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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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 October 28, 2026 was 160,290,546. This number does not include 28,331,779 shares of common stock issuable upon the exercise of pre-funded warrants outstanding as of October 28, 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)

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 102,870	$ 205,326
Short-term marketable securities	413,326	662,553
Accounts receivable, net	18,882	—
Inventory	26,275	—
Prepaid expenses and other current assets	30,355	32,779
Total current assets	591,708	900,658
Long-term marketable securities	491,376	98,322
Property and equipment, net	47,907	52,402
Finance lease right-of-use asset	45,784	48,531
Operating lease right-of-use asset	15,612	19,002
Intangible asset, net	34,500	—
Other non-current assets	29,148	25,939
Total assets	$ 1,256,035	$ 1,144,854
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 13,700	$ 505
Accrued expenses and other current liabilities	81,558	97,846
Total current liabilities	95,258	98,351
Operating lease liability, less current portion	19,280	27,210
Finance lease liability, less current portion	5,449	5,532
Liability related to the revenue participation right agreement	209,661	—
Total liabilities	329,648	131,093
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Convertible preferred stock, $0.01 par value; 40,000,000 shares authorized as of September 30, 2026 and December 31, 2025; 0 shares issued and outstanding as of September 30, 2026 and December 31, 2025	—	—
Common stock, $0.01 par value; 400,000,000 shares authorized as of September 30, 2026 and December 31, 2025; 160,257,940 shares and 156,182,177 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	1,929	1,888
Additional paid-in capital	3,168,215	3,062,715
Accumulated other comprehensive income (loss)	(6,359)	682
Accumulated deficit	(2,237,398)	(2,051,524)
Total stockholders' equity	926,387	1,013,761
Total liabilities and stockholders' equity	$ 1,256,035	$ 1,144,854

See accompanying notes to unaudited condensed consolidated financial statements.

Denali Therapeutics Inc.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenue:				
Product revenue, net	$ 17,778	$ —	$ 21,382	$ —
Total revenue	17,778	—	21,382	—
Operating expenses:				
Cost of goods sold	192	—	285	—
Research and development	106,102	101,950	306,967	320,873
Selling, general and administrative	37,485	35,484	107,279	97,104
Intangible asset amortization	750	—	1,500	—
Total operating expenses	144,529	137,434	416,031	417,977
Loss from operations	(126,751)	(137,434)	(394,649)	(417,977)
Other income:				
Gain on sale of priority review voucher, net	194,000	—	194,000	—
Interest and other income, net	2,877	10,532	14,775	33,986
Total other income	196,877	10,532	208,775	33,986
Net income (loss)	$ 70,126	$ (126,902)	$ (185,874)	$ (383,991)
Other comprehensive income (loss):				
Net unrealized gain (loss) on marketable securities, net of tax	(4,390)	162	(7,041)	(919)
Comprehensive income (loss)	$ 65,736	$ (126,740)	$ (192,915)	$ (384,910)
Net income (loss) per share:				
Basic	$ 0.37	$ (0.74)	$ (0.99)	$ (2.24)
Diluted	$ 0.37	$ (0.74)	$ (0.99)	$ (2.24)
Weighted-average shares used in calculating net income (loss) per share:				
Basic	188,387,660	172,421,492	187,452,793	171,702,183
Diluted	192,077,855	172,421,492	187,452,793	171,702,183

