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, 2025
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: 001-34186

VANDA PHARMACEUTICALS INC.
(Exact name of registrant as specified in its charter)

Delaware	**03-0491827**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

2200 Pennsylvania Avenue NW, Suite 300E
Washington, DC 20037
(202) 734-3400
(Registrant's telephone number, including area code)

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

Title of Each Class	Trading Symbol(s)	Name of Exchange on Which Registered
Common Stock, par value $0.001 per share	**VNDA**	**The Nasdaq Global 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 ☒

As of October 23, 2025, there were 59,096,630 shares of the registrant's common stock issued and outstanding.

Vanda Pharmaceuticals Inc.

Quarterly Report on Form 10-Q
For the Quarter Ended September 30, 2025

Table of Contents

		Page
PART I – FINANCIAL INFORMATION		
ITEM 1	Financial Statements (Unaudited)	5
	Condensed Consolidated Balance Sheets as of September 30, 2025 and December 31, 2024	5
	Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2025 and 2024	6
	Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2025 and 2024	7
	Condensed Consolidated Statements of Changes in Stockholders' Equity for the three and nine months ended September 30, 2025 and 2024	8
	Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2025 and 2024	10
	Notes to Condensed Consolidated Financial Statements	11
ITEM 2	Management's Discussion and Analysis of Financial Condition and Results of Operations	27
ITEM 3	Quantitative and Qualitative Disclosures about Market Risk	37
ITEM 4	Controls and Procedures	38
PART II – OTHER INFORMATION		
ITEM 1	Legal Proceedings	38
ITEM 1A	Risk Factors	38
ITEM 2	Unregistered Sales of Equity Securities and Use of Proceeds	38
ITEM 3	Defaults Upon Senior Securities	39
ITEM 4	Mine Safety Disclosures	39
ITEM 5	Other Information	39
ITEM 6	Exhibits	40
Signatures		41

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q (Quarterly Report) contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act). Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "plan," "project," "target," "goal," "likely," "will," "would," and "could," or the negative of these terms and similar expressions or words, identify forward-looking statements. Forward-looking statements are based upon current expectations and assumptions that involve risks, changes in circumstances and uncertainties. If the risks, changes in circumstances or uncertainties materialize or the assumptions prove incorrect, the results of Vanda Pharmaceuticals Inc. (we, our, the Company or Vanda) may differ materially from those expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The forward-looking statements in this Quarterly Report may include, but are not limited to, statements about:

- our ability to commercialize Fanapt® (iloperidone) oral tablets for the acute treatment of manic or mixed episodes associated with bipolar I disorder;
- our ability to continue to generate United States (U.S.) sales of Fanapt® oral tablets for the treatment of schizophrenia;
- our ability to obtain approval from the U.S. Food and Drug Administration (FDA) for Bysanti™ (milsaperidone) for bipolar I disorder, schizophrenia and major depressive disorder (MDD);
- our ability to continue to commercialize HETLIOZ® (tasimelteon) capsules for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in the U.S., in light of existing and potential generic competition, and Europe and HETLIOZ® capsules and oral suspension (HETLIOZ LQ®) for the treatment of nighttime sleep disturbances in Smith-Magenis syndrome (SMS) in the U.S.;
- our ability to obtain approval from the FDA for HETLIOZ® beyond the currently approved indications;
- our ability to increase market awareness of Non-24 and SMS and market acceptance of HETLIOZ®;
- our ability to commercialize PONVORY® (ponesimod) tablets for the treatment of adults with relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease in the U.S. and Canada;
- our ability to obtain approval from the FDA for PONVORY® beyond the currently approved indications;
- our ability to obtain approval from the FDA for tradipitant for the treatment of gastroparesis and motion sickness;
- our ability to obtain approval from the FDA for imsidolimab for the treatment of generalized pustular psoriasis;
- our level of success in commercializing Fanapt® and HETLIOZ® in new markets;
- our ability to overcome the continued reimbursement and patient access challenges we face as a result of third-party payor coverage;
- the impact of public health crises, epidemics, pandemics or similar events on our business and operations, including our revenue, our supply chain, our commercial activities, our ongoing and planned clinical trials and our regulatory activities;
- our dependence on third-party manufacturers to manufacture Fanapt®, HETLIOZ®, HETLIOZ LQ® and PONVORY® in sufficient quantities and quality;
- our ability to prepare, file, prosecute, defend and enforce any patent claims and other intellectual property rights;
- our ability to maintain rights to develop and commercialize our products under our license agreements;
- our ability to obtain and maintain regulatory approval of our products, and the labeling for any approved products;
- our expectations regarding the timing and success of preclinical studies and clinical trials;
- the safety and efficacy of our products;
- regulatory developments in the U.S., Europe and other jurisdictions;
- limitations on our ability to utilize some or all of our prior net operating losses and orphan drug and research and development credits;
- our expectations regarding the size and growth of the current and potential markets for our products and our ability to serve those markets;

- our expectations regarding trends with respect to our revenues, costs, expenses, liabilities and cash, cash equivalents and marketable securities;
- our ability to identify or obtain rights to new products;
- our ability to attract and retain key scientific or management personnel;
- our expectations regarding the cost, time frame, outcome, insurance coverage and effects of any litigation or other dispute;
- our ability to obtain the capital necessary to fund our research and development or commercial activities;
- potential losses incurred from product liability claims made against us; and
- the use of our existing cash, cash equivalents and marketable securities.

All forward-looking statements in this report are expressly qualified in their entirety by the cautionary statements contained throughout this report. We caution you not to rely too heavily on such forward-looking statements. Each forward-looking statement speaks only as of the date of this Quarterly Report, and we undertake no obligation, and specifically decline any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

We encourage you to read *Management's Discussion and Analysis of Financial Condition and Results of Operations* and our unaudited condensed consolidated financial statements contained in this Quarterly Report. In addition to the risks described in Part I, Item 1A, *Risk Factors*, of our annual report on Form 10-K (Annual Report) for the fiscal year ended December 31, 2024 and in Part II, Item 1A, *Risk Factors*, of any Quarterly Report filed subsequent to our Annual Report, other unknown or unpredictable factors also could affect our results. Therefore, the information in this report should be read together with other reports and documents that we file with the Securities and Exchange Commission from time to time, including on Form 10-Q and Form 8-K, which may supplement, modify, supersede or update those risk factors. As a result of these factors, we cannot assure you that the forward-looking statements in this report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all.

