities	(394,579)	(137,926)
Maturities and sales of marketable securities	417,032	323,965
Purchases of property and equipment	(3,271)	(9,356)
Cash paid to acquire finite-lived intangible asset	(28,800)	—
Net cash provided by (used in) investing activities	(9,618)	176,683
Financing activities		
Proceeds from underwriter exercising option to purchase common stock, net of issuance costs	12,366	—
Proceeds from sale of revenue participation right	200,000	—
Proceeds from exercise of awards under equity incentive plans	21,700	4,652
Payments for finance lease right-of-use asset	(38)	(6,791)
Net cash provided by (used in) financing activities	234,028	(2,139)
Net decrease in cash, cash equivalents and restricted cash	(3,796)	(32,222)
Cash, cash equivalents and restricted cash at beginning of period	208,432	176,535
Cash, cash equivalents and restricted cash at end of period	$ 204,636	$ 144,313
Supplemental disclosures of cash flow information		
Payment due on intangible asset acquired	$ 7,200	$ —

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 and lysosomal storage 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 the Securities and Exchange Commission ("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, 2025, as filed with the SEC on February 26, 2026 (the "2025 Annual Report on Form 10-K"). The Condensed Consolidated Balance Sheet as of December 31, 2025 was derived from the audited annual consolidated financial statements as of and for 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, if any, 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 six months ended June 30, 2026 the Company added significant accounting policies related to product revenue, accounts receivable, inventory, cost of goods sold, intangible assets and the liability related to the revenue participation right. Aside from these new accounting policies, there were no material changes to the Company's significant accounting and financial reporting policies from those reflected in the 2025 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 2025 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 subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. For the Company and its subsidiaries, 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, and transactions in foreign currencies are remeasured at average exchange rates. Foreign currency 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 assets and 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 Condensed Consolidated 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 accounts receivable. 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 and its agencies, as well as 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 June 30, 2026 and December 31, 2025, the Company had no off-balance sheet concentrations of credit risk.

The Company's accounts receivable are primarily related to product sales. For the three and six months ended June 30, 2026, one customer accounted for all product revenues. As of June 30, 2026, one customer accounted for all accounts receivable related to product sales. The Company monitors the creditworthiness of its customers and collaboration partners and has not experienced significant credit losses to date.

The Company is subject to a number of risks similar to other early commercial-stage biopharmaceutical companies, including, but not limited to, the risk that its approved product, AVLAYAH™ (tividenofusp alfa-eknm), may not achieve expected levels of market acceptance or commercial success; the need to obtain adequate additional funding to continue as a going concern; its history of significant losses and expectation of continued losses; possible failure or delay of current or future preclinical testing or clinical trials; its reliance on third parties to conduct its clinical trials, manufacture product, and support commercialization; the need to successfully develop, commercialize, and gain market acceptance of its product candidates; competitors developing new technological innovations; its rights to develop and commercialize its product candidates pursuant to the terms and conditions of licenses granted to the Company; protection of proprietary technology; the ability to make milestone, royalty or other payments due under license or collaboration agreements; the need to enforce its intellectual property rights; and the need to scale internal manufacturing and/or secure and maintain adequate manufacturing arrangements with third parties. If the Company does not successfully commercialize AVLAYAH or its other product candidates, it may be unable to generate sufficient product revenue or achieve profitability. Further, the Company is also subject to broad market risks and uncertainties, such as bank failures or instability in the financial services sector, geopolitical instability, war and armed conflicts, inflation, rising interest rates, and recession risks, as well as supply chain and labor shortages.

Investments

The Company holds an equity investment in a venture-backed privately held company. The privately held company is a Variable Interest Entity ("VIE"), but the Company is not the primary beneficiary. The Company does not have the power to direct the activities that most significantly impact the economic performance of the investee. The Company's maximum exposure to loss from this VIE is limited to the value of the equity investment. The equity investment held by the Company lacks a readily determinable fair value and therefore the securities are measured at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or similar equity securities of the same issuer. The Company reviews the carrying value of its equity investment for impairment whenever events or changes in business circumstances indicate the carrying amount of such asset may not be fully recoverable. Impairments, if any, are based on the excess of the carrying amount over the recoverable amount of the asset. There were no impairments during the six months ended June 30, 2026 and 2025.

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.

Cash, cash equivalents, and restricted cash reported within the Condensed Consolidated Statements of Cash Flows is composed of cash and cash equivalents reported in the Condensed Consolidated Balance Sheets and restricted cash of $3.1 million as of June 30, 2026 and December 31, 2025, which is included within other non-current assets in the Condensed Consolidated Balance Sheets. Restricted cash relates to letters of credit supporting the Company's headquarters building lease and a letter of credit supporting the Company's credit card program.

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 are 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, unless intended to fund current operations. 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 represents amounts arising from product sales and is recorded net of allowances for credit losses, if required. The Company estimates an allowance for credit losses by considering factors such as credit quality, the age of the accounts receivable balances, and current economic conditions that may affect a customer's ability to pay. The Company's payment terms are generally less than 90 days from the invoice date. The Company evaluates the creditworthiness of each counterparty on a regular basis. As of June 30, 2026, the credit profile of the customer was deemed to be in good standing and, as such, an allowance for credit losses was not recorded.

Revenue Recognition

The Company recognizes product revenue in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC"), Topic 606, Revenue from Contracts with Customers ("ASC 606").

In March 2026, the U.S. Food and Drug Administration granted accelerated approval of AVLAYAH™ (tividenofusp alfa-eknm), and the Company commenced commercial sales in the United States during the three months ended June 30, 2026. AVLAYAH is the Company's only commercial product, and all product revenue to date has been generated in the United States.

Under ASC 606, the Company is required to complete the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

The Company sells AVLAYAH to a single specialty distributor ("Distributor") in the US, which is the Company's sole customer, who delivers to (i) hospitals where patients are administered the medication in a healthcare setting and (ii) to a specialty pharmacy ("SP") provider where patients are administered by a healthcare professional in either a healthcare professional or home setting.

The Company's distribution agreements with the Distributor, together with each accepted purchase order, is accounted for as a contract with a single performance obligation — the delivery of AVLAYAH to the Distributor. Revenue is recognized when the Company satisfies a performance obligation by transferring control of the promised goods to the customer.

Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring AVLAYAH. The Company sells AVLAYAH at a Wholesale Acquisition Cost ("WAC") and records product revenue at the net selling price (the transaction price) — WAC reduced by variable consideration and by consideration payable to the Distributor and to other parties in the distribution channel that does not represent payment for a distinct good or service. The Company estimates variable consideration using the most-likely-amount method and includes it in the transaction price only to the extent it is probable that a significant reversal of cumulative revenue recognized will not occur when the related uncertainty is resolved. Estimates are reassessed each reporting period, with any change recognized in net product revenue in the period of change. The components of variable consideration are:

- *Distributor service fees* — fees payable to the Distributor for distribution. These services are not distinct from the sale of AVLAYAH and the related fees, calculated as a contractual percentage of the WAC of product sold, are recorded as a reduction of product revenue when the related sales are recognized.

- *Government rebates* — amounts owed under the Medicaid Drug Rebate Program and supplemental state Medicaid agreements, refunds under the Medicare Part B discarded-drug provisions, and rebates to the U.S. Department of Veterans Affairs and the Department of Defense (including under the TRICARE program). The Company estimates these amounts using statutory and contractual rebate

rates and probability-weighted assumptions for the expected payer and channel mix, recorded as a reduction of product revenue with a corresponding current liability.

• *Product returns* — the product may be returned only in the limited circumstances specified in the distribution agreement, principally product that is damaged or within a defined period of its expiration date. The Company records a reserve for estimated returns as a reduction of product revenue with a corresponding refund liability.

• *Other fees and incentives* — amounts payable to a specialty pharmacy that dispenses AVLAYAH purchased through the Distributor and co-pay assistance program for eligible patients with commercial insurance in the U.S. The co-pay assistance programs assist commercially insured patients and are intended to reduce each participating patient's portion of the financial responsibility of the purchase price up to a specified dollar amount of assistance. The Company records funds paid under co-pay assistance program for each patient as a reduction of revenue.

Variable consideration payable to the Distributor, and to parties against which the Distributor has a contractual right of off-set — Distributor service fees, third-party-logistics fees, and government chargebacks processed through the Distributor is presented as a reduction of accounts receivable. Variable consideration payable to parties other than the Distributor is presented within other accrued costs and current liabilities.

Inventory

Inventory is stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out ("FIFO") basis. Inventory costs consist primarily of raw materials, third-party contract manufacturing organization ("CMO") costs, and other direct production costs, including allocable overhead, related to our commercial product AVLAYAH. Inventory is valued using standard costing methodology, which approximates actual cost.

Prior to FDA approval, all costs incurred in connection with the manufacture of AVLAYAH were recorded as research and development expenses in the consolidated statements of operations in the period incurred. As of June 30, 2026, we had $12.6 million of expensed pre-launch inventory, which we expect to be sold through by January 2027.

The Company expenses costs associated with the manufacture of product candidates prior to regulatory approval. Inventory consists of the Company's currently approved product, including raw materials and work-in-process.

The Company began capitalizing inventory costs associated with AVLAYAH upon receiving U.S. Food and Drug Administration ("FDA") accelerated approval in March 2026, at which time the inventory was determined to have probable future economic benefit. Additionally, inventory used in research and development activities is expensed to research and development at the time of such designation.

The Company evaluates its inventory on a periodic basis for obsolescence, slow-moving, excess, or otherwise unsalable items, and records a write-down to net realizable value when the carrying value is in excess of net realizable value and there are no alternative future uses for the inventory, or if inventory quantities exceed expected future demand prior to expiration. If the Company determines an adjustment is required to the carrying value of inventory, those adjustments are recognized as Cost of Goods Sold in the Consolidated Statements of Operations and Comprehensive Loss.

Inventory that is not expected to be consumed beyond our normal operating cycle is classified as non-current inventory and included within other non-current assets in the balance sheet.

Cost of Goods Sold

Cost of Goods Sold consists primarily of direct and indirect costs related to the manufacture of AVLAYAH for commercial sale, including third-party manufacturing costs, raw material and component costs, packaging services, freight, and storage costs.

Prior to the FDA approval of AVLAYAH in March 2026, costs incurred for the manufacture of AVLAYAH were recorded as research and development expenses and therefore will not be included in cost of sales. As a result, the cost of goods sold related to AVLAYAH will initially reflect a lower average per unit cost of materials, as previously expensed inventory is utilized and sold to customers.

Intangible Assets

Milestone payments made to acquire or maintain rights to intellectual property associated with an approved product are capitalized when the related contingency is resolved and the payment becomes probable and payable. Amounts capitalized are recorded as intangible assets and generally amortized on a straight-line basis over the estimated useful life of the underlying intellectual property. The Company evaluates such intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

Leases

The Company leases real estate and certain equipment for use in its operations. A determination is made as to whether an arrangement is a lease at inception. The Company recognizes finance and operating lease right-of-use ("ROU") assets, and finance and operating lease liabilities based on the present value of the future minimum lease payments at the commencement date. The Company adjusts ROU assets as needed for any lease incentives it receives and for assets it purchases that are regarded as landlord-owned. 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.

The Company recognizes amortization of the ROU assets and interest on the lease liabilities for its finance lease. Finance lease ROU assets are amortized on a straight-line basis from the commencement date to the earlier of the end of the useful life of the ROU asset or the end of the lease term. Operating lease expense is recognized on a straight-line basis over the lease term.

Leases with an initial term of twelve 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 has leases with lease and non-lease components, which the Company has elected to account for as a single lease component.

Liability Related to the Revenue Participation Right

The Company accounts for the synthetic royalty funding agreement with Royalty Pharma Investments 2023 ICAV ("Royalty Pharma") pursuant to which Royalty Pharma agreed to provide up to $275.0 million in funding to the Company in exchange for a 9.25% royalty on worldwide net sales of AVLAYAH as a debt financing under ASC Topic 470, Debt (ASC 470). The $200.0 million of proceeds received in March 2026 are recorded as a liability on the Company's Condensed Consolidated Balance Sheets, net of transaction costs.

The liability will be amortized under the effective interest method based on the Company's estimates of future royalty payments to Royalty Pharma over the life of the agreement. The resulting non-cash interest expense is recognized in Interest and other income, net in the Condensed Consolidated Statements of Operations and Comprehensive Loss.

The liability related to the revenue participation right and related interest expense are based on current estimates of the amount and timing of projected royalty payments, which are based on estimates

of future AVLAYAH net sales. The Company periodically assesses the forecasted net sales and to the extent the amount or timing of estimated royalty payments are materially different than previous estimates, the Company will account for any such change by adjusting the liability related to the sale of future revenues and prospectively recognizing the related non-cash interest expense.

The Company classifies the portion of the liability related to the revenue participation right that is expected to be amortized or settled within twelve months of the reporting date as current, with the remainder classified as non-current. Classification is based on forecasted royalty payments and the related recognition of interest and principal under the effective interest method.

Comprehensive Loss

Comprehensive 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. The weighted-average common shares outstanding as of June 30, 2026 include the pre-funded warrants to purchase shares of common stock that were issued in connection with the February 2024 private placement and December 2025 public offering, as discussed further in Note 11.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued Accounting Standards Update No. 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40):* D*isaggregation of Income Statement Expenses*, which is intended to improve the disclosures of expenses by providing more detailed information about the types of expenses in commonly presented expense captions. The amendments in this update are effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The amendments can be applied either prospectively or retrospectively. The Company has not early adopted this update, and is currently evaluating the impact of this new standard on its consolidated financial statements and related disclosures.

2. Fair Value Measurements

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

	June 30, 2026			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 148,024	$ —	$ —	$ 148,024
Short-term marketable securities:				
U.S. government treasuries	408,829	—	—	408,829
Corporate debt securities	—	100,112	—	100,112
Long-term marketable securities:				
U.S. government treasuries	163,401	—	—	163,401
Corporate debt securities	—	66,133	—	66,133
Total	$ 720,254	$ 166,245	$ —	$ 886,499

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 149,874	$ —	$ —	$ 149,874
Commercial paper	—	24,899	—	24,899
Short-term marketable securities:				
U.S. government treasuries	600,084	—	—	600,084
Corporate debt securities	—	62,469	—	62,469
Long-term marketable securities:				
U.S. government treasuries	58,545	—	—	58,545
Corporate debt securities	—	39,777	—	39,777
Total	$ 808,503	$ 127,145	$ —	$ 935,648

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.

The Company has not transferred any assets or liabilities between the fair value measurement levels for the six months ended June 30, 2026 or for the year ended December 31, 2025.

3. Marketable Securities

All marketable securities were considered available-for-sale at June 30, 2026 and December 31, 2025. 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):

	June 30, 2026			
	Amortized Cost	Unrealized Holding Gains	Unrealized Holding Losses	Aggregate Fair Value
Short-term marketable securities:				
U.S. government treasuries	$ 409,364	$ 20	$ (555)	$ 408,829
Corporate debt securities	100,342	16	(246)	100,112
Total short-term marketable securities	509,706	36	(801)	508,941
Long-term marketable securities:				
U.S. government treasuries	164,059	—	(658)	163,401
Corporate debt securities	66,328	—	(195)	66,133
Total long-term marketable securities	230,387	—	(853)	229,534
Total	$ 740,093	$ 36	$ (1,654)	$ 738,475

	December 31, 2025			
	Amortized Cost	Unrealized Holding Gains	Unrealized Holding Losses	Aggregate Fair Value
Short-term marketable securities:				
U.S. government treasuries	$ 599,200	$ 893	$ (9)	$ 600,084
Corporate debt securities	62,407	71	(9)	62,469
Total short-term marketable securities	661,607	964	(18)	662,553
Long-term marketable securities:				
U.S. government treasuries	58,524	21	—	58,545
Corporate debt securities	39,710	69	(2)	39,777
Total long-term marketable securities	98,234	90	(2)	98,322
Total	$ 759,841	$ 1,054	$ (20)	$ 760,875

As of June 30, 2026 and December 31, 2025, some of the Company's marketable securities were in an unrealized loss position. The Company has not recognized an allowance for credit losses as of June 30, 2026 or December 31, 2025. 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, a majority of these marketable securities are held in U.S. government securities, and the remainder 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.

As of June 30, 2026, all of the Company's marketable securities have an effective maturity of less than two years.

4. Inventory

Inventory consisted of the following (in thousands):

	June 30, 2026	December 31, 2025
Raw materials	$ —	$ —
Work in process	4,139	—
Finished goods	—	—
Total inventory	$ 4,139	$ —

No adjustments to the carrying value of inventory were recorded during the three and six months ended June 30, 2026 and 2025, respectively. All inventory as of June 30, 2026 is classified as current.