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	1,617,307	16	24,298	—	—	24,314
Vesting of restricted stock units	1,711,988	17	(17)	—	—	—
Stock-based compensation	—	—	68,861	—	—	68,861
Net loss	—	—	—	—	(185,874)	(185,874)
Other comprehensive loss	—	—	—	(7,041)	—	(7,041)
Balance at September 30, 2026	160,257,940	$ 1,929	$ 3,168,215	$ (6,359)	$ (2,237,398)	$ 926,387
Balance at June 30, 2026	159,755,526	$ 1,924	$ 3,142,747	$ (1,969)	$ (2,307,524)	$ 835,178
Issuances under equity incentive plans	132,382	1	2,613	—	—	2,614
Vesting of restricted stock units	370,032	4	(4)	—	—	—
Stock-based compensation	—	—	22,859	—	—	22,859
Net income	—	—	—	—	70,126	70,126
Other comprehensive loss	—	—	—	(4,390)	—	(4,390)
Balance at September 30, 2026	160,257,940	$ 1,929	$ 3,168,215	$ (6,359)	$ (2,237,398)	$ 926,387
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	1,042,249	11	5,224	—	—	5,235
Vesting of restricted stock units	1,362,487	14	(14)	—	—	—
Stock-based compensation	—	—	76,188	—	—	76,188
Net loss	—	—	—	—	(383,991)	(383,991)
Other comprehensive loss	—	—	—	(919)	—	(919)
Balance at September 30, 2025	146,625,722	$ 1,793	$ 2,846,278	$ 1,101	$ (1,922,975)	$ 926,197
Balance at June 30, 2025	145,685,442	$ 1,783	$ 2,820,404	$ 939	$ (1,796,073)	$ 1,027,053
Issuances under equity incentive plans	586,914	6	577	—	—	583
Vesting of restricted stock units	353,366	4	(4)	—	—	—
Stock-based compensation	—	—	25,301	—	—	25,301
Net loss	—	—	—	—	(126,902)	(126,902)
Other comprehensive income	—	—	—	162	—	162
Balance at September 30, 2025	146,625,722	$ 1,793	$ 2,846,278	$ 1,101	$ (1,922,975)	$ 926,197

See accompanying notes to unaudited condensed consolidated financial statements.

Denali Therapeutics Inc.

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

	Nine Months Ended September 30,	
	2026	**2025**
Operating activities		
Net loss	$ (185,874)	$ (383,991)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	9,989	8,317
Stock-based compensation expense	68,861	75,682
Net accretion of discounts on marketable securities	(3,722)	(8,611)
Non-cash adjustment to operating lease expense	(3,595)	(3,305)
Right-of-use asset amortization for finance lease	2,747	2,713
Gain on sale of priority review voucher, net	(194,000)	—
Non-cash interest expense related to revenue participation right liability	11,725	—
Other non-cash items	(1,252)	—
Changes in operating assets and liabilities:		
Accounts receivable	(18,882)	—
Inventory	(26,275)	—
Prepaid expenses and other current assets	2,522	(2,287)
Other non-current assets	(3,628)	1,305
Accounts payable	13,007	(4,112)
Accruals and other current liabilities	(12,591)	(12,262)
Deferred research and development funding liability	(4,681)	12,489
Net cash used in operating activities	(345,649)	(314,062)
Investing activities		
Purchases of marketable securities	(749,801)	(188,555)
Maturities and sales of marketable securities	602,655	431,046
Purchases of property and equipment	(4,281)	(7,978)
Cash paid to acquire finite-lived intangible asset	(36,000)	—
Proceeds from sale of priority review voucher, net of transaction costs paid	194,000	—
Net cash provided by investing activities	6,573	234,513
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	24,314	5,235
Payments for finance lease right-of-use asset	(60)	(8,152)
Net cash provided by (used in) financing activities	236,620	(2,917)
Net decrease in cash, cash equivalents and restricted cash	(102,456)	(82,466)
Cash, cash equivalents and restricted cash at beginning of period	208,432	176,535
Cash, cash equivalents and restricted cash at end of period	$ 105,976	$ 94,069

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 nine months ended September 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 Income (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 Income (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 September 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 nine months ended September 30, 2026, one customer accounted for substantially all product revenues. As of September 30, 2026, one customer accounted for substantially 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 nine months ended September 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 September 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 Income (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 September 30, 2026, the credit profiles of the customers were 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 second quarter of 2026. AVLAYAH is the Company's only commercial product, and substantially 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 program assists commercially insured patients and is 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 the 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 expenses and other 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.

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 Condensed Consolidated Statements of Operations and Comprehensive Income (Loss).

Inventory that is 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 are not 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 Income (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 Income (Loss)

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

Net Income (Loss) Per Share

Basic net income (loss) per share is calculated by dividing the net income (loss) by the weighted-average number of shares of common stock outstanding during the period, without consideration for common stock equivalents. The weighted-average common shares outstanding for the three and nine months ended September 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.

Diluted net income (loss) per share gives effect to potentially dilutive common stock equivalents, including outstanding stock options, unvested restricted stock units and shares issuable under the Employee Stock Purchase Plan, using the treasury stock method. Potential common shares are excluded from diluted net income (loss) per share when their effect would be anti-dilutive. For periods in which the Company reports a net loss, diluted net loss per share is the same as basic net loss per share because the effect of all potentially dilutive common shares is anti-dilutive.