Part I — FINANCIAL INFORMATION

ITEM 1 Financial Statements (Unaudited)

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

(in thousands, except for share and per share amounts)	September 30, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 70,022	$ 102,316
Marketable securities	223,730	272,327
Accounts receivable, net	50,541	47,101
Inventory	2,042	1,726
Prepaid expenses and other current assets	21,161	15,420
Total current assets	367,496	438,890
Property and equipment, net	2,460	2,132
Operating lease right-of-use assets	4,368	5,602
Finance lease right-of-use assets	5,071	4,943
Intangible assets, net	108,841	114,096
Deferred tax assets	103,073	81,440
Non-current inventory and other	9,831	9,101
Total assets	$ 601,140	$ 656,204
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 47,619	$ 39,086
Product revenue allowances	70,251	60,895
Total current liabilities	117,870	99,981
Operating lease non-current liabilities	3,419	4,944
Finance lease non-current liabilities	2,808	3,146
Other non-current liabilities	11,044	9,587
Total liabilities	135,141	117,658
Commitments and contingencies (Notes 8 and 14)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 20,000,000 shares authorized, and no shares issued or outstanding at September 30, 2025 and December 31, 2024	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized; 59,095,630 and 58,310,644 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	59	58
Additional paid-in capital	718,979	712,706
Accumulated other comprehensive income	540	74
Accumulated deficit	(253,579)	(174,292)
Total stockholders' equity	465,999	538,546
Total liabilities and stockholders' equity	$ 601,140	$ 656,204

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

(in thousands, except for share and per share amounts)	Three Months Ended		Nine Months Ended	
	September 30, 2025	September 30, 2024	September 30, 2025	September 30, 2024
Revenues:				
Net product sales	$ 56,258	$ 47,651	$ 158,889	$ 145,587
Total revenues	56,258	47,651	158,889	145,587
Operating expenses:				
Cost of goods sold excluding amortization	2,954	2,551	9,211	8,724
Research and development	22,563	16,776	80,265	54,591
Selling, general and administrative	60,273	37,573	174,973	107,132
Intangible asset amortization	1,752	1,751	5,255	5,521
Total operating expenses	87,542	58,651	269,704	175,968
Loss from operations	(31,284)	(11,000)	(110,815)	(30,381)
Other income, net	2,894	4,756	10,170	13,957
Loss before income taxes	(28,390)	(6,244)	(100,645)	(16,424)
Benefit for income taxes	(5,804)	(920)	(21,358)	(2,436)
Net loss	$ (22,586)	$ (5,324)	$ (79,287)	$ (13,988)
Net loss per share:				
Basic	$ (0.38)	$ (0.09)	$ (1.35)	$ (0.24)
Diluted	$ (0.38)	$ (0.09)	$ (1.35)	$ (0.24)
Weighted average shares outstanding:				
Basic	59,091,478	58,261,961	58,873,268	58,095,566
Diluted	59,091,478	58,261,961	58,873,268	58,095,566

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (Unaudited)

(in thousands)	Three Months Ended		Nine Months Ended	
	September 30, 2025	September 30, 2024	September 30, 2025	September 30, 2024
Net loss	$ (22,586)	$ (5,324)	$ (79,287)	$ (13,988)
Other comprehensive income (loss):				
Net foreign currency translation gain (loss)	(3)	36	82	14
Change in net unrealized gain (loss) on marketable securities	190	1,283	496	924
Tax provision on other comprehensive income (loss)	(43)	(287)	(112)	(206)
Other comprehensive income, net of tax	144	1,032	466	732
Comprehensive loss	$ (22,442)	$ (4,292)	$ (78,821)	$ (13,256)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (Unaudited)

(in thousands, except for share amounts)	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Par Value				
Balances at December 31, 2024	58,310,644	$ 58	$ 712,706	$ 74	$ (174,292)	$ 538,546
Issuance of common stock from the exercise of stock options and settlement of restricted stock units, net of shares withheld for taxes	623,338	1	(916)	—	—	(915)
Stock-based compensation expense	—	—	2,971	—	—	2,971
Net loss	—	—	—	—	(29,494)	(29,494)
Other comprehensive income, net of tax	—	—	—	309	—	309
Balances at March 31, 2025	58,933,982	$ 59	$ 714,761	$ 383	$ (203,786)	$ 511,417
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	146,648	—	—	—	—	—
Stock-based compensation expense	—	—	2,106	—	—	2,106
Net loss	—	—	—	—	(27,207)	(27,207)
Other comprehensive income, net of tax	—	—	—	13	—	13
Balances at June 30, 2025	59,080,630	$ 59	$ 716,867	$ 396	$ (230,993)	$ 486,329
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	15,000	—	—	—	—	—
Stock-based compensation expense	—	—	2,112	—	—	2,112
Net loss	—	—	—	—	(22,586)	(22,586)
Other comprehensive income, net of tax	—	—	—	144	—	144
Balances at September 30, 2025	59,095,630	$ 59	$ 718,979	$ 540	$ (253,579)	$ 465,999

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (Unaudited) (Continued)

(in thousands, except for share amounts)	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Par Value				
Balances at December 31, 2023	57,534,499	$ 58	$ 700,274	$ (30)	$ (155,392)	$ 544,910
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	662,024	—	—	—	—	—
Stock-based compensation expense	—	—	3,584	—	—	3,584
Net loss	—	—	—	—	(4,146)	(4,146)
Other comprehensive loss, net of tax	—	—	—	(353)	—	(353)
Balances at March 31, 2024	58,196,523	$ 58	$ 703,858	$ (383)	$ (159,538)	$ 543,995
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	90,785	—	—	—	—	—
Stock-based compensation expense	—	—	2,986	—	—	2,986
Net loss	—	—	—	—	(4,518)	(4,518)
Other comprehensive income, net of tax	—	—	—	53	—	53
Balances at June 30, 2024	58,287,308	$ 58	$ 706,844	$ (330)	$ (164,056)	$ 542,516
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	18,836	—	—	—	—	—
Stock-based compensation expense	—	—	2,999	—	—	2,999
Net loss	—	—	—	—	(5,324)	(5,324)
Other comprehensive income, net of tax	—	—	—	1,032	—	1,032
Balances at September 30, 2024	58,306,144	$ 58	$ 709,843	$ 702	$ (169,380)	$ 541,223