5. Intangible Asset

In connection with the May 2018 acquisition of F-star Gamma Limited ("F-star Gamma") and related license arrangements, the Company is obligated to make contingent payments upon the achievement of specified preclinical, clinical, regulatory and commercial milestones. Additional information regarding these arrangements is included in Note 4, “Acquisition, License Agreement and Research and Development Funding Collaboration Agreement,” to the consolidated financial statements included in the Company’s 2025 Annual Report on Form 10-K.

In March 2026, following the U.S. Food and Drug Administration’s accelerated approval of AVLAYAH, a $36.0 million milestone payment became due under this arrangement. The amount was capitalized as an intangible asset and is amortized on a straight-line basis over its estimated useful life. The Company paid $28.8 million of the milestone payment during the three months ended June 30, 2026, and the remaining $7.2 million is included in accounts payable in the Condensed Consolidated Balance Sheet as of June 30, 2026.

The Company recognized amortization expense of $0.7 million for the three and six months ended June 30, 2026. As of June 30, 2026, the accumulated amortization expense was $0.7 million, and the carrying value of the intangible asset was $35.3 million.

Future annual amortization expense for the unamortized intangible assets is as follows (in thousands):

Years Ending December 31:	Amount
2026 (six months)	$ 1,500
2027	3,000
2028	3,000
2029	3,000
2030	3,000
Thereafter	21,750
Total	$ 35,250

In addition to the U.S. regulatory milestone described above, the Company may be required to make additional contingent consideration payments of up to $174.0 million, composed of $24.0 million due upon regulatory approval of AVLAYAH in the European Union, and up to $150.0 million in commercial contingent payments.

6. Research and Development Funding Collaboration Agreement

In January 2024, the Company entered into a Collaboration and Development Funding Agreement with an unrelated third party, which obligates the third party to provide up to $75.0 million of funding and collaborate with the Company to conduct a global Phase 2a study of DNL151 in patients with Parkinson's disease and confirmed pathogenic variants of LRRK2. This arrangement is further described in Note 4, " Acquisition, License Agreement and Research and Development Funding Collaboration Agreement", to the consolidated financial statements in the 2025 Annual Report on Form 10-K.

Under this arrangement, the Company received $12.5 million during the three months ended June 30, 2026, resulting in cumulative payments received of $62.5 million as of June 30, 2026. Payments received are recorded as a deferred research and development funding liability and recognized as an offset to research and development expenses as the underlying research and development costs are incurred. The Company recognized an offset to research and development expenses of $7.6 million and $3.8 million for the three months ended June 30, 2026 and 2025, respectively, and $13.6 million and $8.8 million for the six months ended June 30, 2026 and 2025, respectively, in the Condensed Consolidated Statements of Operations and Comprehensive Loss. The Company recorded current deferred research and development funding liabilities of $20.0 million and $21.1 million on the Condensed Consolidated Balance Sheets as of June 30, 2026 and December 31, 2025, respectively.

7. Collaboration Agreements

Biogen

In October 2020, the Company entered into a Definitive Collaboration and License Agreement ("LRRK2 Agreement"), pursuant to which it granted Biogen a license to co-develop and co-commercialize its small molecule LRRK2 inhibitor program (the "LRRK2 Program"), and a Right of First Negotiation, Option and License Agreement (the "ROFN and Option Agreement"), pursuant to which it granted an option and right of first negotiation to certain of the Company's programs utilizing our TransportVehicle™ ("TV") platform, including its amyloid beta program (collectively the "Biogen Collaboration Agreement"), with Biogen Inc.'s subsidiaries, Biogen MA Inc. ("BIMA") and Biogen International GmbH ("BIG") (BIMA and BIG, collectively, "Biogen"). The details of the Biogen Collaboration Agreement, the August 2023 amendment and July 2024 side letter to the ROFN and Option Agreement, and the payments the Company has received, and is entitled to receive, are further described in Note 5, "Collaboration Agreements", to the consolidated financial statements in the 2025 Annual Report on Form 10-K.

In May 2026, the Company and Biogen announced topline results from the Phase 2b LUMA study of BIIB122/DNL151 in individuals with early-stage Parkinson's disease. The LUMA study did not meet its primary or secondary endpoints. Based on these results, the Company and Biogen discontinued further development of BIIB122 in idiopathic Parkinson's disease. The Company continues to independently conduct the Phase 2a BEACON study evaluating the small molecule inhibitor in carriers of a pathogenic LRRK2 variant.

The Company has no remaining performance obligations under the Biogen Collaboration Agreement, and therefore no contract liability remained on the Condensed Consolidated Balance Sheets as of June 30, 2026 or December 31, 2025. As of June 30, 2026, the Company had not recorded milestone revenue or product sales under the 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"). The details of the Sanofi Collaboration Agreement, the February 2025 side letter, and the payments the Company has received, and is entitled to receive, are further described in Note 5, "Collaboration Agreements", to the consolidated financial statements in the Company's 2025 Annual Report on Form 10-K. The Company has no remaining performance obligations under the Sanofi Collaboration Agreement, and therefore no contract liability remains on the Condensed Consolidated Balance Sheets as of June 30, 2026 or December 31, 2025.

Under the Sanofi Collaboration Agreement, the Company is eligible to receive milestone payments totaling up to approximately $495.0 million upon achievement of certain clinical, regulatory and sales milestone events for Peripheral Products, and variable royalties on worldwide net sales. As of June 30, 2026, the Company had earned milestone payments of $100.0 million and had not recorded any product sales 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"). The details of the Takeda Collaboration Agreement are further described in Note 5, "Collaboration Agreements", to the consolidated financial statements in the Company's 2025 Annual Report on Form 10-K. There are no remaining performance obligations or potential payments remaining under the initial Takeda Option and Collaboration Agreement.

The opt-in by Takeda on the PTV:PGRN and ATV:TREM2 programs represented two new contracts with a customer for accounting purposes (the "PTV:PGRN Collaboration Agreement" and the "ATV:TREM2 Collaboration Agreement"), both of which became effective in December 2021. The February 2025 ATV:TREM2 discontinuation and the PTV:PGRN Collaboration Agreement are further described in Note 5, "Collaboration Agreements", to the consolidated financial statements in the Company's 2025 Annual Report on Form 10-K.

In April 2026, Takeda notified the Company of its decision to terminate the PTV:PGRN collaboration agreement in its entirety. As a result, the Company regained full rights to DNL593 and the related intellectual property portfolio. Subsequent to the effective date of the termination, there are no future milestones, cost, or profit sharing obligations related to this agreement. The Company did not recognize any revenue, gain, asset or other material accounting impact in connection with the termination, other than the final cost-sharing settlement. The final cost-sharing settlement related to the PTV:PGRN Collaboration Agreement is reflected in the cost sharing table below.

As of June 30, 2026, the Company had earned an aggregate of $10.0 million in option fee payments and $10.0 million in milestone payments from Takeda under the PTV:PGRN and ATV:TREM2 Collaboration Agreements, and had not recorded any product sales under either agreement.

Cost Sharing Payments and Reimbursements

Cost sharing payments to collaboration partners recorded as expenses in research and development expenses in the Condensed Consolidated Statements of Operations and Comprehensive Loss, and cost sharing reimbursements from collaboration partners recorded as an offset to expense in research and development expenses in the Condensed Consolidated Statements of Operations and Comprehensive Loss are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Takeda Collaboration Agreement:				
PTV:PGRN cost sharing (reimbursements)	$ (1,513)	$ (1,439)	$ (3,130)	$ (2,935)
ATV:TREM2 cost sharing (reimbursements)	—	(10)	—	(147)
Total Takeda cost sharing (reimbursements)[1]	(1,513)	(1,449)	(3,130)	(3,082)
Biogen Collaboration Agreement: LRRK2 cost sharing payments[2]	2,024	4,229	5,887	8,880
Net cost sharing payments (reimbursements)	$ 511	$ 2,780	$ 2,757	$ 5,798

(1) Cost sharing reimbursements of $1.5 million and $1.6 million were recorded as a receivable within prepaid expenses and other current assets on the Condensed Consolidated Balance Sheets as of June 30, 2026 and December 31, 2025, respectively.

(2) Cost sharing payments due to Biogen of $2.0 million and $2.8 million were recorded within other accrued costs and current liabilities on the Condensed Consolidated Balance Sheets as of June 30, 2026 and December 31, 2025, respectively.

8. Balance Sheet Components

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consists of the following (in thousands):

	As of	
	June 30, 2026	December 31, 2025
Accrued compensation	$ 13,424	$ 32,179
Accrued clinical and other research & development costs	19,871	22,283
Accrued manufacturing costs	10,659	5,336
Operating lease liability, current	10,084	9,463
Finance lease liability, current	97	83
Deferred research and development funding liability, current	19,975	21,101
Other accrued costs and current liabilities	4,166	7,401
Total accrued expenses and other current liabilities	$ 78,276	$ 97,846

9. Liability Related to the Revenue Participation Right

In December 2025, the Company entered into a synthetic royalty funding agreement (the “Royalty Agreement”) with Royalty Pharma. Pursuant to the Royalty Agreement, Royalty Pharma agreed to provide up to $275.0 million in funding to the Company in exchange for a 9.25% royalty on worldwide net sales of AVLAYAH ("Revenue Participation Right").

The Company received $200.0 million in gross proceeds in March 2026 triggered by the U.S. Food and Drug Administration’s accelerated approval of AVLAYAH. The Company is entitled to receive an additional $75.0 million upon approval of AVLAYAH by the European Medicines Agency ("EMA") on or before December 31, 2029. The Company retains all worldwide development and commercialization rights to AVLAYAH.

The royalty obligation to Royalty Pharma will cease upon cumulative royalty payments reaching a cap of 3.0 times the total funding received, or 2.5 times the funding received if such cap is reached in respect of sales that occur on or before the end of the first quarter of 2039.

The $200.0 million, net of transaction costs of approximately $0.4 million, is recorded as a non-current liability on the Company's Condensed Consolidated Balance Sheet as of June 30, 2026 based on the estimated timing of future royalty payments. The royalty payments to Royalty Pharma will be recorded as a reduction of the liability. The additional $75.0 million contingent upon EMA approval of AVLAYAH has not been recognized as a liability as of June 30, 2026, as the receipt is contingent upon a future regulatory event. Upon receipt, the additional proceeds will be recorded as an increase to the liability, net of any incremental transaction costs, and the effective interest rate will be adjusted prospectively.

As of June 30, 2026, the Company's estimate of total future royalty payments resulted in an effective annual interest rate of approximately 12% and recorded $5.9 million of non-cash interest expense during the three months ended June 30, 2026. No payments were made during the three and six months ended June 30, 2026.

As of June 30, 2026, the carrying value of the liability approximates its estimated fair value. The Company’s projections of future royalty payments are subject to estimation uncertainty and are based on various assumptions underlying projected net product sales over the term of the agreement. These inputs are considered to be Level 3 inputs in the fair value hierarchy, as they involve unobservable inputs and judgment. Changes in these assumptions could have a material impact on the effective interest rate.

10. Commitments and Contingencies

Lease Obligations

In May 2018, the Company entered into an operating lease for its corporate headquarters in South San Francisco (the "Headquarters Lease"), and in April 2023, the Company entered into a finance lease for its clinical manufacturing site in Salt Lake City (the "SLC Lease"). Both leases are further described in Note 7, "Commitments and Contingencies," to the consolidated financial statements in the Company's 2025 Annual Report on Form 10-K.

There were no changes to the terms of the leases recognized under ASC 842 during the three and six months ended June 30, 2026 or 2025.

The following table summarizes lease costs recognized for the periods presented (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Operating lease cost	$ 1,821	$ 1,893	$ 3,674	$ 3,786
Finance lease cost:				
Amortization of ROU assets	915	911	1,831	1,798
Interest	178	180	357	361
Variable lease cost	1,792	1,338	2,832	2,691
Total lease costs	$ 4,706	$ 4,322	$ 8,694	$ 8,636

Operating cash flows for operating leases were $3.0 million and $2.9 million for the three months ended June 30, 2026 and 2025, respectively, and $6.0 million and $5.8 million for the six months ended June 30, 2026 and 2025, respectively.

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

In the normal course of business, the Company enters into firm purchase commitments primarily related to supply of commercial product, certain research and development services, and clinical manufacturing activities. The Company had contractual obligations of $104.7 million as of June 30, 2026, of which $91.9 million related to supply of commercial product, and $44.3 million as of December 31, 2025.

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.

11. Common Stock

In December 2025, the Company entered into a public offering of 9,142,857 shares of the Company's common stock and Pre-Funded Warrants to purchase 2,285,714 shares of Common Stock. This public offering and the Pre-Funded Warrants are both further described in Note 8, "Common Stock," to the consolidated financial statements in the Company's 2025 Annual Report on Form 10-K. In January 2026, the underwriters of the Company's December 2025 public offering exercised their option to purchase an additional 746,468 shares of common stock, resulting in aggregate net proceeds to the Company of approximately $12.4 million.

As of June 30, 2026, 28,331,779 shares of pre-funded warrants remained outstanding, and no pre-funded warrants were exercised during the six months ended June 30, 2026. These warrants are classified as permanent equity because they are freestanding financial instruments that are immediately exercisable, do not embody an obligation for the Company to repurchase its shares and permit the holders to receive a fixed number of shares of common stock upon exercise.

12. Stock-Based Awards

The Company has issued stock-based awards from various equity incentive and stock purchase plans, as more fully described in Note 9, "Stock-Based Awards" to the consolidated financial statements in the Company's 2025 Annual Report on Form 10-K.

Stock Option Activity

The following table summarizes stock option activity for the six months ended June 30, 2026:

	Number of Options	Weighted-Average Exercise Price
Balance at December 31, 2025	21,326,333	$ 26.39
Granted	2,601,349	16.84
Exercised	(992,867)	15.81
Forfeited	(698,185)	21.15
Expired	(893,471)	34.89
Balance at June 30, 2026	21,343,159	$ 25.53
Vested and expected to vest at June 30, 2026	21,343,159	$ 25.53
Exercisable at June 30, 2026	14,065,727	$ 28.80

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

	Six Months Ended June 30,	
	2026	2025
Expected term (in years)	5.50 - 6.08	5.50 - 6.08
Volatility	61.7% - 66.7%	64.8% - 68.7%
Risk-free interest rate	3.7% - 4.3%	3.7% - 4.5%
Dividend yield	—	—

Restricted Stock Activity

The following table summarizes restricted stock unit ("RSU") activity for the six months ended June 30, 2026:

	Number of RSU shares	Weighted-Average Fair Value at Date of Grant per Share
Unvested at December 31, 2025	5,124,629	$ 21.74
Granted	3,385,121	16.52
Vested and released	(1,341,956)	23.92
Forfeited	(563,254)	19.84
Unvested and expected to vest at June 30, 2026	6,604,540	$ 18.78

Stock-Based Compensation Expense

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Research and development	$ 13,453	$ 15,188	$ 27,047	$ 30,325
General and administrative	9,462	10,199	18,955	20,222
Total	$ 22,915	$ 25,387	$ 46,002	$ 50,547

13. Net Loss Per Share

The following table sets forth the computation of basic and diluted net loss per share (in thousands, except share and per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Numerator:				
Net loss	$ (127,553)	$ (124,119)	$ (256,000)	$ (257,089)
Denominator:				
Weighted average number of:				
Common stock shares outstanding	158,982,722	145,403,782	158,645,833	145,290,503
Pre-funded warrants	28,331,779	26,046,065	28,331,779	26,046,065
Total	187,314,501	171,449,847	186,977,612	171,336,568
Net loss per share	$ (0.68)	$ (0.72)	$ (1.37)	$ (1.50)

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, including options issued and outstanding, Employee Stock Purchase Plan (“ESPP”) shares issuable, and restricted shares subject to future vesting that were not included in the diluted per share calculations for the periods presented because they would be anti-dilutive totaled approximately 28.5 million and 28.5 million shares as of June 30, 2026 and 2025, respectively.

14. Non-Marketable Equity Investment

In March 2024, the Company divested certain assets, including specified intellectual property, tangible assets, and equipment used to conduct early stage small molecule drug discovery ("Divested Assets") through an Asset Purchase and License Agreement (the "Asset Purchase Agreement") executed with Tenvie Therapeutics, Inc. ("Tenvie"). This arrangement is further described in Note 13, "Divestiture of Preclinical Small Molecule Programs", to the consolidated financial statements in the 2025 Annual Report on Form 10-K.