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):

	September 30, 2026			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 56,541	$ —	$ —	$ 56,541
U.S. government treasuries	9,998	—	—	9,998
Short-term marketable securities:				
U.S. government treasuries	322,971	—	—	322,971
Corporate debt securities	—	90,355	—	90,355
Long-term marketable securities:				
U.S. government treasuries	336,811	—	—	336,811
Corporate debt securities	—	154,565	—	154,565
Total	$ 726,321	$ 244,920	$ —	$ 971,241

	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 nine months ended September 30, 2026 or for the year ended December 31, 2025.

3. Marketable Securities

All marketable securities were considered available-for-sale at September 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):

	September 30, 2026			
	Amortized Cost	Unrealized Holding Gains	Unrealized Holding Losses	Aggregate Fair Value
Short-term marketable securities:				
U.S. government treasuries	$ 323,797	$ —	$ (826)	$ 322,971
Corporate debt securities	90,690	—	(335)	90,355
Total short-term marketable securities	414,487	—	(1,161)	413,326
Long-term marketable securities:				
U.S. government treasuries	339,842	—	(3,031)	336,811
Corporate debt securities	156,378	—	(1,813)	154,565
Total long-term marketable securities	496,220	—	(4,844)	491,376
Total	$ 910,707	$ —	$ (6,005)	$ 904,702

	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 September 30, 2026 and December 31, 2025, the Company had marketable securities in an unrealized loss position. The Company has not recognized an allowance for credit losses as of September 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 September 30, 2026, all of the Company's marketable securities have an effective maturity of less than three years.

4. Inventory

Inventory consisted of the following (in thousands):

	September 30, 2026	December 31, 2025
Raw materials	$ 21,435	$ —
Work in process	4,376	—
Finished goods	464	—
Total inventory	$ 26,275	$ —

No adjustments to the carrying value of inventory were recorded during the three and nine months ended September 30, 2026 and 2025, respectively. All inventory as of September 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. As of September 30, 2026, the Company had paid the $36.0 million milestone payment in full.

The Company recognized amortization expense of $0.8 million and $1.5 million for the three and nine months ended September 30, 2026, respectively. As of September 30, 2026, the accumulated amortization expense was $1.5 million, and the carrying value of the intangible asset was $34.5 million.

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

Years Ending December 31:	Amount
2026 (three months)	$ 750
2027	3,000
2028	3,000
2029	3,000
2030	3,000
Thereafter	21,750
Total	$ 34,500

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 nine months ended September 30, 2026, resulting in cumulative payments received of $62.5 million as of September 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 $3.6 million and $3.7 million for the three months ended September 30, 2026 and 2025, respectively, and $17.2 million and $12.5 million for the nine months ended September 30, 2026 and 2025, respectively, in the Condensed Consolidated Statements of Operations and Comprehensive Income (Loss). The Company recorded current deferred research and development funding liabilities of $16.4 million and $21.1 million on the Condensed Consolidated Balance Sheets as of September 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 September 30, 2026 or December 31, 2025. As of September 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 September 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 September 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, costs, 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 September 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 Income (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 Income (Loss) are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Takeda Collaboration Agreement:				
PTV:PGRN cost sharing (reimbursements)	$ —	$ (1,929)	$ (3,130)	$ (4,864)
ATV:TREM2 cost sharing (reimbursements)	—	—	—	(147)
Total Takeda cost sharing (reimbursements)[1]	—	(1,929)	(3,130)	(5,011)
Biogen Collaboration Agreement: LRRK2 cost sharing payments[2]	732	4,100	6,619	12,980
Net cost sharing payments (reimbursements)	$ 732	$ 2,171	$ 3,489	$ 7,969

(1) No cost sharing reimbursement asset or liability was recorded as of September 30, 2026. As of December 31, 2025, $1.6 million of cost sharing reimbursements was recorded as a receivable within prepaid expenses and other current assets on the Condensed Consolidated Balance Sheets.

(2) Cost sharing payments due to Biogen of $0.7 million and $2.8 million were recorded within other accrued expenses and other current liabilities on the Condensed Consolidated Balance Sheets as of September 30, 2026 and December 31, 2025, respectively.