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

(in thousands)	Nine Months Ended	
	September 30, 2025	**September 30, 2024**
Cash flows from operating activities		
Net loss	$ (79,287)	$ (13,988)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	799	638
Stock-based compensation	7,189	9,569
Amortization of premiums and accretion of discounts on marketable securities	(1,797)	(5,479)
Intangible asset amortization	5,255	5,521
Deferred income taxes	(21,743)	(4,568)
Other non-cash adjustments, net	4,277	1,643
Changes in operating assets and liabilities:		
Accounts receivable	(3,388)	(8,581)
Prepaid expenses and other assets	(6,123)	(3,179)
Inventory	(2,186)	78
Accounts payable and other liabilities	6,743	3,835
Product revenue allowances	10,236	571
Net cash used in operating activities	(80,025)	(13,940)
Cash flows from investing activities		
Asset acquisition	—	(4,229)
Purchases of property and equipment	(896)	(276)
Purchases of marketable securities	(110,347)	(272,369)
Sales and maturities of marketable securities	161,237	255,451
Net cash provided by (used in) investing activities	49,994	(21,423)
Cash flows from financing activities		
Principal payments on finance leases	(1,351)	—
Tax obligations paid in connection with settlement of restricted stock units	(915)	—
Net cash used in financing activities	(2,266)	—
Effect of exchange rate changes on cash, cash equivalents and restricted cash	3	39
Net change in cash, cash equivalents and restricted cash	(32,294)	(35,324)
Cash, cash equivalents and restricted cash		
Beginning of period	102,785	136,290
End of period	$ 70,491	$ 100,966

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

VANDA PHARMACEUTICALS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

1. Business Organization and Presentation

Business Organization

Vanda Pharmaceuticals Inc. (the Company or Vanda) is a global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high unmet medical needs and improve the lives of patients. The Company commenced its operations in 2003.

The Company's commercial portfolio is currently comprised of three products: Fanapt® for the acute treatment of manic or mixed episodes associated with bipolar I disorder and the treatment of schizophrenia, HETLIOZ® for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) and for the treatment of nighttime sleep disturbances in Smith-Magenis syndrome (SMS) and PONVORY® for the treatment of relapsing forms of multiple sclerosis (RMS) including clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease. HETLIOZ® is the first product approved by the United States Food and Drug Administration (FDA) for patients with Non-24 and for patients with SMS. In addition, the Company has a number of drugs and/or additional indications for current products in development, including:

- Fanapt® (iloperidone) long acting injectable (LAI) formulation for the treatment of schizophrenia;
- Bysanti™ (milsaperidone), the active metabolite of Fanapt®, for the acute treatment of manic or mixed episodes associated with bipolar I disorder and for the treatment of schizophrenia and major depressive disorder (MDD);
- HETLIOZ® (tasimelteon) for the treatment of jet lag disorder, insomnia, pediatric insomnia, delayed sleep phase disorder (DSPD) and pediatric Non-24;
- PONVORY® (ponesimod) for the treatment of psoriasis and ulcerative colitis;
- Tradipitant (VLY-686), a small molecule neurokinin-1 (NK-1) receptor antagonist, for the treatment of gastroparesis, motion sickness and atopic dermatitis;
- Imsidolimab, an IL-36R antagonist, for the treatment of generalized pustular psoriasis (GPP);
- VTR-297, a small molecule histone deacetylase (HDAC) inhibitor for the treatment of onychomycosis and hematologic malignancies and with potential use as a treatment for several oncology indications;
- Portfolio of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) activators and inhibitors, including VSJ-110 for the treatment of dry eye and ocular inflammation and VPO-227 for the treatment of secretory diarrhea disorders, including cholera;
- VQW-765, a small molecule nicotinic acetylcholine receptor partial agonist, for the treatment of social/performance anxiety and psychiatric disorders; and
- Antisense oligonucleotide (ASO) molecules, including VCA-894A for the treatment of Charcot-Marie-Tooth Disease, Type 2S (CMT2S), caused by cryptic slice site variants within the IGHMBP2 gene and VGT-1849A for the treatment of polycythemia vera (PV), a form of a rare hematologic malignancy.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include the accounts of Vanda Pharmaceuticals Inc. and its wholly-owned subsidiaries and have been prepared in accordance with United States generally accepted accounting principles (GAAP) for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the Company's consolidated financial statements and accompanying notes included in the Company's annual report on Form 10-K (Annual Report) for the fiscal year ended December 31, 2024. The financial information as of September 30, 2025 and for the three and nine months ended September 30, 2025 and 2024 is unaudited, but in the opinion of management, all adjustments considered necessary for a fair statement of the results for these interim periods have been included. All intercompany accounts and transactions have been eliminated in consolidation. The condensed consolidated balance sheet data as of December 31, 2024 was derived from audited financial statements but does not include all disclosures required by GAAP. The results of the Company's operations for any interim period are not necessarily indicative of the results that may be expected for any other interim period or any future year or period.

2. Summary of Significant Accounting Policies

There have been no material changes to the significant accounting policies previously disclosed in the Annual Report.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of revenue and expenses during the reported periods. Management continually re-evaluates its estimates, judgments and assumptions, and management's evaluation could change. Actual results could differ from those estimates under different assumptions or conditions.

Cash, Cash Equivalents and Restricted Cash

For purposes of the Condensed Consolidated Balance Sheets and Condensed Consolidated Statements of Cash Flows, cash equivalents represent highly-liquid investments with a maturity date of three months or less at the date of purchase. Cash and cash equivalents include investments in money market funds with commercial banks and financial institutions, and commercial paper of high-quality corporate issuers. Restricted cash relates primarily to amounts held as collateral for letters of credit for office space leases at the Company's Washington, D.C. headquarters.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the Condensed Consolidated Balance Sheets to the total end of period cash, cash equivalents and restricted cash reported within the Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2025 and 2024:

(in thousands)	September 30, 2025	September 30, 2024
Cash and cash equivalents	$ 70,022	$ 100,497
Restricted cash included in:		
Prepaid expenses and other current assets	103	—
Non-current inventory and other	366	469
Total cash, cash equivalents and restricted cash	$ 70,491	$ 100,966

Revenue from Net Product Sales

The Company's net product sales consist of sales of Fanapt®, HETLIOZ® and PONVORY®. Net sales by product for the three and nine months ended September 30, 2025 and 2024 were as follows:

	Three Months Ended		Nine Months Ended	
(in thousands)	September 30, 2025	September 30, 2024	September 30, 2025	September 30, 2024
Fanapt® net product sales	$ 31,245	$ 23,919	$ 84,084	$ 67,648
HETLIOZ® net product sales	17,978	17,870	55,042	56,631
PONVORY® net product sales	7,035	5,862	19,763	21,308
Total net product sales	$ 56,258	$ 47,651	$ 158,889	$ 145,587