The Company recorded the investment in the shares of Series A Preferred Stock at $15.0 million which represents the fair value of the shares on the date of issuance. There have been no subsequent observable price changes in orderly transactions for the identical or similar equity securities of Tenvie, and as such, the measurement of this investment remains unchanged, with the $15.0 million included within other non-current assets in the Condensed Consolidated Balance Sheets as of both June 30, 2026 and December 31, 2025.

15. Segment Information

The Company has one operating segment with the goal to discover, develop and commercialize therapeutics (“Therapeutics”). There have been no material changes to the Company's segment structure, the basis of segmentation, or the measurement basis for segment profit or loss or segment assets, compared to those disclosed in Note 14, "Segment Information", to the consolidated financial statements in the Company's 2025 Annual Report on Form 10-K.

The following table presents selected financial information with respect to the Company’s single operating segment for the three and six months ended June 30, 2026 and 2025 (in thousands):

	Therapeutics Segment			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Product revenue, net	$ 3,604	$ —	$ 3,604	$ —
Less:				
Cost of goods sold	93	—	93	—
External research and development expenses - TV programs, including cost sharing	40,419	37,594	78,883	84,052
Other research and development expenses, including small molecule programs	16,494	24,847	40,048	54,347
Personnel related research and development expenses	40,106	40,255	81,934	80,524
Total research and development expenses	97,019	102,696	200,865	218,923
Personnel related selling, general and administrative expenses	22,921	20,115	45,485	38,853
Other selling, general and administrative expenses	13,362	12,152	24,309	22,767
Total selling, general and administrative expenses	36,283	32,267	69,794	61,620
Intangible asset amortization	$ 750	$ —	$ 750	$ —
Segment operating expenses	134,145	134,963	271,502	280,543
Segment loss from operations	(130,541)	(134,963)	(267,898)	(280,543)
Segment interest and other income, net	2,988	10,844	11,898	23,454
Segment net loss	$ (127,553)	$ (124,119)	$ (256,000)	$ (257,089)

There is no difference between the segment net loss and total consolidated net loss for the three and six months ended June 30, 2026 and 2025.

16. Subsequent Event

On June 12, 2026, the Company entered into an asset purchase agreement (the "PRV Transfer Agreement") pursuant to which the Company agreed to sell its Rare Pediatric Disease Priority Review Voucher ("PRV") for gross proceeds of $195.0 million in cash. The Company received the PRV in connection with the FDA accelerated approval of AVLAYAH in March 2026. On July 27, 2026, the Company completed the sale and received gross proceeds of $195.0 million pursuant to the terms of the PRV Transfer Agreement. No proceeds or gain from the sale were recognized in the condensed consolidated financial statements as of and for the three and six months ended June 30, 2026.

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 commercial success of AVLAYAH and any other products for which we obtain marketing approval;*
- *the progress, success, cost, and timing of our development activities, preclinical studies and clinical trials, and in particular the development of our blood-brain barrier ("BBB") platform technology, programs, and biomarkers, including the initiation and completion of studies or trials and related preparatory work, enrollment in such trials, the timing of when data from clinical trials will become available, the advancement of new molecule entities into clinical development and related timing, and the filing of investigational new drug applications or clinical trial applications;*
- *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;*
- *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 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 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 Transport Vehicle™ ("TV");*
- *our ability to obtain funding for our operations, including funding necessary to develop and commercialize our current and potential future product candidates;*
- *future agreements with third parties in connection with the commercialization of our product candidates;*

- *the size and growth potential of the markets for AVLAYAH and any other product candidates 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 ability to successfully conduct in-house manufacturing;*
- *the pricing and reimbursement of AVLAYAH and any other product candidates that receive approval;*
- *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;*
- *the impact of adverse economic conditions such as instability in the financial services sector, rising interest rates, rising inflation and increased labor market competition;*
- *the impact of increased geopolitical uncertainty and related global economic disruptions and social conditions on our business; and*
- *our financial performance.*

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

Key elements of our strategy include:

1) **Discover:** Invent a new class of barrier-crossing therapeutics by leveraging our TV platforms and deep expertise in blood-brain barrier ("BBB") biology to enhance the delivery of biotherapeutics to the brain and throughout the body.

2) **Develop:** Accelerate and expand a broad portfolio of TV-based product candidates to fully unlock the potential of barrier-crossing therapeutics, applying patient-informed development and driving biomarker-guided regulatory approvals.

3) **Deliver:** Launch initial products targeting rare lysosomal storage diseases as a strategic foundation for expansion into common neurodegenerative conditions and other serious diseases, while building integrated capabilities for long-term growth and profitability.

Commercial Product: AVLAYAH™

We currently have one approved product. Our commercial product, AVLAYAH™ (tividenofusp alfa-eknm) received accelerated approval from the U.S. Food and Drug Administration ("FDA") on March 24, 2026 and is approved for the treatment of neurologic manifestations in patients with Hunter syndrome or mucopolysaccharidoses II (MPS II) when initiated in presymptomatic or symptomatic pediatric patients weighing at least 5 kg prior to advanced neurologic impairment. AVLAYAH's accelerated approval was based on a surrogate endpoint (reduction in CSF HS), and continued approval is contingent upon confirmation of clinical benefit in the ongoing global Phase 2/3 COMPASS trial, as further described under "Clinical-Stage Programs" below.

We began commercial distribution of AVLAYAH in April 2026. Since launch, our commercial activities have focused on executing our commercialization strategy, including supporting product availability through market access, specialty distribution and patient support services.

In connection with the approval of AVLAYAH, the FDA granted us a Rare Pediatric Disease Priority Review Voucher ("PRV"). In June 2026, we entered into an agreement to sell the PRV for gross proceeds of $195.0 million. The transaction closed and proceeds were received in July 2026.

Clinical-Stage Programs

- Tividenofusp alfa-eknm (ETV:IDS), is an ETV-enabled enzyme replacement therapy designed to systemically deliver iduronate 2-sulfatase (IDS) throughout the body, including the brain for the treatment of neurologic manifestations of Hunter syndrome (MPS II). The ongoing global Phase 2/3 COMPASS study is intended to support generation of confirmatory evidence, expansion of the U.S. label to adult patients and future global regulatory submissions;

- Zafinofusp alfa (DNL126; ETV:SGSH) is an investigational ETV-enabled enzyme replacement therapy designed to systemically deliver N-sulfoglucosamine sulfohydrolase (SGSH) throughout the body, including the brain, for the treatment of Sanfilippo syndrome type A (MPS IIIA);

- DNL593 (PTV:PGRN) is an investigational Protein TransportVehicle (PTV)-enabled protein replacement therapy designed to systemically deliver progranulin (PGRN) across the blood-brain barrier for the treatment of granulin (*GRN*)-related frontotemporal dementia (FTD-*GRN*);

- DNL952 (ETV:GAA) is an investigational ETV-enabled enzyme replacement therapy designed to systemically deliver acid alpha-glucosidase (GAA) to muscle tissue and the brain by crossing the blood-brain barrier for the treatment of Pompe disease;

- DNL628 (OTV:MAPT) is an investigational Oligonucleotide TransportVehicle (OTV)-enabled antisense oligonucleotide designed for systemic delivery across the blood-brain barrier to reduce tau by targeting the *MAPT* gene for the treatment of Alzheimer's disease ("AD");

- DNL921 (ATV:Abeta) is an investigational Antibody TransportVehicle (ATV)-enabled antibody designed for systemic delivery across the blood-brain barrier to target amyloid plaques for the treatment of Alzheimer's disease. In the first half of 2026, we submitted a clinical trial application ("CTA") to initiate a Phase 1/1b study of DNL921;

- DNL151 is an investigational small molecule inhibitor of leucine-rich repeat kinase 2 (LRRK2) for the treatment of Parkinson's disease. Denali conducts the Phase 2a BEACON study evaluating DNL151 in individuals with Parkinson's disease who are confirmed by genetic testing to be carriers of a pathogenic LRRK2 variant; and

- Eclitasertib (SAR443122/DNL758), a peripheral and non-central nervous system ("CNS") penetrant small molecule RIPK1 inhibitor, is being developed by Sanofi to address peripheral inflammatory diseases such as ulcerative colitis ("UC").

The following table summarizes key information about our ongoing clinical studies for our approved product and clinical-stage programs:

Program	Product Candidate	Clinical Study(ies)	Indication	Operational Control
ETV:IDS	tividenofusp alfa	Ph 1/2 Ph 2/3	Hunter syndrome (MPS II)	Denali
ETV:SGSH	zafinofusp alfa	Ph 1/2	Sanfilippo syndrome Type A (MPS IIIA)	Denali
PTV:PGRN	DNL593	Ph 1/2	FTD-GRN	Denali
ETV:GAA	DNL952	Ph 1	Pompe disease	Denali
OTV:MAPT	DNL628	Ph 1b	Alzheimer’s disease	Denali
ATV: Abeta	DNL 921	Ph 1/1b	Alzheimer’s disease	Denali
LRRK2	DNL151	Ph 2a	Parkinson's disease	Denali
RIPK1 (Peripheral)	eclitasertib, or SAR443122/DNL758	Ph 2	UC	Sanofi

Since we commenced operations, we have devoted substantially all of our resources to discovering, acquiring and developing product candidates, building our TV platform, assembling our core capabilities in understanding key neurodegenerative and lysosomal storage disease pathways, operationalizing clinical trials, building manufacturing capabilities and establishing commercial capabilities.

Key operational and financing milestones in 2026 to date include:

- In January 2026, we announced that the FDA has lifted the clinical hold on the IND application for DNL952 (ETV:GAA), and we are enrolling the Phase 1 study;

- In January 2026, we announced that the CTA for DNL628 (OTV:MAPT) to initiate a Phase 1b study in Alzheimer’s disease was approved. In March 2026, the first patient was dosed in the Phase 1b study of DNL628;

- In February 2026, we presented preliminary open-label Phase 1/2 data for our zafinofusp alfa study at the 2026 WORLDSymposium demonstrating that treatment with zafinofusp alfa resulted in substantial reductions in both cerebrospinal fluid (CSF) and urine heparan sulfate (HS), including normalization of CSF HS, with a safety profile generally consistent with established enzyme replacement therapies;

- In March 2026, we announced the FDA granted accelerated approval for AVLAYAH, the first FDA-approved biologic specifically designed to cross the blood-brain barrier and reach the whole body, including the brain. We began commercial distribution of AVLAYAH in April 2026. In connection with the approval of AVLAYAH, the FDA granted us a Rare Pediatric Disease PRV;

- In March 2026, we received $200.0 million in gross proceeds in connection with the closing of the synthetic royalty funding agreement with Royalty Pharma Investments 2023 ICAV ("Royalty Pharma");

- In April 2026, we received notification from Takeda of its decision to terminate the collaboration agreement to co-develop and co-commercialize DNL593 (PTV:PGRN) for FTD-*GRN*. The termination became effective in June 2026, at which time all rights in the DNL593 program reverted to Denali. Takeda's decision to terminate the collaboration agreement for DNL593 was driven by strategic considerations and not related to efficacy or safety data. We continue to conduct the Phase 1/2 study of DNL593 for FTD-*GRN*;

- In May 2026, we and Biogen announced topline results from the Phase 2b LUMA study of BIIB122/DNL151 in individuals with early-stage Parkinson's disease. The LUMA study did not meet its primary or secondary endpoints, and we and Biogen decided to discontinue further development of BIIB122/DNL151 in idiopathic Parkinson's disease. We continue to independently conduct the Phase 2a BEACON study evaluating DNL151 in individuals with Parkinson's disease who carry a pathogenic LRRK2 variant;

- In June 2026, we entered into a definitive agreement to sell our Rare Pediatric Disease Priority Review Voucher for gross proceeds of $195.0 million. The transaction closed and proceeds were received in July 2026; and

- In the first half of 2026, we submitted a clinical trial application to initiate a Phase 1/1b study of DNL921 (ATV:Abeta) in healthy volunteers and participants with Alzheimer's disease, and we are conducting the study;

Until March 2026, we had no clinical products approved for commercial sale and thus had not generated any revenue from product candidates that are or were under development. Subsequent to receiving FDA approval for AVLAYAH, we began commercial distribution in April 2026. We expect it to take time to generate sufficient revenue to offset our expenses, and we can provide no assurance as to when, if ever, this will occur. Through June 30, 2026, we have funded our operations primarily from the issuance and sale of convertible preferred stock, the sale of common stock and pre-funded warrants to purchase shares of our common stock in public offerings and private placements, and payments received from our collaboration, synthetic royalty and other funding agreements with Takeda, Sanofi, Biogen, Royalty Pharma and other third parties.

We have incurred significant operating losses to date and expect to continue to incur operating losses for the foreseeable future. We had net losses of $127.6 million and $256.0 million for the three and six months ended June 30, 2026, respectively, and $124.1 million and $257.1 for the three and six months ended June 30, 2025, respectively. As of June 30, 2026, we had an accumulated deficit of $2.31 billion. Our ability to generate product revenue will depend on the successful development and eventual commercialization of one or more of our product candidates. We expect to continue to incur significant expenses and operating losses as we advance our approved product AVLAYAH to full US and broader global approval; advance our current clinical stage programs through healthy volunteer and patient trials; broaden and improve our TV platform; acquire, discover, validate and develop additional product candidates; obtain, maintain, protect and enforce our intellectual property portfolio; and hire additional personnel.

Through 2024, we relied entirely on third-party contract manufacturers to manufacture and supply our preclinical and clinical materials to be used during the development of our product candidates through 2024. In early 2025, we opened our clinical biomanufacturing facility in Salt Lake City, Utah, expanding U.S. manufacturing capabilities and strengthening supply chain control and operational efficiency. Going forward, we plan to use both our SLC facility and third-party contract manufacturers to supply our preclinical and clinical materials. We currently use third-party contract manufacturers to supply commercial product of AVLAYAH, and expect to continue to do so for the foreseeable future.

Components of Operating Results

Product Revenue

Following FDA approval of AVLAYAH in March 2026, we commenced commercial distribution in the United States during the second quarter of 2026. Product revenue consists of sales of AVLAYAH, our only commercial product, and is recognized at the net selling price. Product revenue is reduced by estimates of variable consideration, including distributor service fees, government rebates, product returns and other fees and incentives. Product revenue may fluctuate based on patient demand, reimbursement, payer mix and distributor ordering patterns.

Operating Expenses

Cost of Goods Sold

Cost of goods sold consists primarily of direct and indirect costs related to the manufacture of AVLAYAH for commercial distribution, including third-party manufacturing costs, raw material and component costs, packaging services, freight, and storage costs.

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 TV platform 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 external expenses incurred by us relating to our Takeda 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 also incur personnel and other operating expenses for our research and development programs which are presented in aggregate. These expenses primarily relate to salaries and benefits, stock-based compensation, facility expenses including rent and depreciation, and lab consumables. Where we share costs with our collaboration partners, such as in our Biogen Collaboration Agreement and Takeda Collaboration Agreement, research and development expenses may include cost sharing reimbursements from, or payments to, our collaboration partners. Further, where we receive R&D funding from third parties, this may be recognized as a reduction to research and development expenses.

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 increased geopolitical uncertainty. 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 and commercial, sales and marketing 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.

Selling, General and Administrative

Selling, general and administrative expenses include personnel related expenses, such as salaries, benefits, travel and stock-based compensation expense, expenses for outside professional services, commercialization activities, and allocated expenses. Outside professional services consist of legal, accounting and audit services and other consulting fees, including those associated with our commercial organization. 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 have increased our headcount to support the commercialization of AVLAYAH and may continue to increase headcount to support our commercial and research and development activities, which we expect will increase selling, general and administrative expenses.

Intangible Asset Amortization

Intangible asset amortization consists of amortization of our intangible asset, which represents the developed technology recognized in connection with the FDA approval of AVLAYAH in March 2026. We amortize this asset on a straight-line basis over its estimated useful life. We began recognizing intangible asset amortization in the second quarter of 2026 and did not record any such expense prior to that period.

Interest and Other Income, Net

Interest and other income, net, consists primarily of interest income, investment income earned on our cash, cash equivalents and marketable securities, and sublease income, as well as an offset for non-cash interest expense related to the revenue participation right liability and interest expense on our finance lease liability.