8. Balance Sheet Components

Accrued Expenses and Other Current Liabilities

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

	As of	
	September 30, 2026	December 31, 2025
Accrued compensation	$ 20,693	$ 32,179
Accrued clinical and other research & development costs	16,568	22,283
Accrued manufacturing costs	9,502	5,336
Operating lease liability, current	10,407	9,463
Finance lease liability, current	105	83
Deferred research and development funding liability, current	16,420	21,101
Other accrued costs and current liabilities	7,863	7,401
Total accrued expenses and other current liabilities	$ 81,558	$ 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 September 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 September 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 September 30, 2026, the Company's estimate of total future royalty payments resulted in an effective annual interest rate of approximately 12%, and the Company recorded $6.1 million and $12.1 million of interest expense during the three and nine months ended September 30, 2026, respectively. A royalty payment of $0.3 million was made during the three and nine months ended September 30, 2026.

As of September 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 nine months ended September 30, 2026 or 2025.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating lease cost	$ 1,853	$ 1,896	$ 5,527	$ 5,682
Finance lease cost:				
Amortization of ROU assets	916	915	2,747	2,713
Interest	177	180	534	541
Variable lease cost	1,449	1,581	4,281	4,272
Total lease costs	$ 4,395	$ 4,572	$ 13,089	$ 13,208

Operating cash flows for operating leases were $3.1 million and $3.0 million for the three months ended September 30, 2026 and 2025, respectively, and $9.1 million and $8.8 million for the nine months ended September 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 Income (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 $95.8 million as of September 30, 2026, of which $84.5 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 September 30, 2026, pre-funded warrants to purchase 28,331,779 shares of common stock remained outstanding, and no pre-funded warrants were exercised during the nine months ended September 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 nine months ended September 30, 2026:

	Number of Options	Weighted-Average Exercise Price
Balance at December 31, 2025	21,326,333	$ 26.39
Granted	2,980,999	17.70
Exercised	(1,125,249)	16.27
Forfeited	(879,600)	20.66
Expired	(1,058,477)	36.42
Balance at September 30, 2026	21,244,006	$ 25.44
Vested and expected to vest at September 30, 2026	21,244,006	$ 25.44
Exercisable at September 30, 2026	14,444,354	$ 28.34

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

	Nine Months Ended September 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% - 4.6%	3.6% - 4.5%
Dividend yield	—	—

Restricted Stock Activity

The following table summarizes restricted stock unit ("RSU") activity for the nine months ended September 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	3,904,424	17.49
Vested and released	(1,711,988)	23.99
Forfeited	(781,347)	19.34
Unvested and expected to vest at September 30, 2026	6,535,718	$ 18.90

Stock-Based Compensation Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 12,976	$ 15,178	$ 40,024	$ 45,503
General and administrative	9,883	9,957	28,837	30,179
Total	$ 22,859	$ 25,135	$ 68,861	$ 75,682

13. Net Income (Loss) Per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Numerator:				
Net income (loss)	$ 70,126	$ (126,902)	$ (185,874)	$ (383,991)
Denominator:				
Weighted-average number of:				
Common stock shares outstanding	160,055,881	146,375,427	159,121,014	145,656,118
Pre-funded warrants	28,331,779	26,046,065	28,331,779	26,046,065
Weighted-average number of shares outstanding, basic	188,387,660	172,421,492	187,452,793	171,702,183
Dilutive effect of outstanding common stock options, ESPP shares issuable, and restricted shares	3,690,195	—	—	—
Weighted-average number of shares outstanding, diluted	192,077,855	172,421,492	187,452,793	171,702,183
Net income (loss) per share, basic	$ 0.37	$ (0.74)	$ (0.99)	$ (2.24)
Net income (loss) per share, diluted	$ 0.37	$ (0.74)	$ (0.99)	$ (2.24)

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 16.6 million and 28.3 million shares for the three and nine months ended September 30, 2026, respectively, and 27.4 million shares for both the three and nine months ended September 30, 2025.