The Company's HETLIOZ® net product sales as reported for the three months ended March 31, 2023 reflected higher unit sales as compared to recent prior periods. The higher unit sales during the three months ended March 31, 2023 resulted in a significant increase of inventory stocking at specialty pharmacy customers at March 31, 2023. During the remainder of 2023, although there was continued destocking at specialty pharmacy customers, inventory levels remained elevated relative to inventory levels prior to the entrance of generic competition and remained elevated throughout 2024 and 2025. Going forward, HETLIOZ® net product sales may reflect lower unit sales as a result of the reduction of elevated levels at specialty pharmacy customers or may be variable depending upon when specialty pharmacy customers need to purchase again. Further, HETLIOZ® net product sales may decline in future periods, potentially significantly, related to continued generic competition in the U.S. The Company constrained HETLIOZ® net product sales for the three and nine months ended September 30, 2025 and 2024 to an amount not probable of significant revenue reversal. The amount of HETLIOZ® net product sales recognized during the three months ended September 30, 2025 and 2024 related to changes in estimates on revenue constrained during prior periods was $1.2 million and $0.8 million, respectively. The amount of revenue recognized during the nine months ended September 30, 2025 and 2024 related to changes in estimates on revenue constrained during prior periods was $0.8 million and $1.4 million, respectively. HETLIOZ® net product sales could experience variability in future periods as the remaining uncertainties associated with variable consideration related to inventory stocking by specialty pharmacy customers are resolved. An amount

of variable consideration related to PONVORY® net product sales is subject to dispute, of which approximately $3.0 million was recognized for the three months ended December 31, 2024. The Company recognized $5.8 million of net product sales during the nine months ended September 30, 2025 for change in estimates on variable consideration for performance obligations satisfied in previous periods, primarily related to product revenue allowances for rebates and chargebacks.

Major Customers

Fanapt® is available in the United States (U.S.) for distribution through a limited number of wholesalers and is available in retail pharmacies. HETLIOZ® is available in the U.S. for distribution through a limited number of specialty pharmacies and is not available in retail pharmacies. PONVORY® is available in the U.S. for distribution primarily through a limited number of specialty distributors and specialty pharmacies. The Company invoices and records revenue when its customers, wholesalers, specialty pharmacies and specialty distributors, receive product from the third-party logistics warehouse, which is the point at which control is transferred to the customer. Revenues and accounts receivable are concentrated with these customers. Outside the U.S., the Company has a distribution agreement for the commercialization of Fanapt® in Israel and sells HETLIOZ® in Germany. There were four major customers that each accounted for more than 10% of total revenues and, as a group, represented 77% of total revenues for the nine months ended September 30, 2025. There were four major customers that each accounted for more than 10% of accounts receivable and, as a group, represented 80% of total accounts receivable at September 30, 2025. Receivables are carried at transaction price, net of allowance for credit losses. Allowance for credit losses is measured using historical loss rates based on the aging of receivables and incorporating current conditions and forward-looking estimates.

Recent Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which is intended to provide enhancements to annual income tax disclosures. The standard will require more detailed information in the rate reconciliation table and for income taxes paid, among other enhancements. The standard is effective for years beginning after December 15, 2024 and early adoption is permitted. Upon adoption of the standard, the Company's income tax footnote will include the additional required disclosures, including additional detail in the rate reconciliation table.

In November 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Topic 220-40), which addresses the disaggregation of income statement expenses. This standard is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. The Company is evaluating this standard to determine if adoption will have a material impact on the Company's consolidated financial statements.

3. Marketable Securities

The following is a summary of the Company's available-for-sale marketable securities as of September 30, 2025, which all have contractual maturities of less than two years:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
U.S. Treasury and government agencies	$ 179,049	$ 558	$ (21)	$ 179,586
Corporate debt	44,084	62	(2)	44,144
Total marketable securities	$ 223,133	$ 620	$ (23)	$ 223,730

The following is a summary of the Company's available-for-sale marketable securities as of December 31, 2024, which all have contractual maturities of less than two years:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
U.S. Treasury and government agencies	$ 227,720	$ 371	$ (261)	$ 227,830
Corporate debt	44,506	9	(18)	44,497
Total marketable securities	$ 272,226	$ 380	$ (279)	$ 272,327

4. Fair Value Measurements

Authoritative guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include:

- Level 1 — defined as observable inputs such as quoted prices in active markets
- Level 2 — defined as inputs other than quoted prices in active markets that are either directly or indirectly observable
- Level 3 — defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions

The Company's assets classified in Level 1 and Level 2 as of September 30, 2025 and December 31, 2024 consist of cash equivalents and available-for-sale marketable securities. The valuation of Level 1 instruments is determined using a market approach and is based upon unadjusted quoted prices for identical assets in active markets. The valuation of Level 2 instruments is also determined using a market approach based upon quoted prices for similar assets in active markets, or other inputs that are observable for substantially the full term of the financial instrument. Level 2 securities include certificates of deposit, commercial paper and corporate notes that use as their basis readily observable market parameters.

The Company held certain assets that are required to be measured at fair value on a recurring basis as of September 30, 2025, as follows:

		Fair Value Measurement as of September 30, 2025 Using		
(in thousands)	Total Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
U.S. Treasury and government agencies	$ 179,586	$ 179,586	$ —	$ —
Corporate debt	44,144	—	44,144	—
Total assets measured at fair value	$ 223,730	$ 179,586	$ 44,144	$ —

The Company held certain assets that are required to be measured at fair value on a recurring basis as of December 31, 2024, as follows:

		Fair Value Measurement as of December 31, 2024 Using		
(in thousands)	Total Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
U.S. Treasury and government agencies	$ 227,830	$ 227,830	$ —	$ —
Corporate debt	44,497	—	44,497	—
Total assets measured at fair value	$ 272,327	$ 227,830	$ 44,497	$ —

Total assets measured at fair value as of September 30, 2025 and December 31, 2024 include no cash equivalents.

The Company also has financial assets and liabilities not required to be measured at fair value on a recurring basis, which primarily consist of cash, accounts receivable, restricted cash, accounts payable and accrued liabilities, and product revenue allowances, the carrying values of which materially approximate their fair values.

5. Inventory

Inventory consisted of the following as of September 30, 2025 and December 31, 2024:

(in thousands)	September 30, 2025	December 31, 2024
Current assets		
Finished goods	2,042	1,726
Total inventory, current	$ 2,042	$ 1,726
Non-Current assets		
Raw materials	$ 934	$ 934
Work-in-process	5,167	6,236
Finished goods	1,896	617
Total inventory, non-current	7,997	7,787
Total inventory	$ 10,039	$ 9,513

Inventory, which is recorded at the lower of cost or net realizable value, includes the cost of third-party manufacturing and other direct and indirect costs and is valued using the first-in, first-out method. The Company evaluates the risk of excess inventory and product expiry by evaluating current and future product demand relative to product shelf life, taking into account all possible alternative uses for the inventory available in the ordinary course of business. The Company builds demand forecasts by considering factors such as, but not limited to, overall market potential, market share, market acceptance, patient usage and generic competition. The Company's inventory balance consisted of $1.7 million of Fanapt® product, $8.0 million of HETLIOZ® product and $0.3 million of PONVORY® product as of September 30, 2025. The Company's inventory balance consisted of $2.0 million of Fanapt® product, $7.3 million of HETLIOZ® product and $0.2 million of PONVORY® product as of December 31, 2024.