Results of Operations

Comparison of the three and six months ended June 30, 2026 and 2025

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

	Three Months Ended June 30,		Change	
	2026	2025	$	%
Revenue:				
Product revenue, net	$ 3,604	$ —	$ 3,604	* %
Total revenue	3,604	—	3,604	*
Operating expenses:				
Cost of goods sold	93	—	93	*
Research and development	97,019	102,696	(5,677)	(6)
Selling, general and administrative	36,283	32,267	4,016	12
Intangible asset amortization	750	—	750	*
Total operating expenses	134,145	134,963	(818)	(1)
Loss from operations	(130,541)	(134,963)	4,422	(3)
Interest and other income, net	2,988	10,844	(7,856)	(72)
Net loss	$ (127,553)	$ (124,119)	$ (3,434)	3 %

	Six Months Ended June 30,		Change	
	2026	2025	$	%
Revenue:				
Product revenue, net	$ 3,604	$ —	$ 3,604	* %
Total revenue	3,604	—	3,604	*
Operating expenses:				
Cost of goods sold	93	—	93	*
Research and development	200,865	218,923	(18,058)	(8)
Selling, general and administrative	69,794	61,620	8,174	13
Intangible asset amortization	750	—	750	*
Total operating expenses	271,502	280,543	(9,041)	(3)
Loss from operations	(267,898)	(280,543)	12,645	(5)
Interest and other income, net	11,898	23,454	(11,556)	(49)
Net loss	$ (256,000)	$ (257,089)	$ 1,089	— %

* Percentage is not meaningful.

Product revenue, net

Product revenue was $3.6 million for the three and six months ended June 30, 2026, compared to no product revenue in the prior-year periods. The increase was due to the FDA approval of AVLAYAH in March 2026 and commencement of commercial sales in the United States during the second quarter of 2026. Product revenue reflects sales of AVLAYAH, net of estimates for variable consideration, including distributor service fees, government rebates, product returns and other fees and incentives.

Cost of goods sold

Cost of goods sold was $0.1 million for the three and six months ended June 30, 2026, compared to no cost of goods sold in the prior-year periods. Because manufacturing costs incurred prior to FDA approval of AVLAYAH were expensed to research and development, cost of goods sold during the initial commercialization period reflects a lower average per-unit cost of materials as previously expensed inventory is sold.

Research and development expenses

Research and development expenses were $97.0 million and $102.7 million for the three months ended June 30, 2026 and 2025, respectively, and $200.9 million and $218.9 million for the six months ended June 30, 2026 and 2025, respectively.

The following tables provide a breakdown of our research and development expenses by category (in thousands):

	Three Months Ended June 30,		Change	
	2026	2025	$	%
External research and development expenses - TV programs, including cost sharing	$ 40,419	$ 37,594	$ 2,825	8 %
Other research and development expenses, including small molecule programs	16,494	24,847	(8,353)	(34)
Personnel related expenses[1]	40,106	40,255	(149)	—
Total research and development expenses	$ 97,019	$ 102,696	$ (5,677)	(6) %

(1) Personnel related expenses include stock-based compensation expense of $13.5 million and $15.2 million for the three months ended June 30, 2026 and 2025, respectively, reflecting a decrease of $1.7 million.

The decrease in research and development expenses of approximately $5.7 million for the three months ended June 30, 2026 compared to the three months ended June 30, 2025, was primarily attributable to the following:

- a decrease of $8.4 million in other research and development expenses is driven by lower cost for BIIB122/DNL151 and DNL343; partially offset by increased purchasing of raw materials at our large molecule manufacturing facility in Salt Lake City, Utah;
- an increase of $2.8 million in TV programs external research and development expenses is driven by manufacturing expenses and clinical expenses for zafinofusp alfa; partially offset by lower manufacturing expenses for DNL628, and lower clinical expense for tividenofusp alfa.

	Six Months Ended June 30,		Change	
	2026	2025	$	%
External research and development expenses - TV programs, including cost sharing	$ 78,883	$ 84,052	$ (5,169)	(6
Other research and development expenses	40,048	54,347	(14,299)	(26
Personnel related expenses[1]	81,934	80,524	1,410	2
Total research and development expenses	$ 200,865	$ 218,923	$ (18,058)	(8

(1) Personnel related expenses include stock-based compensation expense of $27.0 million and $30.3 million for the six months ended June 30, 2026 and 2025 respectively, reflecting a decrease of $3.3 million.

The decrease in research and development expenses of approximately $18.1 million for the six months ended June 30, 2026 compared to the six months ended June 30, 2025, was primarily attributable to the following:

- a decrease of $14.3 million in other research and development expenses is driven by lower clinical expenses for BIIB122/DNL151 and DNL343; partially offset by increased purchasing of raw material at our large molecule manufacturing facility in Salt Lake City, Utah;
- a decrease of $5.2 million in external TV research and development expenses driven by lower external manufacturing expense partially offset by higher clinical expenses for zafinofusp alfa, DNL952 and DNL628, and higher pre-clinical expenses;

- an increase of $1.4 million in personnel-related expenses driven by increased headcount year over year.

Selling general and administrative expenses

Selling, general and administrative expense was $36.3 million and $32.3 million for the three months ended June 30, 2026 and 2025 respectively. The $4.0 million increase was primarily driven by:

- An increase of $2.8 million in personnel expenses driven by increased headcount related to the commercial launch of AVLAYAH
- An increase of $1.2 million in other selling general and administration costs driven by increased South San Francisco site costs

Selling, general and administrative expense was $69.8 million and $61.6 million for the six months ended June 30, 2026, and 2025, respectively. The $8.2 million increase was primarily driven by:

- An increase of $6.6 million in personnel expenses driven by increased headcount related to the commercial launch of AVLAYAH
- An increase of $1.5 million in other selling general and administration costs driven by increased South San Francisco site costs; partially offset by lower IT project expenses

Intangible Asset Amortization

Intangible asset amortization was $0.7 million and zero for both the three and six months ended June 30, 2026 and 2025, respectively. The intangible asset, which consists of developed technology recognized in connection with the FDA approval of AVLAYAH in March 2026, began amortizing in the second quarter of 2026 on a straight-line basis over its estimated useful life.

Interest and other income, net

Interest and other income, net was $3.0 million and $10.8 million for the three months ended June 30, 2026 and 2025, respectively. The decrease of approximately $7.8 million was primarily driven by $5.9 million of non-cash interest expense related to the revenue participation right liability under the Royalty Pharma synthetic royalty funding agreement, which commenced in the second quarter of 2026.

Interest and other income, net was $11.9 million and $23.5 million for the six months ended June 30, 2026 and 2025, respectively. The decrease of approximately $11.6 million was primarily driven by:

- Lower interest income due to lower average cash and investment balances;
- Lower yields on our investment portfolio; and
- $5.9 million of non-cash interest expense related to the revenue participation right liability under the Royalty Pharma funding agreement, which commenced in the second quarter of 2026.

Liquidity and Capital Resources

Sources of Liquidity

As of June 30, 2026, we had cash, cash equivalents and marketable securities in the amount of $940.0 million. We fund our operations primarily with the proceeds from the sale of common stock and payments received from our collaboration partners, including those received under agreements with Takeda, Sanofi, and Biogen. Following the commercial launch of AVLAYAH, we expect product revenue to contribute to funding our operations, and our liquidity requirements will include working capital to support commercial inventory, patient support programs, market access activities, distribution arrangements, pharmacovigilance obligations and continued investment in commercial infrastructure. Although we expect AVLAYAH product revenue to contribute to funding our operations, we do not expect such revenue to be sufficient to offset our operating expenses in the near term. We have sold common stock and other securities in public offerings, a private placement, and stock purchase agreements with Takeda and Biogen.

Through June 30, 2026, we have obtained aggregate net proceeds of approximately $956.1 million from public offerings of our common stock, including $12.4 million obtained through the sale of 746,468 shares of common stock in January 2026. In March 2026, we received $200.0 million in gross proceeds in connection with the closing of the synthetic royalty funding agreement with Royalty Pharma, triggered by the U.S. Food and Drug and Administration's accelerated approval of AVLAYAH. Under stock purchase agreements with collaboration partners we have received a further $575.0 million through June 30, 2026.

Further, in February 2024, we received net proceeds of approximately $499.3 million from our private placement through the sale of approximately 3.2 million shares of common stock and pre-funded warrants to purchase approximately 26.0 million shares of our common stock.

In February 2025, we established a registered "at-the-market" facility for the potential future sale of up to $400.0 million of shares of common stock from time to time by entering into an equity distribution agreement with Goldman Sachs & Co. LLC and Leerink Partners LLC as sales agents. To date, no shares have been sold under either equity distribution agreement. All sales under the current equity distribution agreement are conditioned upon satisfaction of customary closing conditions.

Through June 30, 2026, we have received $115.0 million, $225.0 million, $565.0 million and $62.5 million, pursuant to our collaboration and research and development funding agreements with Takeda, Sanofi, Biogen and an unrelated third party, respectively. These payments include upfront, option and milestone payments. Additionally, we have received $58.2 million and $16.2 million in gross cost sharing reimbursements from Takeda and Biogen, respectively, and received $13.7 million in specified reimbursements from Sanofi.

In July 2026, we completed the sale of our Rare Pediatric Disease PRV for gross proceeds of $195.0 million.

Future Funding Requirements and Commitments

Prior to the FDA approval of AVLAYAH, we had not generated any product revenue. Following the FDA approval of AVLAYAH, we commenced commercialization in April 2026 and have begun generating product revenue; however, we expect it to take time to generate sufficient revenue to offset our expenses, and we can provide no assurance as to when, if ever, this will occur. We do not expect to generate any product revenue from our other product candidates unless and until we obtain regulatory approval for those product candidates, and we do not know when, if ever, this 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 commercialize AVLAYAH and any additional approved products. Further, we expect general and administrative expenses to increase as we continue to incur additional costs associated with supporting our growing operations, including commercialization activities. We are subject to all of the risks typically related to the development of new product candidates, as well as risks associated with the commercialization of an approved product, 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 sufficient revenue from the commercialization of AVLAYAH and any future approved products, 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, debt or other alternative 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, or our commercial operations. 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 $2.31 billion as of June 30, 2026. We expect to incur substantial additional losses in the future as we support the commercialization of AVLAYAH and 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 the twelve months following the filing date of this Quarterly Report on Form 10-Q, including our existing commitments as outlined below. 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. In the longer term, we anticipate that we will need substantial additional resources to fund our operations and meet future commitments.

Our existing commitments primarily relate to our obligations under existing lease agreements, certain commercial product, clinical and manufacturing agreements. As of June 30, 2026, we had total undiscounted lease payment obligations of $47.8 million. We had total non-refundable purchase commitments of $104.7 million as of June 30, 2026. While the lease obligations span multiple years, the majority of the purchase commitments are due within the upcoming twelve months. Further, we may be required to make contingent payments under existing arrangements upon the achievement of defined clinical, regulatory and commercial milestones in certain programs, including contingent consideration payments to former shareholders of F-star under the F-star Gamma license, and milestone and royalty payments to Genentech under the Genentech License Agreement. These commitments are more fully described in Note 10 "Commitments and Contingencies" of our unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, and in Note 4, "Acquisition, License Agreement and Research and Development Funding Collaboration Agreement" and Note 7, "Commitments and Contingencies" to the consolidated financial statements included in Item 8. of our Annual Report on Form 10-K filed on February 26, 2026.

In March 2026, we received $200.0 million in gross proceeds under the Royalty Agreement with Royalty Pharma, which was initially recorded as a liability related to the revenue participation right on our Condensed Consolidated Balance Sheet in the first quarter of 2026. Under the Royalty Agreement, we may receive an additional $75.0 million upon approval of AVLAYAH by the EMA on or before December 31, 2029. In exchange, Royalty Pharma is entitled to a 9.25% royalty on worldwide net sales of AVLAYAH until cumulative royalty payments reach a cap of 3.0 times the total funding received, or 2.5 times the total funding received if such cap is reached on or before the first quarter of 2039. These obligations are described in this Quarterly Report on Form 10-Q in Note 9, “Liability Related to the Revenue Participation Right”.

Our future funding requirements, including any changes to existing commitments or the establishment of new commitments, will depend on many factors, including:

- our ability to obtain regulatory approval for our product candidates, establish sales and marketing capabilities, and successfully market such approved product candidates, including the successful commercialization of AVLAYAH;
- 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 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;
- the rate and degree of market acceptance of AVLAYAH, including physician adoption, persistence and payer coverage;
- the amount and timing of product revenue from AVLAYAH, including the impact of variable consideration, reimbursement timing and distributor ordering patterns;
- the cost of commercialization activities, including sales, marketing, market access, medical affairs, patient support, distribution and pharmacovigilance;
- our ability to maintain adequate commercial supply of AVLAYAH through third-party manufacturers and manage commercial inventory levels.

A change in the outcome of any of these or other variables with respect to the development and delivery of any of our product candidates could significantly change the costs and timing associated with the development and delivery 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):

	Six Months Ended June 30,	
	2026	**2025**
Net cash used in operating activities	$ (228,206)	$ (206,766)
Net cash provided by (used in) investing activities	(9,618)	176,683
Net cash provided by (used in) financing activities	234,028	(2,139)
Net decrease in cash, cash equivalents and restricted cash	$ (3,796)	$ (32,222)

Net Cash Used In Operating Activities

During the six months ended June 30, 2026, net cash used in operating activities was $228.2 million, which consisted of a net loss of $256.0 million, adjusted by non-cash items primarily related to stock-based compensation expense, depreciation and amortization, net accretion of discounts on marketable securities, non-cash interest expense related to revenue participation right liability, and non-cash rent expenses. Cash used in operating activities was also driven by changes in our operating assets and liabilities.

Net Cash Used In Investing Activities

During the six months ended June 30, 2026, net cash used in investing activities was $9.6 million, which consisted of $394.6 million for purchases of marketable securities, $28.8 million in milestone payments related to intangible assets, and $3.3 million in capital expenditures to purchase property and equipment. partially offset by $417.0 million in proceeds from the maturities of marketable securities.

Net Cash Provided By Financing Activities

During the six months ended June 30, 2026, cash provided by financing activities was $234.0 million, which consisted of $200.0 million in gross proceeds related to the sale of the revenue participation right under the synthetic royalty funding agreement with Royalty Pharma, $12.4 million in proceeds from public offerings of our common stock, and $21.7 million in proceeds from the exercise of stock options.

Critical Accounting Estimates

This discussion and analysis of our financial condition and results of operations is based on our 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 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. Our significant accounting policies are described in detail in the notes to our condensed consolidated financial statements included elsewhere in this report. In our "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, 2025, as filed with the SEC on February 26, 2026, we described the accounting estimates that we believe involve a significant level of estimation uncertainty which could have a material impact on our financial condition or results of operations. There have been no material changes to these critical accounting estimates during the six months ended June 30, 2026, except as discussed in the notes to our condensed consolidated financial statements with respect to accounting policies adopted upon the commercialization of AVLAYAH.

Recent Accounting Pronouncements

There have been no new accounting pronouncements or changes to accounting pronouncements during the six months ended June 30, 2026, as compared to the recent accounting pronouncements described in our Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the SEC on February 26, 2026, 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 $940.0 million as of June 30, 2026, 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, Swiss Franc 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.

ITEM 4. CONTROLS AND PROCEDURES

Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures

As of June 30, 2026, management, with the participation of our Chief Executive Officer and Chief Operating and Financial Officer, has 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 Operating and 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 Operating and Financial Officer concluded that, as of June 30, 2026, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

Our management, with the participation of our Chief Executive Officer and Chief Operating and Financial Officer, has evaluated any changes in our internal control over financial reporting during the quarter ended June 30, 2026, to identify any change that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting, as required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act. During the quarter ended June 30, 2026, in connection with the commercial launch of AVLAYAH in April 2026, we implemented new processes related to product revenue recognition, accounts receivable, inventory management, and cost of goods sold during the three months ended June 30, 2026. Except for these changes, there were no other changes in our internal control over financial reporting during the three months ended June 30, 2026 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management attention and resources and other factors.

ITEM 1A. RISK FACTORS

In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the risk factors previously disclosed in Part I, Item 1A. “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on February 26, 2026, as updated and supplemented by Part II, Item 1A. “Risk Factors” of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, filed with the SEC on May 7, 2026, which are incorporated herein by reference. There have been no material changes to the risk factors previously disclosed in such filings.

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

Recent Sales of Unregistered Securities

On February 27, 2024, we entered into a securities purchase agreement (the “Purchase Agreement”) with certain existing accredited investors for the private placement of (i) 3,244,689 shares of our common stock at a price of $17.07 per share and (ii) pre-funded warrants to purchase an aggregate of 26,046,065 shares of our common stock (the “Pre-Funded Warrants”) at a purchase price of $17.06 per Pre-Funded Warrant. The private placement closed on February 29, 2024, at which time we received net proceeds of approximately $499.3 million. The Pre-Funded Warrants are exercisable at an exercise price of $0.01 and will be exercisable until exercised in full. The holders of Pre-Funded Warrants may not exercise a Pre-Funded Warrant if the holder, together with its affiliates, would beneficially own more than 4.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise. The holders of Pre-Funded Warrants may increase or decrease such percentage not in excess of 19.99%, in the case of an increase, by providing at least 61 days’ prior notice to the Company. We have also granted a certain investor certain director nomination and additional registration rights, subject to certain exceptions, conditions, and limitations. We intend to use the net proceeds from the private placement to support our ongoing research and development activities, the acceleration and expansion of our proprietary BBB-crossing TV technology, as well as general corporate purposes and working capital. We have invested the funds received in short-term and long-term, interest-bearing investment-grade securities and government securities. We filed a registration statement to register the shares of common stock sold in the private placement (including the shares of common stock underlying the Pre-Funded Warrants) on March 22, 2024.