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 September 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 nine months ended September 30, 2026 and 2025 (in thousands):

	Therapeutics Segment			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Product revenue, net	$ 17,778	$ —	$ 21,382	$ —
Less:				
Cost of goods sold	192	—	285	—
External research and development expenses - TV programs, including cost sharing	43,574	35,157	122,457	119,209
Other research and development expenses, including small molecule programs	21,145	25,056	61,193	79,403
Personnel related research and development expenses	41,383	41,737	123,317	122,261
Total research and development expenses	106,102	101,950	306,967	320,873
Personnel related selling, general and administrative expenses	22,502	22,079	67,987	60,932
Other selling, general and administrative expenses	14,983	13,405	39,292	36,172
Total selling, general and administrative expenses	37,485	35,484	107,279	97,104
Intangible asset amortization	750	—	1,500	—
Segment operating expenses	144,529	137,434	416,031	417,977
Segment loss from operations	(126,751)	(137,434)	(394,649)	(417,977)
Gain on sale of priority review voucher, net	194,000	—	194,000	—
Segment interest and other income, net	2,877	10,532	14,775	33,986
Segment net income (loss)	$ 70,126	$ (126,902)	$ (185,874)	$ (383,991)

There is no difference between the segment net income (loss) and total consolidated net income (loss) for the three and nine months ended September 30, 2026 and 2025.

16. Sale of Priority Review Voucher

In June 2026, the Company entered into an asset purchase agreement (the "PRV Transfer Agreement") for the sale of 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.

In July 2026, the Company completed the sale and received net proceeds of $194.0 million after deducting transaction costs paid at closing. These net proceeds were recognized as a gain, presented separately within Other income in the Company's Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) for the three and nine months ended September 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, including sales and revenue forecasts;*
- *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 AD;

- DNL151 is an investigational small molecule inhibitor of leucine-rich repeat kinase 2 (LRRK2). Denali is conducting 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 Ph 3 (start-up)	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	DNL921	Ph 1/1b	Alzheimer’s disease	Denali
LRRK2	DNL151	Ph 2a	Parkinson's disease	Denali
RIPK1 (Peripheral)	eclitasertib, or SAR443122/DNL758	Ph 2	UC	Sanfi

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 PRV for gross proceeds of $195.0 million. The transaction closed and proceeds were received in July 2026;

- 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 the first healthy volunteer was dosed in August 2026; and

- In the third quarter of 2026, the Phase 1/2 study of zafinofusp alfa (DNL126; ETV:SGSH) for Sanfilippo syndrome type A completed the prespecified treatment duration for the primary endpoint. The study enrolled 20 participants across the pediatric age range. A Biologic License Application seeking accelerated approval remains on track for submission in 2027, and we are conducting start-up activities for a global Phase 3 confirmatory 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 September 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 income of $70.1 million and a net loss of $185.9 million for the three and nine months ended September 30, 2026, respectively, and net losses of $126.9 million and $384.0 million for the three and nine months ended September 30, 2025, respectively. Net income for the three months ended September 30, 2026, included a one-time gain of $194.0 million from the sale of our priority review voucher, as described above. As of September 30, 2026, we had an accumulated deficit of $2.24 billion. Our ability to grow product revenue will depend on the continued commercialization of AVLAYAH and the successful development and commercialization of our product candidates. We expect to continue to incur significant expenses and operating losses as we advance our approved product AVLAYAH to full U.S. 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 nine months ended September 30, 2026 and 2025

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

	Three Months Ended September 30,		Change	
	2026	2025	$	%
Revenue:				
Product revenue, net	$ 17,778	$ —	$ 17,778	* %
Total revenue	17,778	—	17,778	*
Operating expenses:				
Cost of goods sold	192	—	192	*
Research and development	106,102	101,950	4,152	4
Selling, general and administrative	37,485	35,484	2,001	6
Intangible asset amortization	750	—	750	*
Total operating expenses	144,529	137,434	7,095	5
Loss from operations	(126,751)	(137,434)	10,683	(8)
Other income:				
Gain on sale of priority review voucher, net	194,000	—	194,000	*
Interest and other income, net	2,877	10,532	(7,655)	(73)
Total other income	196,877	10,532	186,345	*
Net income (loss)	$ 70,126	$ (126,902)	$ 197,028	* %

	Nine Months Ended September 30,		Change	
	2026	2025	$	%
Revenue:				
Product revenue, net	$ 21,382	$ —	$ 21,382	* %
Total revenue	21,382	—	21,382	*
Operating expenses:				
Cost of goods sold	285	—	285	*
Research and development	306,967	320,873	(13,906)	(4)
Selling, general and administrative	107,279	97,104	10,175	10
Intangible asset amortization	1,500	—	1,500	*
Total operating expenses	416,031	417,977	(1,946)	—
Loss from operations	(394,649)	(417,977)	23,328	(6)
Other income:				
Gain on sale of priority review voucher, net	194,000	—	194,000	*
Interest and other income, net	14,775	33,986	(19,211)	(57)
Total other income	208,775	33,986	174,789	*
Net income (loss)	$ (185,874)	$ (383,991)	$ 198,117	(52) %

* Percentage is not meaningful.