6. Intangible Assets

HETLIOZ®. In January 2014, the Company announced that the FDA had approved the New Drug Application (NDA) for HETLIOZ®. As a result of this approval, the Company met a milestone under its license agreement with Bristol-Myers Squibb (BMS) that required the Company to make a license payment of $8.0 million to BMS. In April 2018, the Company met its final milestone under its license agreement with BMS when cumulative worldwide sales of HETLIOZ® reached $250.0 million. As a result of the achievement of this milestone, the Company made a payment to BMS of $25.0 million in 2018. These milestone payments were determined to be additional consideration for the acquisition of HETLIOZ® and capitalized as an intangible asset and are being amortized on a straight-line basis over the estimated economic useful life of the related product patents.

PONVORY®. On December 7, 2023, the Company acquired the U.S. and Canadian rights to PONVORY® from Actelion Pharmaceuticals Ltd. (Janssen), a Johnson & Johnson Company. The total purchase price of $104.9 million, $100.7 million of which was paid in 2023 and the remaining $4.2 million in 2024, was allocated to the acquired intangible asset for the U.S. and Canadian rights to PONVORY®. The PONVORY® intangible asset is being amortized on a straight-line basis over the estimated economic useful life of the related product rights. During the first quarter of 2024, the estimated useful life for the PONVORY® intangible asset was changed from 2035 to 2042 based on a change in the estimated economic useful life of the related product rights.

The following is a summary of the Company's amortizing intangible assets as of September 30, 2025:

		September 30, 2025		
(in thousands)	Estimated Useful Life	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	2035	$ 33,000	$ 18,497	$ 14,503
PONVORY®	2042	104,894	10,556	94,338
Total amortizing intangible assets		$ 137,894	$ 29,053	$ 108,841

The following is a summary of the Company's amortizing intangible assets as of December 31, 2024:

(in thousands)	Estimated Useful Life	December 31, 2024 Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	2035	$ 33,000	$ 17,400	$ 15,600
PONVORY®	2042	104,894	6,398	98,496
Total amortizing intangible assets		$ 137,894	$ 23,798	$ 114,096

As of September 30, 2025 and December 31, 2024, the Company also had $27.9 million of fully amortized intangible assets related to Fanapt®.

Intangible assets are amortized over their estimated useful economic life using the straight-line method. Amortization expense was $1.8 million for each of the three months ended September 30, 2025 and 2024. Amortization expense was $5.3 million and $5.5 million for the nine months ended September 30, 2025 and 2024, respectively. The following is a summary of the future intangible asset amortization schedule as of September 30, 2025:

(in thousands)	Total	2025	2026	2027	2028	2029	Thereafter
HETLIOZ®	$ 14,503	$ 366	$ 1,463	$ 1,463	$ 1,463	$ 1,463	$ 8,285
PONVORY®	94,338	1,386	5,544	5,544	5,544	5,544	70,776
Total amortizing intangible assets	$ 108,841	$ 1,752	$ 7,007	$ 7,007	$ 7,007	$ 7,007	$ 79,061

7. Accounts Payable and Accrued Liabilities

The following is a summary of the Company's accounts payable and accrued liabilities as of September 30, 2025 and December 31, 2024:

(in thousands)	September 30, 2025	December 31, 2024
Professional fees	$ 15,823	$ 9,226
Research and development expenses	13,272	11,962
Compensation and employee benefits	8,754	8,465
Finance lease liabilities	2,371	1,814
Operating lease liabilities	2,317	2,456
Royalties payable	1,942	1,665
Accounts payable and other accrued liabilities	3,140	3,498
Total accounts payable and accrued liabilities	$ 47,619	$ 39,086

8. Commitments and Contingencies

Guarantees and Indemnifications

The Company has entered into a number of standard intellectual property indemnification agreements in the ordinary course of its business. Pursuant to these agreements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally the Company's business partners or customers, in connection with any U.S. patent or any copyright or other intellectual property infringement claim by any third party with respect to the Company's products. The term of these indemnification agreements is generally perpetual from the date of execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. Since inception, the Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements. The Company also indemnifies its officers and directors for certain events or occurrences, subject to certain conditions.

License Agreements

The Company's rights to develop and commercialize its products are subject to the terms and conditions of licenses granted to the Company by other pharmaceutical companies.

Fanapt®. Pursuant to the terms of a settlement agreement with Novartis Pharma AG (Novartis), Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to the Company on December 31, 2014. The Company paid directly to Sanofi S.A.

(Sanofi) a fixed royalty of 3% of net sales through December 2019 related to manufacturing know-how. The Company is also obligated to pay Sanofi a fixed royalty on Fanapt® net sales equal to 6% on Sanofi know-how not related to manufacturing under certain conditions for a period of up to 10 years in markets where the new chemical entity patent has expired or was not issued. The Company is obligated to pay this 6% royalty on net sales in the U.S. through November 2026.

HETLIOZ®. In February 2004, the Company entered into a license agreement with BMS under which it received an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize HETLIOZ®. As of September 30, 2025, the Company has paid BMS $37.5 million in upfront fees and milestone obligations, including $33.0 million of regulatory approval and commercial milestones capitalized as intangible assets (see Note 6, *Intangible Assets*). The Company has no remaining milestone obligations to BMS. Additionally, the Company is obligated to make royalty payments on HETLIOZ® net sales to BMS. The royalty period in each territory where the Company commercializes HETLIOZ® is 10 years following the first commercial sale in the territory. In territories outside the U.S., the royalty is 5% on net sales. In the U.S., the royalty on net sales decreased from 10% to 5% in December 2022. This U.S. royalty ended in April 2024. The Company is also obligated under the license agreement to pay BMS a percentage of any sublicense fees, upfront payments and milestone and other payments (excluding royalties) that it receives from a third party in connection with any sublicensing arrangement, at a rate which is in the mid-twenties. The Company is obligated to use its commercially reasonable efforts to develop and commercialize HETLIOZ®.

Tradipitant. In April 2012, the Company entered into a license agreement with Eli Lilly and Company (Lilly) pursuant to which the Company acquired an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize an NK-1 receptor antagonist, tradipitant, for all human indications. Lilly is eligible to receive future payments based upon achievement of specified development, regulatory approval and commercialization milestones as well as tiered-royalties on net sales at percentage rates up to the low double digits. As of September 30, 2025, the Company has paid Lilly $5.0 million in upfront fees and development milestones, including a $2.0 million milestone paid to Lilly during the year ended December 31, 2023 for the filing of the first application for marketing authorization for tradipitant in either the U.S. or European Union (E.U.). As of September 30, 2025, remaining milestone obligations include $10.0 million and $5.0 million milestones for the first approval of an application for marketing authorization for tradipitant in the U.S. and E.U., respectively, and up to $80.0 million for sales milestones. The Company is obligated to use its commercially reasonable efforts to develop and commercialize tradipitant.