We are relying on the exemptions from registration available under Section 4(a)(2) and/or Rule 506(b) of Regulation D promulgated under the Securities Act with respect to transactions by an issuer not involving any public offering, and we expect to file a Form D with respect to the private placement.

Use of Proceeds from Registered Securities

In October 2022, we sold 11,933,962 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 $26.50 per share for aggregate net proceeds of approximately $296.2 million.

In December 2025, we sold 9,142,857 shares of common stock, par value $0.01 per share (the “Common Stock”), at a price to the public of $17.50 per share (the “Firm Shares”) and 2,285,714 shares of pre-funded warrants at a price to the public of $17.49 per underlying share, which represents the per share public offering price of each share of common stock less the $0.01 per share exercise price for each pre-funded warrant, through an underwritten public offering for aggregate net proceeds of approximately $189.2 million, after deducting issuance costs of approximately $0.7 million. In January 2026, the underwriters exercised their option to purchase an additional 746,468 shares of the Company’s Common Stock, on which date the Company received aggregate net proceeds of approximately $12.4 million.

There have been no material changes in the planned use of the net proceeds from the follow-on public offering as described in the Registration Statement. We have invested the funds received in short-term and long-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

Securities Trading Plans of Directors and Executive Officers

Our policy governing transactions in our securities by our directors, officers, and employees permits our officers, directors and employees to enter into trading plans complying with Rule 10b5-1 under the Securities Exchange Act of 1934, as amended. As disclosed in the table below, during the second quarter of 2026, certain directors adopted a “Rule 10b5-1 trading arrangement”. This plan provides for the sale of our common stock and is intended to satisfy the affirmative defense in Rule 10b5-1(c).

Name	Position	Date of Plan Adoption	Scheduled End Date of Trading Arrangement[1]	Maximum Total Shares of Common Stock to be Sold Under the Plan[2]
Nancy Thornberry	Director	6/3/2026	9/2/2027	35,377

(1) In each case, the trading arrangement may expire on an earlier date if and when all transactions under the arrangement are completed.
(2) This amount represents the maximum total shares that could be sold under the plan, but the amounts may change for executive officers due to the sale of shares to satisfy tax withholding requirements.

No other officers or directors, as defined in Rule 16a-1(f), adopted and/or terminated of a “Rule 10b5-1 trading arrangement” or a “non-Rule 10b5-1 trading arrangement,” as defined in Regulation S-K Item 408, during the second quarter ended June 30, 2026.

ITEM 6. EXHIBITS

EXHIBIT INDEX

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Number	Filing Date
10.1	Asset Purchase Agreement, dated June 12, 2026	—	—	—	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 June 30, 2026, 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 Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

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: August 6, 2026

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

Date: August 6, 2026

By: /s/ Alexander O. Schuth
Alexander O. Schuth, M.D.
Chief Operating and Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 10.1

CERTAIN IDENTIFYING INFORMATION MARKED BY [***] HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

ASSET PURCHASE AGREEMENT

BY AND BETWEEN

DENALI THERAPEUTICS INC.

AND

[***]

June 12, 2026

ASSET PURCHASE AGREEMENT

This ASSET PURCHASE AGREEMENT (this "***Agreement***") is made and entered into as of June 12, 2026 (the "***Effective Date***"), by and between [***] ("***Buyer***") and Denali Therapeutics Inc., a corporation organized under the laws of Delaware ("***Seller***"). Buyer and Seller may hereinafter be referred to individually as a "***Party***" and collectively as the "***Parties.***"

RECITALS

WHEREAS, Seller is the sole beneficial and record holder of all right, title and interest in and to the Priority Review Voucher (as defined below);

WHEREAS, Seller and Buyer each (i) desire that Buyer purchase from Seller, and Seller sell, transfer and assign to Buyer, the Purchased Assets (as defined below), all on the terms set forth herein (such transaction and the other transactions contemplated hereunder, collectively, the "***Asset Purchase***"), and (ii) in furtherance thereof, have duly authorized, approved and executed this Agreement, and authorized and approved the other transactions contemplated by this Agreement, in accordance with all applicable Legal Requirements (as defined below); and

WHEREAS, Seller and Buyer desire to make certain representations, warranties, covenants and other agreements in connection with the Asset Purchase as set forth herein.

NOW, THEREFORE, in consideration of the foregoing and their mutual undertakings hereinafter set forth, and intending to be legally bound, the Parties hereto agree as follows:

ARTICLE I
DEFINITIONS

1.1 Certain Definitions. As used in this Agreement, the following terms shall have the meanings indicated below:

(a) "***Affiliate***" means any Person which, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with, a Party to this Agreement, for so long as such control exists, whether such Person is or becomes an Affiliate on or after the Effective Date. A Person shall be deemed to "control" another Person if it: (i) with respect to such other Person that is a corporation, owns, directly or indirectly, beneficially or legally, at least fifty percent (50%) of the outstanding voting securities or capital stock (or such lesser percentage which is the maximum allowed to be owned by such Person in a particular jurisdiction) of such other Person, or, with respect to such other Person that is not a corporation, has other comparable ownership interest, or (ii) has the power, whether pursuant to Contract, ownership of securities or otherwise, to direct the management and policies of such other Person.

(b) "***Alternative Transaction***" means, other than the transactions contemplated by this Agreement, any proposal or offer from any Person or group of Persons (other than Buyer or its Affiliates or their respective Representatives) for any acquisition by, or transfer, assignment, encumbrance, license or other grant of rights or disposition to, such Person or group of Persons of any right, title or interest in or to the Purchased Assets; *provided*, that "***Alternative Transaction***" shall not include any debt or equity financing transaction of the Seller or any acquisition of substantially all of Seller's assets or a majority of the direct or indirect equity

interests in Seller (whether through a stock purchase, merger, sale of all or substantially all assets or otherwise) so long as such acquisition provides that this Agreement continues to be binding, enforceable and in full force and effect on the same terms in effect as of the Effective Date.

(c) "***Antitrust Laws***" means the HSR Act, the Sherman Act, the Clayton Act, the Federal Trade Commission Act, and any other United States federal or state or foreign Legal Requirements that are designed to prohibit, restrict or regulate actions having the purpose or effect of monopolization or restraint of trade, abuse of dominant position, or acquisitions, mergers or other business combinations, the effect of which may be to lessen or impede competition or to tend to create or strengthen a dominant position.

(d) "***BLA***" means a human biologics license application submitted under Section 351(a) of the PHSA.

(e) "***Business Day***" means a day (i) other than Saturday or Sunday and (ii) on which commercial banks are open for business in New York, New York.

(f) "***Confidential Information***" means (i) any and all confidential and proprietary information, including, but not limited to, data, results, conclusions, know-how, experience, financial information, plans and forecasts, that may be delivered, made available, disclosed or communicated by a Party or its Affiliates or their respective Representatives to the other Party or its Affiliates or their respective Representatives, related to the subject matter hereof or otherwise in connection with this Agreement and (ii) the terms, conditions and existence of this Agreement. "***Confidential Information***" will not include information that (A) at the time of disclosure, is generally available to the public, (B) after disclosure hereunder, becomes generally available to the public, except as a result of a breach of this Agreement by the recipient of such information, (C) becomes available to the recipient of such information from a Third Party that is not legally or contractually prohibited by the disclosing Party from disclosing such Confidential Information; or (D) was developed by or for the recipient of such information without the use of or reference to any of the Confidential Information of the disclosing Party or its Affiliates, as evidenced by the recipient's contemporaneous written records. Notwithstanding anything herein to the contrary, all Confidential Information included within the Purchased Assets (which for the avoidance of doubt shall not include any confidential and proprietary information relating specifically to the Product) shall constitute Confidential Information of the Buyer from and after the Closing Date.

(g) "***Confidentiality Agreement***" means that certain Confidentiality Agreement, by and between Buyer and Seller, effective as of [***].

(h) "***Contract***" means any written or oral legally binding contract, agreement, instrument, commitment or undertaking (including leases, licenses, mortgages, notes, guarantees, sublicenses, subcontracts and purchase orders).

(i) "***Encumbrance***" means any lien, pledge, charge, mortgage, easement, encroachment, imperfection of title, title exception, title defect, right of possession, right of negotiation or refusal, lease, security interest, encumbrance, adverse claim, interference or any other restriction on use, ownership or transfer (other than the requirement to pay the Priority Review Fee).

(j) "***FDA***" means the United States Food and Drug Administration.

(k) "***FDA Approval Letter***" means the BLA approval letter dated March 24, 2026, from the FDA to Seller, approving the Subject BLA and granting the Priority Review Voucher, attached hereto as **Exhibit A**.

(l) "***FDCA***" means the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq*. as amended, and including any rules, regulations and requirements promulgated thereunder.

(m) "***Governmental Entity***" means any supranational, national, state, municipal, local or foreign government, any court, tribunal, arbitrator, administrative agency, commission, institutional review board, independent ethics committee or other governmental official, authority or instrumentality, in each case whether domestic or foreign, any stock exchange or similar self-regulatory organization or any quasi-governmental or private body exercising any regulatory, taxing or other governmental or quasi-governmental authority.

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

(o) "***Knowledge***" means, with respect to Seller, the actual knowledge of the facts and information, [***].

(p) "***Legal Requirements***" means any federal, state, foreign, local, municipal or other law, statute, constitution, principle of common law, resolution, ordinance, code, rule, regulation, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Entity and any Orders applicable to a Party or to any of its assets, properties or businesses. Legal Requirements shall include, without limitation, with respect to Seller or its Affiliates, any FDA-related or other responsibilities, requirements, obligations, parameters and conditions relating to the Priority Review Voucher, the Product, or the Subject BLA set forth in (i) the FDA Approval Letter, (ii) any other correspondence received by Seller or its Affiliates from the FDA regarding the Priority Review Voucher, the Product, or the Subject BLA, (iii) the FDCA, (iv) the PHSA, or (v) the FDA's Draft Guidance, "Rare Pediatric Disease Priority Review Vouchers – Guidance for Industry" (July 2019).

(q) "***Liabilities***" means all debts, liabilities and obligations, whether presently in existence or arising hereafter, accrued or fixed, absolute or contingent, matured or unmatured, determined or determinable, asserted or unasserted, known or unknown, including those arising under any Legal Requirement or any Contract.

(r) "***Order***" means any order, decree, edict, injunction, writ, award or judgment of any Governmental Entity.

(s) "***Person***" means any natural person, company, corporation, limited liability company, general partnership, limited partnership, trust, proprietorship, joint venture, business organization or Governmental Entity.

*(t) "**PHSA**"* means the United States Public Health Service Act, 42 U.S.C. § 201, *et seq*. as amended, and including any rules, regulations and requirements promulgated thereunder.

(u) "***Priority Review***" means a priority review of and action by the FDA on a human drug application under Section 505(b)(1) of the FDCA or a BLA under Section 351(a) of the PHSA in accordance with the timelines and procedures for "priority review" applications set forth in the then-current version of the Prescription Drug User Fee Act Performance Goals Letter or other then-current FDA policies, procedures, or Legal Requirements.

(v) "***Priority Review Voucher***" means the priority review voucher issued by the FDA to Seller, as the sponsor of an approved rare pediatric disease product application, and assigned tracking number BLA 761485, that entitles the holder of such voucher to Priority Review, as evidenced by a copy of the FDA Approval Letter.

(w) "***Proceeding***" means any claim, action, arbitration, audit, hearing, investigation, litigation, proceeding or suit (whether civil, criminal, administrative, judicial or investigative, whether formal or informal, whether public or private) commenced, brought, conducted or heard by or before, or otherwise involving, any Governmental Entity or arbitrator.

(x) "***Product***" means AVLAYAH™ (tividenofusp alfa-eknm), a product indicated for the treatment of neurologic manifestations of Hunter syndrome (mucopolysaccharidosis type II) when initiated in presymptomatic or symptomatic pediatric patients weighing at least 5 kg prior to advanced neurologic impairment.

(y) "***Purchased Assets***" means (i) the Priority Review Voucher, and (ii) any and all rights, benefits and entitlements with respect thereto afforded to the holder of the Priority Review Voucher.

(z) "***Regulatory Change***" means any term or condition that is not set forth in the FDA Approval Letter imposed by the FDA on the Priority Review Voucher that (i) is not generally imposed on priority review vouchers under the FDCA, (ii) has been enacted, adopted, approved or imposed between the Effective Date and the Closing Date and (iii) adversely affects, in any material respect, the manner in which Buyer may use, receive, hold, transfer or otherwise exploit the Priority Review Voucher.

(aa) "***Representative***" means, with respect to a particular Person, any director, officer, manager, employee, agent, consultant, advisor, accountant, financial advisor, legal counsel or other representative of that Person.

(bb) "***Subject BLA*"** means BLA No. 761485 approved by FDA on March 24, 2026, with respect to the Product.

(cc) "***Third Party***" means any Person other than a Party and such Party's Affiliates.

Other capitalized terms defined elsewhere in this Agreement and not defined in this Section 1.1 shall have the meanings assigned to such terms in this Agreement.

ARTICLE II
PURCHASE AND SALE

2.1 Purchase and Sale; No Assumed Liabilities.

(a) Upon the terms and subject to the conditions of this Agreement, Buyer agrees to purchase from Seller, and Seller agrees to sell, transfer, convey, assign and deliver to Buyer, at the Closing all of Seller's right, title and interest in, to and under the Purchased Assets, in each case free and clear of all Encumbrances.

(b) For the avoidance of doubt, the sale, transfer, conveyance, assignment and delivery of the Purchased Assets from Seller to Buyer shall not include the sale, transfer, conveyance, assignment, delivery or assumption of any Liabilities of any nature from Seller to Buyer and, accordingly, Buyer shall not assume or be liable for, or otherwise be obligated to pay, perform or discharge, any such Liabilities of Seller or its Affiliates (fixed, contingent or otherwise, and whether or not accrued), including Liabilities relating to the Purchased Assets (other than such obligations as are generally imposed by applicable Legal Requirements solely on the holder of the Priority Review Voucher in respect of its use or transfer following the sale thereof pursuant to this Agreement, including, without limitation, the Priority Review Fee) (such Liabilities, "***Excluded Liabilities***"). Seller shall be solely responsible for all such Excluded Liabilities.

2.2 Purchase Price. The total consideration to be paid by Buyer to Seller at the Closing for all of the Purchased Assets shall be one hundred ninety five million U.S. Dollars (U.S. $195,000,000) (the "***Purchase Price***").

2.3 Tax Withholding. In the event any payments to be made to Seller under this Agreement are subject to withholding tax under applicable Legal Requirements, Buyer shall be authorized to deduct the withholding tax from the payments, and shall pay all such withholding tax to the relevant tax authority, so that only the correspondingly reduced amount of payments (i.e. the full amount payable less withholding tax) is paid out to Seller. Buyer shall notify Seller at least five (5) Business Days prior to deducting or withholding any amounts of its intent to deduct or withhold and shall cooperate with Seller to minimize any such deduction or withholding.

ARTICLE III
CLOSING

3.1 Closing. The consummation of the Asset Purchase contemplated by this Agreement (the "***Closing***") shall be conducted telephonically and/or via email or other similar means of correspondence on the [***] Business Day after all of the conditions set forth in Article VI have been satisfied or waived (other than those conditions which, by their terms, are intended to be satisfied at the Closing, but subject to satisfaction or waiver of such conditions), or on such other date as may be mutually agreed upon by Buyer and Seller. The date on which the Closing actually takes place is referred to in this Agreement as the "***Closing Date***."

3.2 Transactions to be Effected at Closing.

(a) Seller's Deliveries. At the Closing, Seller shall deliver, or cause to be delivered, to Buyer:

(i) a duly executed Bill of Sale, in the form attached hereto as **Exhibit B** (the "***Bill of Sale***");

(ii) a copy of the Seller FDA PRV transfer acknowledgement letter, in the form of **Exhibit C-1**;

(iii) a properly completed and duly executed IRS Form W-9 of Seller;
(iv) an executed certificate from a duly authorized officer of Seller certifying as to the matters set forth in Section 6.2(c);

(v) A duly executed certificate of the secretary or an assistant secretary (or equivalent duly authorized officer or other representative) of Seller certifying (A) that attached thereto are true and complete copies of all resolutions adopted by the board of directors of Seller authorizing the execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby, and that all such resolutions are in full force and effect and are all the resolutions adopted in connection with the transactions contemplated hereby, and (B) as to the incumbency of each person executing this Agreement and any other document delivered in connection herewith on behalf of Seller and that the signature of each such person on this Agreement and such other document is such person's genuine signature.