Product revenue, net

Product revenue was $17.8 million and $21.4 million for the three and nine months ended September 30, 2026, respectively, 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 $0.2 million and $0.3 million for the three and nine months ended September 30, 2026, respectively, 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. As of September 30, 2026, we had $4.5 million of expensed pre-launch inventory, which we expect to be sold through by December 2026. We expect cost of goods sold per unit to increase as this inventory is depleted.

Research and development expenses

Research and development expenses were $106.1 million and $102.0 million for the three months ended September 30, 2026 and 2025, respectively, and $307.0 million and $320.9 million for the nine months ended September 30, 2026 and 2025, respectively.

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

	Three Months Ended September 30,		Change	
	2026	2025	$	%
External research and development expenses - TV programs, including cost sharing	$ 43,574	$ 35,157	$ 8,417	24 %
Other research and development expenses, including small molecule programs	21,145	25,056	(3,911)	(16)
Personnel related expenses[(1)]	41,383	41,737	(354)	(1)
Total research and development expenses	$ 106,102	$ 101,950	$ 4,152	4 %

(1) Personnel related expenses include stock-based compensation expense of $13.0 million and $15.2 million for the three months ended September 30, 2026 and 2025, respectively, reflecting a decrease of $2.2 million.

The increase in research and development expenses of approximately $4.2 million for the three months ended September 30, 2026 compared to the three months ended September 30, 2025, was primarily attributable to the following:

- An increase of $8.4 million in TV programs external research and development expenses is driven by increased investment in clinical activity for zafinofusp alfa and DNL921, termination of collaboration agreement on DNL593 with Takeda, and higher contract research services across multiple pre-clinical programs.

- A decrease of $3.9 million in other research and development expenses is driven by timing of purchase of raw materials at our large molecule manufacturing facility in Salt Lake City, Utah, and lower clinical costs for DNL151; partially offset by higher internal manufacturing costs for zafinofusp alfa.

	Nine Months Ended September 30,		Change	
	2026	2025	$	%
External research and development expenses - TV programs, including cost sharing	$ 122,457	$ 119,209	$ 3,248	3
Other research and development expenses	61,193	79,403	(18,210)	(23
Personnel related expenses[1]	123,317	122,261	1,056	1
Total research and development expenses	$ 306,967	$ 320,873	$ (13,906)	(4

(1) Personnel related expenses include stock-based compensation expense of $40.0 million and $45.5 million for the nine months ended September 30, 2026 and 2025, respectively, reflecting a decrease of $5.5 million.

The decrease in research and development expenses of approximately $13.9 million for the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025, was primarily attributable to the following:

- A decrease of $18.2 million in other research and development expenses is driven by lower clinical expenses for our previous small molecule eIF2B activator program DNL343 and lower clinical costs for DNL151.
- An increase of $3.2 million in external TV research and development expenses is driven by higher clinical expenses for zafinofusp alfa, DNL952 and DNL921, higher manufacturing and contract research services expenses across multiple pre-clinical programs; partially offset by lower manufacturing expenses for DNL628 and lower clinical expense for AVLAYAH.

- An increase of $1.1 million in personnel-related expenses is driven by increased R&D headcount year over year.

Selling, general and administrative expenses

Selling, general and administrative expense was $37.5 million and $35.5 million for the three months ended September 30, 2026 and 2025, respectively. The $2.0 million increase was primarily attributable to the following:

- An increase of $1.6 million in other selling, general and administrative expenses is driven by higher commercial and medical affairs expenses and South San Francisco site costs.

- An increase of $0.4 million in personnel expenses is driven by increased headcount related to the commercial launch of AVLAYAH.

Selling, general and administrative expense was $107.3 million and $97.1 million for the nine months ended September 30, 2026 and 2025, respectively. The $10.2 million increase was primarily attributable to the following:

- An increase of $7.1 million in personnel expenses is driven by increased headcount related to the commercial launch of AVLAYAH.
- An increase of $3.1 million in other selling, general and administrative expenses is driven by higher South San Francisco site costs, commercial and medical affairs expenses and consulting.