Imsidolimab. In January 2025, the Company entered into an exclusive global license agreement with AnaptysBio, Inc. (Anaptys) under which it acquired the worldwide rights to develop, manufacture, and commercialize imsidolimab, an IL-36R antagonist. Under the terms of the agreement, which was accounted for as an asset acquisition, the Company made an upfront payment of $10.0 million to Anaptys and an additional $5.0 million payment for drug supply, $14.4 million of which is included in research and development expense on the Condensed Consolidated Statements of Operations for the nine months ended September 30, 2025. Anaptys is eligible to receive future payments based upon achievement of specified regulatory approval and commercialization milestones as well as a 10% royalty on global net sales. As of September 30, 2025, remaining milestone obligations include up to $35.0 million for future regulatory approval and sales milestones, including $5.0 million each for the first approval of an application for marketing authorization for imsidolimab in the U.S. and E.U. and $25.0 million for a sales milestone. The Company is obligated to use its commercially reasonable efforts to develop and commercialize imsidolimab.

Portfolio of CFTR activators and inhibitors. In March 2017, the Company entered into a license agreement with the University of California San Francisco (UCSF), under which the Company acquired an exclusive worldwide license to develop and commercialize a portfolio of CFTR activators and inhibitors. Pursuant to the license agreement, the Company will develop and commercialize the CFTR activators and inhibitors and is responsible for all development costs, including current pre-investigational new drug development work. UCSF is eligible to receive future payments based upon achievement of specified development and commercialization milestones as well as single-digit royalties on net sales. As of September 30, 2025, the Company has paid UCSF $1.8 million in upfront fees and development milestones. As of September 30, 2025, remaining milestone obligations include $11.9 million for development milestones and $33.0 million for future regulatory approval and sales milestones. Included in the $11.9 million of development milestones are $1.1 million of milestone obligations due upon the conclusion of clinical studies for each licensed product, not to exceed $3.2 million in total for the CFTR portfolio.

VQW-765. In connection with a settlement agreement with Novartis relating to Fanapt®, the Company received an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize VQW-765, a Phase II alpha-7 nicotinic acetylcholine receptor partial agonist. Pursuant to the license agreement, the Company is obligated to use its commercially reasonable efforts to develop and commercialize VQW-765 and is responsible for all development costs. The Company has no milestone obligations, but Novartis is eligible to receive tiered-royalties on net sales at percentage rates up to the mid-teens.

Other Agreements

Olipass. In September 2022, the Company entered into an agreement with OliPass Corporation (OliPass) to jointly develop a set of ASO molecules based on OliPass' proprietary modified peptide nucleic acids. As consideration for entering into the arrangement, the Company paid OliPass an upfront fee of $3.0 million, which was recorded as research and development expense in 2022. The Company is funding the research and development activities and has the option to license jointly developed intellectual property upon successful development.

Clinical Trial Agreement. In December 2024, the Company entered into an agreement with a third party to jointly design and complete a pediatric study for PONVORY® required by the FDA and the European Medicines Agency. Pursuant to the agreement, the Company will bear the primary responsibility for completing the clinical trial, and the third party will bear primary responsibility for manufacturing the clinical study product. All costs associated with the pediatric study will be shared equally by the Company and the third party. As the Company and the third party are both active participants in the research activities and both parties are exposed to significant risks and rewards, the agreement is being accounted for under Accounting Standards Codification (ASC) 808. Furthermore, no parts of the agreement are within the scope of ASC 606, because the Company determined that performing research and development activities on behalf of other parties is not part of the ordinary activities of its business. Therefore, reimbursements from the third party for research and development costs are recorded as reductions to research and development expense as incurred. Expenses recognized by the Company related to activities under the collaborative arrangement, which commenced during the first quarter of 2025, were $2.7 million for the nine months ended September 30, 2025, which were reduced by amounts reimbursable from the third party of $1.0 million.

Lease Agreements. In June 2016, the Company entered into a sublease agreement under which it subleases 9,928 square feet of office space for its headquarters at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. The sublease term began in January 2017 and ends in July 2026. Following the expiration of the sublease in July 2026, the Company will lease this space under a separate lease arrangement with a different counterparty, which was signed in June 2025. The lease term will commence in August 2026 upon expiration of the sublease for that space for a period of two years. The lease may be terminated early by the Company or the landlord under certain circumstances.

In August 2024, the Company entered into a master lease agreement for vehicles to be utilized by the Company's sales force. The individual car leases commence upon delivery of the vehicles. Delivery of these vehicles began in the fourth quarter of 2024, and they were determined to be finance leases upon lease commencement. The contractual period of each lease is three years. The Company continued to lease additional cars under the master lease agreement during 2025. The Company capitalized $1.6 million for car leases that commenced during the nine months ended September 30, 2025, all of which were determined to be finance leases. Total fixed payments for the vehicle leases that had not yet commenced as of September 30, 2025 are estimated to be $3.7 million, payable over initial terms of three years, and subject to change upon finalization of each vehicle lease contract.

For further information regarding the Company's lease agreements, see Note 8, *Leases*, to the consolidated financial statements included in the Company's Annual Report for the fiscal year ended December 31, 2024.

Purchase Commitments

In the normal course of its business, the Company regularly enters into agreements with third-party vendors under fee service arrangements, which generally may be terminated on 90 days' notice without incurring additional charges, other than charges for work completed or materials procured but not paid for through the effective date of termination and other costs incurred by the Company's contractors in closing out work in progress as of the effective date of termination. The Company's non-cancellable purchase commitments for agreements with a remaining non-cancellable term longer than one year from September 30, 2025 primarily relate to commitments for data services and marketing activities, of which $4.2 million, $11.3 million, $9.7 million, $6.4 million and $2.6 million are expected to be paid in 2025, 2026, 2027, 2028 and 2029, respectively. Various other long-term agreements entered into for services with other third-party vendors, such as inventory purchase commitments, are cancellable in nature or contain variable commitment terms within the agreement that are within our control.