(b) Buyer's Deliveries. At the Closing, Buyer shall deliver, or cause to be delivered, to Seller:

(i) payment of the Purchase Price, by wire transfer of immediately available funds, to an account previously designated in writing by Seller (at least two (2) Business Days prior to Closing) in full satisfaction of Buyer's obligation to pay the Purchase Price to Seller; and

(ii) a copy of the Buyer FDA PRV transfer acknowledgement letter, in the form attached hereto as **Exhibit C-2**; and

(iii) an executed certificate from a duly authorized officer of Buyer certifying as to the matters set forth in Section 6.3(c).

3.3 Title Passage; Notification.

(a) Title Passage. Upon the Closing, all of the right, title and interest of Seller in and to the Purchased Assets shall pass to Buyer, free and clear of all Encumbrances.

(b) Filings; Notifications. Consistent with the provisions of Section 8.1, Buyer and Seller agree to reasonably cooperate and assist each other with respect to any filings or notifications to any Governmental Entity related to the transfer and assignment of the Purchased Assets.

ARTICLE IV
REPRESENTATIONS AND WARRANTIES OF SELLER

Seller represents and warrants to Buyer, as of the Effective Date and the Closing Date, as follows:

4.1 Organization, Standing and Power. Seller is a corporation, duly organized and validly existing under the laws of the State of Delaware. Seller has the corporate power and authority to own, operate and lease its properties and to carry on its business as presently conducted and is duly qualified or licensed to do business and is in good standing in each jurisdiction where the character of its properties owned or leased or the nature of its activities make such qualification or licensing necessary, except where the failure to be so qualified or licensed would not, individually or in the aggregate, reasonably be expected to adversely affect any of the Purchased Assets or Seller's ability to consummate the Asset Purchase contemplated by this Agreement, including the transfer from Seller to Buyer of ownership and rights with respect to the Purchased Assets at the Closing. Seller is not in violation of its certificate of incorporation or bylaws, in each case as amended to date.

4.2 Due Authority. Seller has all requisite corporate power and authority to enter into, deliver and perform its obligations under, and consummate the Asset Purchase contemplated by, this Agreement. The execution, delivery and performance of this Agreement, and the consummation of the Asset Purchase, have been duly and validly approved and authorized by all necessary corporate action on the part of Seller, and this Agreement has been duly executed and delivered by Seller. This Agreement, upon execution and delivery by the Parties, will constitute a valid and binding obligation of Seller enforceable against Seller in accordance with its terms, subject only to the effect, if any, of (a) applicable bankruptcy and other similar laws affecting the rights of creditors generally, and (b) Legal Requirements governing specific performance, injunctive relief and other equitable remedies.

4.3 Noncontravention. The execution and delivery by Seller of this Agreement does not, and the consummation of the Asset Purchase contemplated hereby, including the transfer of title to, ownership in, and possession of the Purchased Assets, will not, (a) result in the creation of any Encumbrance on any of the Purchased Assets, or (b) conflict with, or result in any violation of or default under (with or without notice or lapse of time, or both), or give rise to a right of termination, revocation, cancellation or acceleration of any obligation or loss of any benefit under, or require any consent, approval or waiver from any Person pursuant to, (i) any provision of the certificate of incorporation or bylaws of Seller, in each case as amended to date, (ii) any Contract to which Seller or any Affiliate of Seller is a party or by which it or its assets are bound which involves or affects in any way any of the Purchased Assets, or (iii) except as may be required to comply with the HSR Act, any Legal Requirements applicable to Seller or any Affiliate of Seller or any of the Purchased Assets.

4.4 No Consents. Except for the letters referenced in Sections 3.2(a)(ii) and 3.2(b)(ii) and the filing of any Premerger Notification and Report Form required under the HSR Act, no filing,

authorization, consent, approval, permit, order, registration or declaration, governmental or otherwise, is necessary to enable or authorize Seller to enter into, and to perform its obligations under, this Agreement.

4.5 Title to Purchased Assets. Seller is the sole and exclusive owner of all right, title and interest in and to the Purchased Assets and at the Closing will transfer to Buyer good and transferable title to the Purchased Assets free and clear of any Encumbrances. Seller has performed all actions, if any, necessary to perfect its ownership of, and its ability to transfer, the Purchased Assets pursuant to this Agreement. Seller has provided to Buyer true, correct and complete copies of the FDA Approval Letter and any other communications between Seller or any of its Affiliates and the FDA regarding the Priority Review Voucher (other than any portion thereof that is not relevant to the Purchased Assets, which may be redacted). No third party is entitled to any portion of the proceeds of the transactions contemplated by this Agreement[***]. As of the Closing, the right, title and interest in and to the Purchased Assets that are to be sold, transferred, conveyed, assigned and delivered by Seller to Buyer in accordance with this Agreement collectively constitutes the entire right, title and interest in and to the Purchased Assets and immediately following the Closing, Buyer shall have all right, title and interest in and to the Purchased Assets free and clear of all Encumbrances.

4.6 Contracts. Except for this Agreement, there is no Contract to which Seller or any Affiliate of Seller is a party or is bound that involves or affects the issuance, the ownership, transfer, licensing, title of or to, or use of any of the Purchased Assets, or that otherwise assigned, transferred, licensed, conveyed or encumbered, or granted or allowed to exist any Encumbrance with respect to, any of Seller's right, title or interest in, to or under the Purchased Assets.

4.7 Compliance With Legal Requirements. Seller and its Affiliates are, and at all times have been, in compliance with all Legal Requirements applicable to the Seller or any such Affiliates with respect to (a) any of the Purchased Assets, (b) the Subject BLA (to the extent impacting any of the Purchased Assets) and (c) Seller's and its Affiliates' conduct, acts, submissions or omissions with respect to any of the Purchased Assets or the Subject BLA (to the extent impacting any of the Purchased Assets). Neither the Seller nor any of its Affiliates has made any false, misleading, or untrue statement of material fact, or failed to disclose a material fact required to be disclosed to FDA or other Governmental Entity with respect to the Purchased Assets or the Subject BLA (to the extent impacting any of the Purchased Assets), and all required submissions, filings, or other correspondence with FDA or other Governmental Entity with respect to the Purchased Assets and the Subject BLA (to the extent impacting any of the Purchased Assets) were true and complete. Seller and its Affiliates have not, and to Seller's Knowledge, no other such Person has, received any notice or other communication from any Person or Governmental Entity regarding any actual, alleged, possible or potential violation of, or failure to comply with, any such Legal Requirement with respect to the Purchased Assets or the Subject BLA (to the extent impacting any of the Purchased Assets).

4.8 Legal Proceedings. There is no pending, or to Seller's Knowledge, threatened Proceeding that involves or affects the validity of, ownership of, licensing of, title to, use of, or ability to transfer or redeem any of the Purchased Assets. None of the Purchased Assets are subject to any Order of any Governmental Entity or arbitrator.

4.9 Governmental Authorizations. Seller is not required to hold any license, registration, or permit issued by any Governmental Entity to own, use or transfer the Purchased Assets, other than such licenses, registrations or permits that have already been obtained.

4.10 Solvency. Seller is not entering into this Agreement with the actual intent to hinder, delay, or defraud any creditor of Seller. The remaining assets of Seller after the Closing will not be unreasonably small in relation to the business in which Seller will engage after the Closing. Upon and immediately following the Closing Date, after giving effect to the Asset Purchase contemplated by and in this Agreement (including the payment of the Purchase Price), Seller will not be insolvent and will have sufficient capital to continue in business and pay its debts as they become due.

4.11 Revocation; Use of Purchased Assets. The Priority Review Voucher has not been terminated, cancelled, redeemed, sold or otherwise transferred, suspended or revoked, and neither Seller nor any of its Affiliates or any of their respective Representatives has, with respect to the Priority Review Voucher, (i) made any false, misleading, or untrue statement of material fact or a fraudulent statement to the FDA or any other Governmental Entity, (ii) failed to disclose a material fact required to be disclosed to the FDA or made a fraudulent statement to the FDA or any other Governmental Entity or (iii) committed an act, made a statement or failed to make a statement that, at the time such disclosure was made, would reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities," set forth in 56 Fed. Reg. 46191 (September 10, 1991) or for any other Governmental Entity to invoke any similar policy and which would reasonably be expected to result in a revocation of the Priority Review Voucher. To Seller's Knowledge, there are no facts or circumstances that would reasonably be expected to (with or without notice or lapse of time or both) result in the termination, suspension, cancellation or revocation of the Priority Review Voucher, give rise to a right of the FDA to revoke (or that would otherwise result in the revocation of) the Priority Review Voucher, result in the redemption or transfer of the Priority Review Voucher (other than pursuant to the transfer contemplated by this Agreement) or that would reasonably be expected to preclude or interfere with the sale and transfer of the Purchased Assets to the Buyer or Buyer's use of the Purchased Assets to obtain Priority Review or any other benefit associated with the Purchased Assets. The Priority Review Voucher was awarded to Seller by the FDA in respect of Seller's sponsorship of a rare pediatric disease product application pursuant to Section 529 of the FDCA. The Priority Review Voucher has not been transferred to any Person, including any Affiliate of Seller, and the transfer contemplated by this Agreement constitutes the first and only transfer of the Priority Review Voucher since the date that the Priority Review Voucher was issued, and to Seller's Knowledge, there is no term or condition imposed by the FDA on the Priority Review Voucher that is not set forth in the FDA Approval Letter or the FDCA. Seller has provided to Buyer true and complete copies of the FDA Approval Letter and any other material communications between Seller or any of its Affiliates and the FDA regarding the Priority Review Voucher (other than any portion thereof that is not relevant to the Purchased Assets, which may be redacted), and all such communications were true, correct and complete in all material respects as of the date of submission to the FDA or any Governmental Entity.

4.12 Intent to Use. Neither Seller nor any of its Affiliates nor, to the Knowledge of the Seller, any other Third Party has notified the FDA of intent to use the Priority Review Voucher to obtain a Priority Review.

4.13 No Broker. Seller has not engaged, retained or entered into an agreement with any investment banker, broker, finder or other intermediary who has been authorized to act on behalf of Seller who may be entitled to any fee or commission payable by Buyer or its Affiliates in connection with the Asset Purchase contemplated by this Agreement.

4.14 No Other Representations. Neither Seller nor any of its Representatives is making any representation or warranty of any kind or nature whatsoever, oral or written, express or implied, except as otherwise expressly set forth in this Article IV, and Seller hereby disclaims any such other representations and warranties.

ARTICLE V
REPRESENTATIONS AND WARRANTIES OF BUYER

Buyer represents and warrants to Seller, as of the Effective Date and the Closing Date, as follows:

5.1 Organization, Standing and Power. Buyer is a [***]. Buyer has the corporate power and authority to own, operate and lease its properties and to carry on its business as presently conducted and is duly qualified or licensed to do business and is in good standing in each jurisdiction where the character of its properties owned or leased or the nature of its activities make such qualification or licensing necessary, except where the failure to be so qualified or licensed would not, individually or in the aggregate, reasonably be expected to adversely affect Buyer's ability to consummate the Asset Purchase contemplated by this Agreement. Buyer is not in violation of its certificate of incorporation or bylaws, in each case as amended to date.

5.2 Authority. Buyer has all requisite corporate power and authority to enter into and perform its obligations under this Agreement. The execution, delivery and performance of this Agreement, and the consummation of the Asset Purchase, have been duly and validly approved and authorized by all necessary corporate action on the part of Buyer, and this Agreement has been duly executed and delivered by Buyer. This Agreement, upon execution and delivery by the Parties, will constitute a valid and binding obligation of Buyer enforceable against Buyer in accordance with its terms, subject only to the effect, if any, of (a) applicable bankruptcy and other similar laws affecting the rights of creditors generally, and (b) Legal Requirements governing specific performance, injunctive relief and other equitable remedies.

5.3 Noncontravention. The execution and delivery by Buyer of this Agreement does not, and the consummation of the Asset Purchase contemplated hereby will not, conflict with, or result in any violation of or default under (with or without notice or lapse of time, or both), or give rise to a right of termination, revocation, suspension, cancellation or acceleration of any obligation or loss of any benefit under, or require any consent, approval or waiver from any Person pursuant to, (a) any provision of the certificate of incorporation or bylaws of Buyer, in each case as amended to date, (b) any Contract to which Buyer is a party or by which it is bound, or (c) any Legal Requirements applicable to Buyer.

5.4 No Consents. Except for the letters referenced in Sections 3.2(a)(ii) and 3.2(b)(ii) and the filing of any Premerger Notification and Report Form required under the HSR Act, no filing, authorization, consent, approval, permit, order, registration or declaration, governmental or

otherwise, is necessary to enable or authorize Buyer to enter into, and to perform its obligations under, this Agreement.

5.5 No Broker. Buyer has not engaged, retained or entered into an agreement with any investment banker, broker, finder or other intermediary who has been authorized to act on behalf of Buyer who would be entitled to any fee or commission payable by Seller in connection with the Asset Purchase contemplated by this Agreement.

ARTICLE VI
CONDITIONS TO CLOSING

6.1 Conditions Precedent of Buyer and Seller. Each Party's obligations to consummate the transactions contemplated by this Agreement are subject to the satisfaction or waiver, at or prior to the Closing Date, of each of the following conditions precedent:

(a) No temporary restraining order, preliminary or permanent injunction or other material Order issued or promulgated by a Governmental Entity preventing, prohibiting or restraining the consummation of the transactions contemplated by this Agreement shall be in effect, and there shall not be any applicable Legal Requirement that makes consummation of the transactions contemplated by this Agreement illegal.

(b) There shall not be any Proceeding commenced or pending by a Governmental Entity seeking to prohibit, limit, delay, or otherwise restrain the consummation of this Agreement and/or the transactions contemplated hereby.

(c) The waiting period (and any extension thereof, including any timing agreement with the relevant Governmental Entity) applicable to the Asset Purchase under the HSR Act shall have expired or been terminated.

6.2 Buyer's Condition Precedent. The obligations of Buyer to consummate the transactions contemplated by this Agreement are subject to the satisfaction or waiver, at or prior to the Closing Date, of each of the following conditions precedent:

(a) Each of the representations and warranties made by Seller in this Agreement shall be true and correct in all material respects at and as of the Effective Date and as of the Closing Date (or, if made as of a specified date, as of such date).

(b) All of the covenants and obligations that Seller is required to comply with or to perform hereunder at or prior to the Closing Date shall have been complied with and performed in all material respects.

(c) Seller shall have delivered to Buyer a certificate, dated as of the Closing Date and duly executed by Seller, certifying that the conditions set forth in Sections 6.2(a) and 6.2(b) have been satisfied.

(d) There shall not have occurred and remain in effect any Regulatory Change. Seller's

6.3 Condition Precedent. The obligations of Seller to consummate the transactions contemplated by this Agreement are subject to the satisfaction or waiver, at or prior to the Closing Date, of each of the following conditions precedent:

(a) Each of the representations and warranties made by Buyer in this Agreement shall be true and correct in all material respects at and as of the Closing Date.

(b) All of the covenants and obligations that Buyer is required to comply with or to perform hereunder at or prior to the Closing Date shall have been complied with and performed in all material respects.

(c) Buyer shall have delivered to Seller a certificate, dated as of the Closing Date and duly executed by Buyer, certifying that the conditions set forth in Sections 6.3(a) and 6.3(b) have been satisfied.

ARTICLE VII
INDEMNIFICATION

7.1 Indemnification.

(a) Indemnification by Seller. From and after the Closing, Seller will indemnify, defend and hold Buyer and its Affiliates, and their respective directors, officers, employees and agents harmless for, from and against any and all Liabilities, claims, losses, damages, costs and expenses (including reasonable attorneys' fees) whether or not arising from, relating to, or otherwise involving a claim of a third party (collectively, "***Damages***") to the extent arising out of or resulting from (i) any breach of Seller's representations, warranties, covenants or obligations under this Agreement, (ii) Seller's fraudulent, grossly negligent and/or wrongful acts, omissions or misrepresentations, regardless of the form of action, in connection with this Agreement, (iii) any claim by any Third Party against Buyer and its Affiliates that such Third Party is entitled to any proceeds from the sale of the Priority Review Voucher pursuant hereto, and/or (iv) [***], and/or (v) any Excluded Liabilities.