Intangible asset amortization

Intangible asset amortization was $0.8 million and $1.5 million for the three and nine months ended September 30, 2026, 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.

Gain on sale of priority review voucher, net

Gain on sale of priority review voucher, net was $194.0 million for the three and nine months ended September 30, 2026, with no corresponding gain in the prior-year periods. The gain resulted from the sale in July 2026 of the PRV received in connection with the FDA accelerated approval of AVLAYAH in March 2026 and reflects proceeds net of transaction costs paid at closing.

Interest and other income, net

Interest and other income, net was $2.9 million and $10.5 million for the three months ended September 30, 2026 and 2025, respectively. The decrease of approximately $7.7 million was primarily driven by $6.1 million of 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 $14.8 million and $34.0 million for the nine months ended September 30, 2026 and 2025, respectively. The decrease of approximately $19.2 million was primarily driven by:

- $12.1 million of 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;
- lower interest income due to lower average cash and investment balances; and
- lower yields on our investment portfolio.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2026, we had cash, cash equivalents and marketable securities in the amount of $1.0 billion. 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 September 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 Administration’s accelerated approval of AVLAYAH. Under stock purchase agreements with collaboration partners we have received a further $575.0 million through September 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, and all sales under the equity distribution agreement would be conditioned upon satisfaction of customary closing conditions.

Through September 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 $59.8 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 net proceeds of $194.0 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 $2.24 billion as of September 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 September 30, 2026, we had total undiscounted lease payment obligations of $44.5 million. We had total non-refundable purchase commitments of $95.8 million as of September 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 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;
- 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; and
- 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):

	Nine Months Ended September 30,	
	2026	**2025**
Net cash used in operating activities	$ (345,649)	$ (314,062)
Net cash provided by investing activities	6,573	234,513
Net cash provided by (used in) financing activities	236,620	(2,917)
Net decrease in cash, cash equivalents and restricted cash	$ (102,456)	$ (82,466)

Net Cash Used In Operating Activities

During the nine months ended September 30, 2026, net cash used in operating activities was $345.6 million, which consisted of a net loss of $185.9 million, adjusted by gain on sale of priority review voucher, 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 Provided By Investing Activities

During the nine months ended September 30, 2026, net cash provided by investing activities was $6.6 million, which consisted of $602.7 million in proceeds from the maturities of marketable securities and $194.0 million in proceeds from the sale of PRV, partially offset by $749.8 million for purchases of marketable securities, $36.0 million in milestone payments related to intangible assets, and $4.3 million in capital expenditures to purchase property and equipment.

Net Cash Provided By Financing Activities

During the nine months ended September 30, 2026, net cash provided by financing activities was $236.6 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 $24.3 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 nine months ended September 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 nine months ended September 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 $1.0 billion as of September 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, 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, commercial, and manufacturing activities.

ITEM 4. CONTROLS AND PROCEDURES

Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures

As of September 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 September 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

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended September 30, 2026 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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 quarters ended March 31, 2026 and June 30, 2026, filed with the SEC on May 7, 2026 and August 6, 2026, respectively, 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

Use of Proceeds from Registered Securities

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 pre-funded warrants to purchase 2,285,714 shares of Common Stock 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 directors, officers, 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 third quarter of 2026, certain directors and officers adopted "Rule 10b5-1 trading arrangements". These plans provide for the sale of our common stock and are 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]
Ryan Watts	CEO	8/10/2026	2/26/2028	376,751
David Schenkein	Director	8/31/2026	5/20/2028	51,083

(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 a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as defined in Regulation S-K Item 408, during the third quarter ended September 30, 2026.

ITEM 6. EXHIBITS

EXHIBIT INDEX

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Number	Filing Date
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 Inline XBRL document	—	—	—	Furnished herewith
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	—	—	—	Furnished herewith
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	—	—	—	Furnished herewith
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	—	—	—	Furnished herewith
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	—	—	—	Furnished herewith
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	—	—	—	Furnished herewith
104	The cover page from the Company's Quarterly Report on Form 10-Q for the three months ended September 30, 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: November 3, 2026

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

Date: November 3, 2026

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

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: November 3, 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: November 3, 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 September 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: November 3, 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 September 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: November 3, 2026

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