9. Accumulated Other Comprehensive Income

The accumulated balances related to each component of other comprehensive income, net of taxes, were as follows as of September 30, 2025 and December 31, 2024:

(in thousands)	September 30, 2025	December 31, 2024
Foreign currency translation	$ 69	$ (13)
Unrealized gain on marketable securities	471	87
Accumulated other comprehensive income	$ 540	$ 74

10. Stock-Based Compensation

As of September 30, 2025, there were 7,975,115 shares subject to outstanding options and restricted stock units (RSUs) under the 2006 Equity Incentive Plan (2006 Plan) and the Amended and Restated 2016 Equity Incentive Plan (2016 Plan, and together with the 2006 Plan, Plans). The 2006 Plan expired by its terms in April 2016, and the Company adopted the 2016 Plan. Outstanding options under the 2006 Plan remain in effect and the terms of the 2006 Plan continue to apply, but no additional awards can be granted under the 2006 Plan. In June 2016, the Company's stockholders approved the 2016 Plan. The 2016 Plan has been amended a number of times since to increase the number of shares reserved for issuance, among other administrative changes, including, but not limited to, an amendment to eliminate its term. Each of the amendments to the 2016 Plan was approved by the Company's stockholders. There is a total of 18,190,000 shares of common stock authorized for issuance under the 2016 Plan, 5,417,822 shares of which remained available for future grant as of September 30, 2025.

Stock Options

The Company has granted option awards under the Plans with service conditions (service option awards) that are subject to terms and conditions established by the compensation committee of the board of directors. Service option awards have 10-year contractual terms. Service option awards granted to employees and new directors upon their election vest and become exercisable over four years, with the first 25% of the shares subject to service option awards vesting on the first anniversary of the grant date and the remaining 75% of the shares subject to the service option awards in 36 equal monthly installments thereafter. Subsequent annual service option awards granted to directors vest and become exercisable in full on the first anniversary of the grant date. Service option awards granted to executive officers and certain other employees provide for partial acceleration of vesting if the executive officer or employee is subject to an involuntary termination, and full acceleration of vesting if the executive officer or employee is subject to an involuntary termination within 24 months after a change in control of the Company. Service option awards granted to directors provide for accelerated vesting if there is a change in control of the Company or if the director's service terminates as a result of the director's death or total and permanent disability.

As of September 30, 2025, $1.3 million of unrecognized compensation costs related to unvested service option awards are expected to be recognized over a weighted average period of 0.6 years. No option awards are classified as a liability as of September 30, 2025.

A summary of option activity under the Plans for the nine months ended September 30, 2025 follows:

(in thousands, except for share and per share amounts)	Number of Shares	Weighted Average Exercise Price at Grant Date	Weighted Average Remaining Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2024	4,603,581	$ 12.71	5.60	$ —
Expired	(108,757)	11.38		
Outstanding at September 30, 2025	4,494,824	12.74	4.98	—
Exercisable at September 30, 2025	4,151,955	13.15	4.80	—
Vested and expected to vest at September 30, 2025	4,485,438	12.76	4.98	—

There were no stock option exercises during the nine months ended September 30, 2025 and 2024. The weighted average grant date fair value of options granted was $2.95 per share for the nine months ended September 30, 2024.

Restricted Stock Units

An RSU is a stock award that entitles the holder to receive shares of the Company's common stock as the award vests. The fair value of each RSU is based on the closing price of the Company's stock on the date of grant. The Company has granted RSUs under the Plans with service conditions (service RSUs) that are subject to terms and conditions established by the compensation

committee of the board of directors. Service RSUs granted to employees and new directors upon their election vest in four equal annual installments. Subsequent annual service RSUs granted to directors vest on the first anniversary of the date of grant. Service RSUs granted to executive officers and certain other employees provide for accelerated vesting if the executive officer or employee is subject to an involuntary termination within 24 months after a change in control. Service RSUs granted to directors provide for accelerated vesting if there is a change in control of the Company.

As of September 30, 2025, $13.6 million of unrecognized compensation costs related to unvested service RSUs are expected to be recognized over a weighted average period of 1.7 years. No RSUs are classified as a liability as of September 30, 2025.

A summary of RSU activity for the Plans for the nine months ended September 30, 2025 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2024	2,650,006	$ 6.82
Granted	1,966,625	4.46
Forfeited	(158,512)	6.05
Vested	(977,828)	8.65
Unvested at September 30, 2025	3,480,291	5.00

The grant date fair value for the 977,828 shares underlying RSUs that vested during the nine months ended September 30, 2025 was $8.5 million.

Stock-Based Compensation Expense

Stock-based compensation expense recognized for the three and nine months ended September 30, 2025 and 2024 was comprised of the following:

	Three Months Ended		Nine Months Ended	
(in thousands)	September 30, 2025	September 30, 2024	September 30, 2025	September 30, 2024
Research and development	$ 458	$ 703	$ 1,819	$ 2,241
Selling, general and administrative	1,654	2,296	5,370	7,328
Total stock-based compensation expense	$ 2,112	$ 2,999	$ 7,189	$ 9,569

The fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton option pricing model. Expected volatility rates are based on the historical volatility of the Company's publicly traded common stock and other factors. The expected terms are determined based on a combination of historical exercise data and hypothetical exercise data for unexercised stock options. The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The Company has never paid cash dividends to its stockholders and does not plan to pay dividends in the foreseeable future. There were no options granted during the nine months ended September 30, 2025. Assumptions used in the Black-Scholes-Merton option pricing model for employee and director stock options granted during the nine months ended September 30, 2024 were as follows:

	Nine Months Ended
	September 30, 2024
Expected dividend yield	0 %
Weighted average expected volatility	50 %
Weighted average expected term (years)	6.27
Weighted average risk-free rate	4.52 %

11. Income Taxes

For the three months ended September 30, 2025 and 2024, the Company recorded an income tax benefit of $5.8 million and $0.9 million, respectively. The income tax benefit for the three months ended September 30, 2025 and 2024 was primarily driven by the estimated effective tax rate for the year, as well as discrete income tax expense of $0.1 million and $0.2 million, respectively.

For the nine months ended September 30, 2025 and 2024, the Company recorded an income tax benefit of $21.4 million and $2.4 million, respectively. The income tax benefit for the nine months ended September 30, 2025 and 2024 was primarily driven by the estimated effective tax rate for the year, as well as discrete income tax expense of $0.9 million and $1.0 million, respectively.

The Company assesses the need for a valuation allowance against its deferred tax asset each quarter through the review of all available positive and negative evidence. Deferred tax assets are reduced by a tax valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. The analysis is highly dependent upon historical and projected pretax income. As of September 30, 2025, after considering all available positive and negative evidence, including but not limited to historical, current and future projected results and significant risks and uncertainties related to forecasts, the Company concluded, consistent with prior periods, that it is more likely than not that substantially all of its deferred tax assets in the U.S. are realizable in future periods. The Company maintains a valuation allowance against certain state net deferred tax assets.