(b) Indemnification by Buyer. From and after the Closing, Buyer will indemnify, defend and hold Seller and its Affiliates, and their respective directors, officers, employees and agents harmless for, from and against any and all Damages to the extent arising out of or resulting from (i) any breach of Buyer's representations, warranties, covenants or obligations under this Agreement, (ii) Buyer's fraudulent, grossly negligent and/or wrongful acts, omissions or misrepresentations, regardless of the form of action, in connection with this Agreement, and/or (iii) Buyer's, its Affiliates', or any subsequent transferee's use of the Purchased Assets.

7.2 Indemnification Procedures for Third Party Claims.

(a) A Person entitled to indemnification pursuant to Section 7.1 will hereinafter be referred to as an "***Indemnitee***." A Party obligated to indemnify an Indemnitee hereunder will hereinafter be referred to as an "***Indemnitor***." Indemnitee shall inform Indemnitor of any indemnifiable Damages arising out of a claim by a third party in respect of which an Indemnitee may seek indemnification pursuant to Section 7.1 (a "***Third Party Claim***") as soon as reasonably practicable after the Third Party Claim arises, it being understood and agreed that the failure to give such notice will not relieve the Indemnitor of its indemnification obligation under this

Agreement except and only to the extent that such Indemnitor is actually and materially prejudiced as a result of such failure to give notice.

(b) If the Indemnitor has acknowledged in writing to the Indemnitee within fifteen (15) days after receipt of the Third Party Claim the Indemnitor's responsibility for defending such Third Party Claim, the Indemnitor shall have the right to defend, at its sole cost and expense, such Third Party Claim by all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnitor to a final conclusion or settled at the discretion of the Indemnitor; provided, however, that the Indemnitor may not enter into any compromise or settlement unless (i) such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnitee of a release from all liability in respect of such Third Party Claim, and (ii) the Indemnitee consents to such compromise or settlement, which consent shall not be withheld or delayed unless such compromise or settlement involves (A) any admission of legal wrongdoing by the Indemnitee, (B) any payment by the Indemnitee that is not indemnified hereunder or (C) the imposition of any equitable relief against the Indemnitee, in any of which cases the Indemnitee may withhold its consent in its sole discretion. If the Indemnitor does not elect to assume control of the defense of a Third Party Claim or if a good faith and diligent defense is not being or ceases to be materially conducted by the Indemnitor, the Indemnitee shall have the right, at the expense of the Indemnitor, upon at least ten (10) Business Days' prior written notice to the Indemnitor of its intent to do so, to undertake the defense of such Third Party Claim for the account of the Indemnitor (with counsel reasonably selected by the Indemnitee and approved by the Indemnitor, such approval not to be unreasonably withheld or delayed), provided, that the Indemnitee shall keep the Indemnitor apprised of all material developments with respect to such Third Party Claim and promptly provide the Indemnitor with copies of all correspondence and documents exchanged by the Indemnitee and the opposing party(ies) to such litigation. The Indemnitee may not compromise or settle such litigation without the prior written consent of the Indemnitor, such consent not to be unreasonably withheld or delayed.

(c) The Indemnitee may participate in, but not control, any defense or settlement of any Third Party Claim controlled by the Indemnitor pursuant to this Section 7.2 and shall bear its own costs and expenses with respect to such participation; provided, however, that the Indemnitor shall bear such costs and expenses if counsel for the Indemnitor shall have reasonably determined that such counsel may not properly represent both the Indemnitor and the Indemnitee.

7.3 Direct Claims. A claim for indemnification for any matter not involving a Third Party Claim may be asserted by written notice from the Indemnitee to the Indemnitor. Such notice shall include the facts constituting the basis for such claim for indemnification, the Sections of this Agreement upon which such claim for indemnification is then based, and an estimate, if possible, of the amount of Damages suffered or reasonably expected to be suffered by the Indemnitee; provided, that the failure to give such notification or any deficiency in such notification will not relieve such Indemnitor from any obligations under this Article VII, except to the extent such failure to give such notification or any deficiency in such notification actually and materially prejudices such Indemnitor.

7.4 Exclusive Remedy. From and after the Closing, except in the case of fraud, intentional or willful misrepresentation or intentional or willful misconduct, the sole and

exclusive remedy of any Indemnitee for any Damages (including any Damages from Liabilities or claims for breach of contract, warranty, or otherwise and whether predicated on common law, statute, strict liability or otherwise) that such Indemnitee may at any time suffer or incur, or become subject to, as a result of, or in connection with this Agreement, including any inaccuracy, violation or breach of any representation and warranty contained in this Agreement by any Party, or any failure by any Party to perform or comply with any covenant or agreement that, by its terms, was to have been performed, or complied with, under this Agreement, shall be indemnification in accordance with this Article VII (subject to the applicable qualifications and limitations set forth in this Agreement).

7.5 Limits on Indemnification. Notwithstanding anything to the contrary contained in this Agreement, except in the case of fraud, intentional or willful misrepresentation or intentional or willful misconduct, the maximum aggregate amount of indemnifiable Damages that may be recovered from (a) Seller pursuant to Section 7.1(a) shall equal the Purchase Price, and (b) Buyer pursuant to Section 7.1(b) shall equal the Purchase Price. Notwithstanding anything to the contrary set forth herein, except to the extent actually awarded against an Indemnitee pursuant to an Order with respect to a Third Party Claim and except for another Party's fraud, no Party shall have any liability under any provision of this Agreement (including this Article VII) for any punitive, incidental, special or indirect damages or damages for or otherwise based on business interruption, diminution of value, loss of future revenue, profits or income, or loss of business reputation or opportunity relating to the breach or alleged breach of this Agreement. Nothing in this Section 7.5 shall operate to limit or exclude in any way Seller's liability for any and all Excluded Liabilities.

7.6 Tax Treatment of Indemnity Payments. Any payments made to any party pursuant to this Article VII shall constitute an adjustment of the Purchase Price for tax purposes.

ARTICLE VIII
COVENANTS AND AGREEMENTS

8.1 Further Assurances.

(a) The Parties shall cooperate reasonably with each other in connection with any steps required to be taken as part of their respective obligations under this Agreement, including, without limitation, any notifications or filings required to be made to the FDA in connection with the transfer from Seller to Buyer of the Purchased Assets following the Closing, and shall (i) furnish upon request to each other such further information, (ii) execute and deliver to each other such other documents, and (iii) do such other acts and things, all as the other Party may reasonably request for the purpose of carrying out the intent of this Agreement and the Asset Purchase contemplated by this Agreement, including the use by Buyer and/or its Affiliates or their respective permitted successors and assigns of the Priority Review Voucher in accordance with its terms and applicable Legal Requirements.

(b) Without limiting the foregoing, Buyer and Seller agree to cooperate and assist each other with respect to all filings or notifications to any Governmental Entity related to the transfer and assignment from Seller to Buyer of the Purchased Assets.

8.2 Regulatory Change Notification. Seller shall, and shall cause its Affiliates and each of their respective successors in interest to the Subject BLA, to at all times comply in all material respects with all Legal Requirements applicable to the Purchased Assets, including any and all Legal Requirements applicable to the validity, maintenance, use or transfer of the Priority Review Voucher, or that would reasonably be expected to result in the revocation of the Priority Review if such Legal Requirements were not complied with. Seller shall, and shall cause its Affiliates and each of their respective successors in interest to the Subject BLA, promptly forward to Buyer any communications or notices it or its Affiliates receive from any Governmental Entity in respect of the Purchased Assets, provided that Seller may redact any portion of such material communications or notices that is not relevant to the Purchased Assets.

8.3 Nondisclosure.

(a) With respect to Confidential Information received from a Party, the other Party will (i) keep the Confidential Information confidential, (ii) not use such Confidential Information for any reason other than to carry out the intent and purpose of this Agreement, and (iii) not disclose such Confidential Information to any Person, except in each case as otherwise expressly permitted by this Agreement or with the prior written consent of the disclosing Party.

(b) A Party may disclose Confidential Information of the other Party only to its Affiliates and their respective Representatives on a need-to-know basis.

(c) A Party will (i) enforce the terms of this Section 8.3 as to its Representatives, (ii) take such action to the extent necessary to cause its Representatives to comply with the terms and conditions of this Section 8.3, and (iii) be responsible and liable for any breach of this Section 8.3 by it or its Representatives.

(d) If a Party becomes compelled by a court or is requested by a Governmental Entity to make any disclosure that is prohibited or otherwise constrained by this Section 8.3, such Party shall (to the extent permitted by applicable law) provide the disclosing Party with prompt notice of such compulsion or request so that it may seek an appropriate protective order or other appropriate remedy or waive compliance with the provisions of this Section 8.3. In the absence of a protective order or other remedy, the Party subject to the requirement to disclose may disclose that portion (and only that portion) of the Confidential Information that, based upon advice of its counsel, it is legally compelled to disclose or that has been requested by such Governmental Entity; provided, however, that such Party shall use reasonable efforts to obtain reliable assurance that confidential treatment will be accorded by any Person to whom any Confidential Information is so disclosed.

(e) Nothing herein shall prohibit or otherwise restrict the disclosure of any Confidential Information by or on behalf of Buyer or its Affiliates to the FDA or other Governmental Entity to the extent required by the FDA or such other Governmental Entity to enable the use or transfer of the Priority Review Voucher; provided that Buyer and its Affiliates shall use commercially reasonable efforts to obtain confidential treatment for any such disclosures.

(f) The Parties hereby agree that, effective as of the Closing, the Confidentiality Agreement shall automatically terminate and be of no further force or effect.

8.4 Disclosures Concerning this Agreement. Seller and Buyer shall consult with each other before issuing, and provide each other the opportunity to review and comment upon, any press release or other public statement with respect to the Asset Purchase contemplated hereby, and shall not issue any such press release or make any such public statement prior to such consultation, except as may be required by applicable Legal Requirements; provided, that, Buyer may, without the prior consent or review by Seller, make filings or disclosures with any applicable tax Governmental Entity that are necessary or desirable to Buyer and its Affiliates. Buyer and Seller each acknowledges that the other Party, or the other Party's parent company, as a publicly traded company, is legally obligated to make timely disclosures of material events relating to its business. The Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement with the United States Securities and Exchange Commission; provided, that if a Party is obligated to so file a copy of this Agreement, such Party shall prepare a proposed redacted version and request confidential treatment thereof, and the other Party may promptly (and in any case within two (2) Business Days) provide comments thereon, which comments shall be considered in good faith by the Party required to so file a copy of this Agreement. Except as expressly provided herein, 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, or other form of publicity or filing that is publicly available without the prior written approval of such other Party in each instance.

8.5 Regulatory Compliance.

(a) Each of the Parties shall, if required by applicable Legal Requirements, as promptly as practicable, and in any event within ten (10) Business Days after the date of this Agreement, file or supply, or cause to be filed or supplied in connection with the transactions contemplated herein, all notifications and information required to be filed or supplied pursuant to the HSR Act. Each Party acknowledges and agrees that it shall pay and shall be solely responsible for its respective filing fees for the Party's filing under the HSR Act.

(b) Each of the Parties, as promptly as practicable, unless otherwise agreed by the Parties, shall make, or cause to be made, all other filings and submissions under applicable Legal Requirements, including Antitrust Laws, applicable to it, or to its subsidiaries and Affiliates, as may be required for it to consummate the Asset Purchase, if any, and use its reasonable best efforts (which shall not require either Party to make any payment or concession to any Person in connection with obtaining such Person's consent) to obtain, or cause to be obtained, all authorizations, approvals, consents and waivers from all Persons and Governmental Entities necessary to be obtained by it, or its subsidiaries or Affiliates, in order for it to consummate such transactions.

(c) Each of Buyer and Seller will use reasonable best efforts to cause all documents that it is responsible to file with any Governmental Entity in accordance with this Section 8.5 to comply in all material respects with all Legal Requirements and rules and regulations of any Governmental Entity.

(d) The Parties shall coordinate and cooperate with one another in exchanging and providing such information to each other and in making the filings and requests referred to in

Sections 8.5(a) and (b) above. Each Party shall supply such reasonable assistance as may be reasonably requested by the other Party in connection with the foregoing.

(e) Each of Buyer and Seller will, and will cause their respective Affiliates to, (i) promptly supply the other with any information which may be reasonably required in order to effectuate any filings and responses to information requests in accordance with this Section 8.5; (ii) as promptly as practicable, cooperate in good faith and use their respective reasonable best efforts to take any and all actions necessary, proper or advisable to consummate and make effective, in the most expeditious manner practicable, the Asset Purchase and to obtain any approvals, actions or non-actions, waivers, consents, Orders, authorizations or clearances required under or in connection with the HSR Act and any other applicable Antitrust Laws, as promptly as practicable, and to enable all waiting periods under the HSR Act and any other applicable Antitrust Laws to terminate or expire (the "***Antitrust Approvals***"), as promptly as practicable, including: (A) promptly furnishing to the other such information and assistance as may reasonably be requested in order to prepare any notification, application, filing or request in connection with an Antitrust Approval, (B) consulting with, and considering in good faith, any suggestions or comments made by the other Party with respect to the Antitrust Approvals process, (C) providing or submitting on a timely basis, and as promptly as practicable, all documentation and information that is required or advisable and (D) cooperating in the preparation and submission of all applications, notices, filings, and submissions to Governmental Entities; (iii) promptly inform the other Party of, and provide copies of, any substantive communication received by that Party in respect of obtaining or concluding the Antitrust Approvals, including the substantive details of any oral communications with any Governmental Entity; (iv) use reasonable best efforts to respond promptly to any request or notice from any Governmental Entity requiring the Parties, or any one of them, to supply additional information that is relevant to the review of the Asset Purchase in respect of obtaining or concluding the Antitrust Approvals, including any Request for Additional Information and Documentary Material from the U.S. Federal Trade Commission or the Antitrust Division of the U.S. Department of Justice; (v) permit the other Party to review in advance any proposed applications, notices, filings and submissions to Governmental Entities (including responses to requests for information and inquiries from any Governmental Entity) in respect of obtaining or concluding the Antitrust Approvals; (vi) promptly provide the other Party with any filed copies of applications, notices, filings and submissions (including responses to requests for information and inquiries from any Governmental Entity) that were submitted to a Governmental Entity in respect of obtaining or concluding the Antitrust Approvals; (vii) whenever practicable, not participate in any substantive meeting or discussion (whether in person, by telephone or otherwise) with Governmental Entities in respect of obtaining or concluding the Antitrust Approvals unless it consults with the other Party in advance and gives the other Party or their legal counsel the opportunity to attend and participate thereat, unless a Governmental Entity requests otherwise; and (viii) keep the other Party promptly informed of the status of discussions relating to obtaining or concluding the Antitrust Approvals.

(f) Notwithstanding anything in this Agreement to the contrary, reasonable best efforts will not obligate Buyer, Seller, any subsidiary of Buyer or any subsidiary of Seller to: (i) undertake or enter into agreements or agree to the entry of an order or decree with any Governmental Entity, (ii) commit to sell, license or dispose of, or hold separate or agree to sell or otherwise dispose of, assets, categories of assets or business of Buyer, Seller, any subsidiary of Buyer or any subsidiary of Seller, (iii) commit to terminate, amend or replace any existing

relationships and contractual rights and obligations of Buyer, Seller, any subsidiary of Buyer or any subsidiary of Seller, (iv) terminate any relevant venture or other arrangement of the Buyer, Seller, any subsidiary of Buyer or any subsidiary of Seller, (v) effectuate any other change or restructuring of Buyer, Seller, any subsidiary of Buyer or any subsidiary of Seller or (vi) otherwise take any action that limits the freedom of action with respect to, or the ability to retain any of the businesses, product lines or assets of Buyer or Seller. Notwithstanding anything to the contrary in this Section 8.5, none of Buyer, Seller, nor any subsidiary of Buyer nor any subsidiary of Seller shall be obligated to initiate or pursue any litigation, administrative proceeding, or formal legal action in connection with obtaining or concluding any Antitrust Approvals; provided, however, that Buyer may elect, in its sole discretion, to do so. Nothing in this Section 8.5 shall be construed to require Buyer or Seller to challenge or appeal any action taken by a Governmental Entity.

(g) Notwithstanding the foregoing or anything in this Agreement to the contrary, but without limiting the obligations of Buyer under this Section 8.5, Buyer will, on behalf of the Parties, determine and control strategy for dealing with any Governmental Entity in respect of obtaining or concluding the Antitrust Approvals, and, to the extent permissible, Seller will use its reasonable best efforts to act consistently with such strategy; provided that Buyer will consult in advance with, and consider in good faith the views of, Seller in respect of strategy for dealing with any Governmental Entity and obtaining or concluding the Antitrust Approvals. Notwithstanding the foregoing, neither Buyer nor Seller will commit to or agree with any Governmental Entity to not consummate the Asset Purchase for any period of time, or to stay, toll or extend, directly or indirectly, any applicable waiting period under the HSR Act or other applicable Antitrust Law, and will not pull and refile any filing made under the HSR Act, in each case without the prior written consent of the other (such consent not to be unreasonably withheld, conditioned or delayed); provided, however, that notwithstanding the foregoing, Buyer may, without the consent of Seller, voluntarily withdraw its notification under the HSR Act on one (1) occasion so long as Buyer refiles its HSR Act notification within two (2) Business Days after withdrawal (unless otherwise agreed by the Parties hereto).

(h) Notwithstanding any other requirement in this Section 8.5, where a Party (a "***Disclosing Party***") is required under this Section 8.5 to provide information to another Party (a "***Receiving Party***") that the Disclosing Party deems to be competitively sensitive information or otherwise reasonably determines in respect thereof that disclosure should be restricted, the Disclosing Party may restrict the provision of such competitively sensitive and other restricted information only to antitrust counsel of the Receiving Party, *provided*, that the Disclosing Party also provides to the Receiving Party upon request of the Receiving Party a redacted version of such information which does not contain any such competitively sensitive or other restricted information.

(i) Each Party will bear its own costs of preparing and fees attendant to its own notifications and similar filings and notices and related expenses incurred to obtain all Antitrust Approvals, including under the HSR Act.

8.6 Exclusivity; Non-Solicitation. Until the earlier of the Closing or the termination of this Agreement, Seller shall not, nor shall it authorize or instruct any of its Affiliates or its or their Representatives to, (a) sell, transfer, convey or assign the Priority Review Voucher to any Person other than Buyer or enter into any Contract with respect thereto, (b) encumber or

otherwise grant or allow to exist any Encumbrance on the Priority Review Voucher (other than pursuant to this Agreement), (c) solicit, initiate or knowingly facilitate or encourage any inquiries, proposals or offers with respect to, or the submission of, any Alternative Transaction by any Person (other than Buyer or its Affiliates or their respective Representatives) or any inquiry, expression of interest, proposal or offer that is reasonably likely to lead to an Alternative Transaction, (d) engage, continue or participate in any discussions or negotiations regarding, or take any other action intended or reasonably expected to facilitate the making of any inquiry, proposal or offer to Seller that constitutes, or may reasonably be expected to lead to, any Alternative Transaction by any Person (other than Buyer or its Affiliates or their respective Representatives) other than to state that they are not permitted to have any such discussions, (e) accept any inquiry, proposal or offer from any Person (other than Buyer) in respect of an Alternative Transaction, (f) take any action or inaction that would reasonably be expected to prevent the satisfaction of the conditions set forth in Article VI or adversely affect any of the Purchased Assets or Buyer's ownership and rights with respect to any of the Purchased Assets after the Closing or (g) resolve to propose or agree to do any of the foregoing. Seller shall, and shall cause each of its Affiliates and shall direct its and their respective Representatives to, immediately cease and cause to be terminated any and all existing activities, discussions or negotiations, if any, with any third party or its Representatives conducted prior to the Effective Date with respect to any Alternative Transaction, or proposal that would reasonably be expected to lead to an Alternative Transaction, and shall use its reasonable best efforts to cause any such third party and its Representatives in possession of Confidential Information heretofore furnished to such Person by or on behalf of Seller to return or destroy all such Confidential Information as promptly as practicable.

ARTICLE IX
TERMINATION

9.1 Termination Prior to Closing. Notwithstanding any contrary provisions of this Agreement, the respective obligations of the Parties to consummate the transactions contemplated by this Agreement may be terminated and abandoned at any time before the Closing only as follows:

(a) upon the mutual written consent of Buyer and Seller;

(b) by either Party, by written notice to the other Party, at any time after 11:59 p.m., Eastern Standard Time, on the date that is ninety (90) days following the Effective Date (the "***Outside Date***"); provided, however, that the right to terminate this Agreement under this Section 9.1(b) shall not be available to any Party whose material breach of any provision set forth in this Agreement is the primary cause of the failure of the Closing to occur on or before such date;

(c) by Buyer, by written notice to Seller, if Buyer is not in material breach of its obligations under this Agreement and there has been a violation or breach by Seller of any of its representations, warranties, covenants, or other agreements contained in this Agreement, which has prevented or would prevent the satisfaction of any condition to the Closing, and (i) such violation or breach has not been waived by Buyer, (ii) Buyer has provided written notice to Seller of such violation or breach, and (iii) such violation or breach cannot be or has not been cured by Seller within twenty (20) Business Days after receiving written notice thereof from

Buyer (provided, that in no event shall such twenty (20) Business Day extend beyond the Outside Date); or

(d) by Seller, by written notice to Buyer, if Seller is not in material breach of its obligations under this Agreement and there has been a violation or breach by Buyer of any of its representations, warranties, covenants, or other agreements contained in this Agreement that has prevented or would prevent the satisfaction of any condition to the Closing, and (i) such violation or breach has not been waived by Seller, (ii) Seller has provided written notice to Buyer of such violation or breach, and (iii) such violation or breach cannot be or has not been cured by Buyer within twenty (20) Business Days after receiving written notice thereof from Seller (provided, that in no event shall such twenty (20) Business Day extend beyond the Outside Date).

9.2 Effect of Termination. In the event of the termination of this Agreement as provided in Section 9.1, this Agreement shall forthwith become null and void (except for the provisions of this Section 9.2, Section 8.3, Section 8.4, Article I and Article X, which shall survive any such termination (together, the "***Surviving Provisions***")) and there shall be no liability on the part of Buyer or Seller except for (i) Damages resulting from any breach of this Agreement prior to termination of this Agreement by Buyer or Seller and (ii) Damages incurred after the termination of this Agreement with respect to the Surviving Provisions.

ARTICLE X
GENERAL PROVISIONS

10.1 Survival. Except as expressly set forth herein, the representations and warranties contained in this Agreement, and liability for the breach thereof, shall survive the Closing Date and shall remain in full force and effect and all covenants and obligations contained herein, shall, in each case, survive the Closing Date and remain in full force and effect until sixty (60) days following the expiration of the applicable statute of limitations.

10.2 Transfer Taxes and Fees. Notwithstanding any other provision in this Agreement to the contrary, each respective Party shall bear and pay any and all sales taxes, value added taxes, stamp taxes, use taxes, transfer taxes, documentary charges, recording fees or similar taxes, charges, or fees (including any penalties, interest and additions thereto) that may become payable by it or its Affiliates in connection with the Asset Purchase. For clarity, the obligation to withhold shall not be deemed "payable" by a Party or its Affiliates pursuant to the foregoing sentence, but shall be considered an obligation of the Party on whose behalf the withholding is paid to the Governmental Entity. Buyer, its Affiliates, or any Buyer transferee of the Priority Review Voucher shall be solely responsible for the payment of the priority use review fee described in 21 U.S.C. § 360ff(c) (the "***Priority Review Fee***") and all other user fees applicable to the human drug application for which the Priority Review Voucher is redeemed, following the Closing. For the avoidance of doubt, following the Closing, Seller shall have no liability or obligation for any such fees.

10.3 Notices. Any notice or other communication required or permitted to be delivered to any Party shall be in writing and shall be deemed properly delivered, given and received: (a) when delivered by hand; or (b) upon such Party's receipt after being sent by registered mail, by courier or express delivery service, in any case to the address set forth beneath the name of such

Party below (or to such other address as such Party shall have specified in a written notice given to the other Party in accordance with this Section 10.3):

(i) if to Buyer, to: [***]

(ii) if to Seller, to:
Denali Therapeutics Inc.
161 Oyster Point Blvd.
South San Francisco, CA 94080
Attention: Alexander Schuth, Chief Operating & Financial Officer
with a copy (which shall not constitute notice) to:

Wilson Sonsini Goodrich & Rosati P.C.
12235 El Camino Real, Suite 200
San Diego, CA 92130
Attention: Miranda Biven & Norm Hovijitra

10.4 Construction.

(a) The Parties agree that any rule of construction to the effect that ambiguities are to be resolved against the drafting Party shall not be applied in the construction or interpretation of this Agreement.

(b) As used in this Agreement, the words "include" and "including," and variations thereof, shall not be deemed to be terms of limitation, but rather shall be deemed to be followed by the words "without limitation."

(c) Except as otherwise indicated, all references in this Agreement to "Articles" and "Sections" are intended to refer to Articles and Sections of this Agreement.

10.5 Counterparts. This Agreement may be executed in two or more counterparts, all of which shall be considered one and the same instrument, and shall become effective when one or more counterparts have been signed by each of the Parties hereto and delivered to the other Party hereto, it being understood that all Parties hereto need not sign the same counterpart. The exchange of a fully executed Agreement (in counterparts or otherwise) by electronic transmission or facsimile (including PDF or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., DocuSign) or other transmission method shall be sufficient to bind the Parties hereto to the terms and conditions of this Agreement.

10.6 Entire Agreement. This Agreement, including all exhibits and schedules attached hereto, set forth the entire understanding of the Parties relating to the subject matter hereof and supersede all prior agreements and understandings among or between the Parties relating to the subject matter hereof (including, without limitation, the Confidentiality Agreement). 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.

10.7 Assignment. No Party will have the right to assign this Agreement, in whole or in part, by operation of law or otherwise, without the other Party's express prior written consent.

Any attempt to assign this Agreement without such consent, will be null and void. Notwithstanding the foregoing, (a) Buyer may assign this Agreement, in whole or in part, without the consent of the Seller (i) to an Affiliate of Buyer, or (ii) to any purchaser, transferee, or assignee of any of the Purchased Assets in a single transaction, or series of transactions, whether by sale, merger, operation of law or otherwise, provided, that such assignment does not materially increase the amount of taxes required to be deducted or withheld from the Purchase Price, and (b) Seller may assign this Agreement, in whole or in part, without the consent of Buyer, to an Affiliate of Seller or to a successor to all or substantially all of the assets or business to which this Agreement pertains, whether by sale, merger, operation of law or otherwise. For the avoidance of doubt, no assignment made pursuant to this Section 10.7 shall relieve the assigning Party of any of its obligations under this Agreement. Subject to the foregoing, this Agreement will bind and inure to the benefit of each Party's successors and permitted assigns.

10.8 Severability. If any provision of this Agreement, or the application thereof, becomes or is declared by a court of competent jurisdiction to be illegal, void or unenforceable, the remainder of this Agreement shall continue in full force and effect and shall be interpreted so as reasonably to effect the intent of the Parties hereto. The Parties hereto shall use commercially reasonable efforts to replace such void or unenforceable provision of this Agreement with a valid and enforceable provision that shall achieve, to the extent possible, the economic, business and other purposes of such void or unenforceable provision.

10.9 Remedies Cumulative.

(a) Except as otherwise provided herein, any and all remedies herein expressly conferred upon a Party hereto shall be deemed cumulative with and not exclusive of any other remedy conferred hereby or by law or equity upon such Party, and the exercise by a Party hereto of any one remedy shall not preclude the exercise of any other remedy and nothing in this Agreement shall be deemed a waiver by any Party of any right to specific performance or injunctive relief.

(b) The Parties agree that irreparable harm may occur if any of the provisions of this Agreement are not performed in accordance with their specific terms or otherwise breached, and that money damages or other legal remedies may not be an adequate remedy for any such harm. Accordingly, the Parties acknowledge and hereby covenant and agree that in the event of any breach or threatened breach of the covenants, agreements, or obligations set forth in this Agreement, then in addition to any other remedy available at law or in equity, the non-breaching Party will be entitled to seek an injunction or injunctions to prevent or restrain any breaches or threatened breaches of this Agreement, and to specifically enforce the terms and provisions of this Agreement to enforce compliance with the covenants, agreements, and obligations under this Agreement. Each Party hereby covenants and agrees not to raise, and irrevocably waives, any objections to the availability of such relief that a remedy at law would be adequate and that a bond or other security will be required.

10.10 Governing Law. This Agreement shall be governed by, and construed in accordance with, the laws of the State of Delaware, regardless of the laws that might otherwise govern under applicable principles of conflicts of law. The Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United States District Court in Wilmington, Delaware (or if such court does not have subject matter jurisdiction, a state court of

the State of Delaware located in Wilmington, Delaware) solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement.

10.11 WAIVER OF JURY TRIAL. TO THE EXTENT NOT PROHIBITED BY APPLICABLE LEGAL REQUIREMENTS THAT CANNOT BE WAIVED, THE PARTIES HEREBY WAIVE, AND COVENANT THAT THEY WILL NOT ASSERT (WHETHER AS PLAINTIFF, DEFENDANT OR OTHERWISE), ANY RIGHT TO TRIAL BY JURY IN ANY PROCEEDING ARISING IN WHOLE OR IN PART UNDER OR IN CONNECTION WITH THIS AGREEMENT OR THE ASSET PURCHASE, WHETHER NOW EXISTING OR HEREAFTER ARISING, AND WHETHER SOUNDING IN CONTRACT, TORT OR OTHERWISE. THE PARTIES AGREE THAT EITHER OF THEM MAY FILE A COPY OF THIS SECTION 10.11 WITH ANY COURT AS WRITTEN EVIDENCE OF THE KNOWING, VOLUNTARY AND BARGAINED-FOR AGREEMENT BETWEEN THE PARTIES IRREVOCABLY TO WAIVE THEIR RESPECTIVE RIGHTS TO TRIAL BY JURY IN ANY PROCEEDING WHATSOEVER BETWEEN THEM RELATING TO THIS AGREEMENT OR THE ASSET PURCHASE AND THAT SUCH ACTIONS WILL INSTEAD BE TRIED IN A COURT OF COMPETENT JURISDICTION BY A JUDGE SITTING WITHOUT A JURY.

10.12 Amendment; Extension; Waiver. Subject to the provisions of applicable law, the Parties hereto may amend this Agreement at any time pursuant to an instrument in writing signed on behalf of each of the Parties hereto. At any time, any Party hereto may, to the extent legally allowed, (a) extend the time for the performance of any of the obligations or other acts of the other Party hereto, (b) waive any inaccuracies in the representations and warranties made to such Party contained herein or (c) waive compliance with any of the agreements or conditions for the benefit of such Party contained herein. Any agreement on the part of a Party hereto to any such extension or waiver shall be valid only if set forth in an instrument in writing signed on behalf of such Party. Without limiting the generality or effect of the preceding sentence, no delay in exercising any right under this Agreement shall constitute a waiver of such right, and no waiver of any breach or default shall be deemed a waiver of any other breach or default of the same or any other provision in this Agreement.

10.13 Representation By Counsel; Interpretation. Seller and Buyer each acknowledge that it has been represented by its own legal counsel in connection with this Agreement and the Asset Purchase contemplated by this Agreement. Accordingly, any rule of law, or any legal decision that would require interpretation of any claimed ambiguities in this Agreement against the Party that drafted it, has no application and is expressly waived.

10.14 Expenses. Except as otherwise expressly set forth in this Agreement, each of the Parties shall bear its own fees and expenses incurred in connection with this Agreement and the Asset Purchase contemplated by this Agreement.

[*Signature Page Follows*]

IN WITNESS WHEREOF, each of Buyer and Seller has caused this Asset Purchase Agreement to be executed and delivered by their respective officers thereunto duly authorized, all as of the date first written above.

DENALI THERAPEUTICS INC.

By:
Name:
Title:

IN WITNESS WHEREOF, each of Buyer and Seller has caused this Asset Purchase Agreement to be executed and delivered by their respective officers thereunto duly authorized, all as of the date first written above.

[***]

Exhibit A

FDA Approval Letter

[***]Exhibit B

Form of Bill of Sale

[***]Exhibit C-1

Form of Seller FDA PRV Transfer Acknowledgement Letter

[***]Exhibit C-2

Form of Buyer FDA PRV Transfer Acknowledgement Letter [***]

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;

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: August 6, 2026

/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, Alexander O. Schuth, M.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;

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: August 6, 2026

/s/ Alexander O. Schuth

Alexander O. Schuth, M.D.
Chief Operating and Financial Officer

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 fiscal period ended June 30, 2026, 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: August 6, 2026

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, Alexander O. Schuth, M.D., Chief Operating and Financial Officer of Denali Therapeutics Inc. (the "Company"), hereby certify that:

1. The Company's Quarterly Report on Form 10-Q for the fiscal period ended June 30, 2026, 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: August 6, 2026

By: /s/ Alexander O. Schuth
Name: Alexander O. Schuth, M.D.
Title: Chief Operating and Financial Officer