The Company generated a pretax loss for the nine months ended September 30, 2025. If the Company continues to generate pretax losses and/or if the Company's projections indicate pretax losses in future periods or if there are meaningful changes to our business operations, the conclusion about the appropriateness of the valuation allowance could change in a future period. An increase in the valuation allowance would result in a non-cash income tax expense during the period of change. The analysis to determine that a valuation allowance is necessary is highly dependent upon historical and future projected earnings, among other factors. Any such adjustment to the valuation allowance could have a material impact on the Company's results of operations and statement of financial position.

In July 2025, the One Big Beautiful Bill Act (OBBBA), which contains a broad range of tax reforms affecting businesses, was signed into law in the U.S. The OBBBA includes numerous changes to existing tax law including extending or making permanent certain business and international tax measures initially established under the 2017 Tax Cuts and Jobs Act, which were set to expire. Additionally, the OBBBA permanently eliminates the requirement to capitalize and amortize U.S.-based research and development expenditures over five years and provides the option to make these expenditures fully deductible in the period incurred. The legislation has multiple effective dates, with certain provisions effective in 2025 and others implemented through 2027.

12. Earnings per Share

Basic earnings per share (EPS) is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding. Diluted EPS is computed by dividing the net loss by the weighted average number of shares of common stock outstanding, plus potential outstanding common stock for the period. Potential outstanding common stock includes stock options and shares underlying RSUs, but only to the extent that their inclusion is dilutive, as calculated using the treasury stock method.

The following table presents the calculation of basic and diluted net loss per share of common stock for the three and nine months ended September 30, 2025 and 2024:

	Three Months Ended		Nine Months Ended	
(in thousands, except for share and per share amounts)	**September 30, 2025**	**September 30, 2024**	**September 30, 2025**	**September 30, 2024**
Numerator:				
Net loss	$ (22,586)	$ (5,324)	$ (79,287)	$ (13,988)
Denominator:				
Weighted average shares outstanding, basic and diluted	59,091,478	58,261,961	58,873,268	58,095,566
Net loss per share, basic and diluted	$ (0.38)	$ (0.09)	$ (1.35)	$ (0.24)
Antidilutive securities excluded from calculations of diluted net loss per share	5,445,436	6,383,154	6,180,855	6,603,367

The Company incurred a net loss for the three and nine months ended September 30, 2025 and 2024 causing inclusion of any potentially dilutive securities to have an anti-dilutive effect, resulting in dilutive loss per share and basic loss per share attributable to common stockholders being equivalent.

13. Segments

The Company operates in one reportable segment, which includes all activities related to the development and commercialization of innovative therapies to address high unmet medical needs and improve the lives of patients. The determination of a single reportable segment is consistent with the consolidated financial information regularly provided to the Company's chief operating decision maker (CODM), which is its chief executive officer, who reviews and evaluates consolidated net income (loss) for purposes of assessing performance, making operating decisions, allocating resources and planning and forecasting for future periods. The measure of segment assets is reported on the balance sheet as total assets.

The following table presents the segment revenue and significant expense categories included within the product segment's measure of profit or loss for the three and nine months ended September 30, 2025 and 2024:

	Three Months Ended		Nine Months Ended	
(in thousands)	September 30, 2025	September 30, 2024	September 30, 2025	September 30, 2024
Revenue	$ 56,258	$ 47,651	$ 158,889	$ 145,587
Less:				
Cost of goods sold excluding amortization	2,954	2,551	9,211	8,724
Research and development	22,563	16,776	80,265	54,591
Selling, general and administrative	60,273	37,573	174,973	107,132
Intangible asset amortization	1,752	1,751	5,255	5,521
Other income, net	(2,894)	(4,756)	(10,170)	(13,957)
Benefit for income taxes	(5,804)	(920)	(21,358)	(2,436)
Net loss	$ (22,586)	$ (5,324)	$ (79,287)	$ (13,988)

14. Legal Matters

HETLIOZ®. In December 2022, the Company filed patent infringement lawsuits, including Hatch-Waxman Act claims, against each of Teva Pharmaceuticals USA, Inc. (Teva) and Apotex Inc. and Apotex Corp. (Apotex) in the U.S. District Court for the District of New Jersey (NJ District Court) asserting that U.S. Patent No. 11,285,129 ('129 Patent), will be infringed by Teva's and Apotex' generic versions of HETLIOZ®, each of which was approved by the FDA. The Company asked the NJ District Court to, among other things, order that the effective date of the FDA's approval of Teva's and Apotex' generic versions of HETLIOZ® be a date that is no earlier than the expiration of the '129 Patent, or such later date that the NJ District Court may determine, and enjoin each of Teva and Apotex from the commercial manufacture, use, import, offer for sale and/or sale of their generic versions of HETLIOZ® until the expiration of the '129 Patent, or such later date that the NJ District Court may determine. In February 2023, the case was transferred to the U.S. District Court for the District of Delaware (Delaware District Court). In April 2023, Teva and Apotex moved for judgment on the pleadings. In June 2024, the Delaware District Court denied those motions, allowing the Company's lawsuit to proceed. In March 2025, the Delaware District Court held a claim construction hearing, which resolved two claim term disputes in the Company's favor and deferred ruling on a third dispute between the parties. In May 2025, the Delaware District Court consolidated this action with the Company's action relating to the '556 Patent (as defined below). The Company's lawsuit remains pending, and a trial is scheduled to begin on August 3, 2026.

In January 2023, the Company filed a lawsuit in the NJ District Court against Teva challenging Teva's advertising and marketing practices related to its at risk launch of its generic version of HETLIOZ® for the single indication of Non-24. The Company believes that Teva's advertising and marketing practices related to its generic version of HETLIOZ® promote its product for uses beyond the limited labeling that Teva sought, and the FDA approved. The Company seeks to, among other things, enjoin Teva from engaging in false and misleading advertising and recover monetary damages. In December 2023, the case was transferred to the Delaware District Court following Teva's motion to transfer and dismiss the case earlier that year. In February 2025, the Delaware District Court denied Teva's motion to dismiss, allowing the Company's lawsuit to proceed. In March 2025, Teva filed its answer and asserted counterclaims against the Company for alleged violations of the Lanham Act, antitrust and state trade laws. In the same month, the Delaware District Court declined to consolidate this action with the Company's cases alleging infringement of the '129 Patent and the '556 Patent (as defined below). The Company's lawsuit remains pending.

In January 2023, the Company filed a lawsuit in the U.S. District Court for the District of Columbia (DC District Court) against the FDA challenging the FDA's approval of Teva's Abbreviated New Drug Application (ANDA) for its generic version of

HETLIOZ® capsules under the Administrative Procedure Act (APA), the Food, Drug, and Cosmetic Act (FDCA), and FDA regulations. Under the FDCA, every ANDA must contain information to show that the labeling proposed for the generic drug is the same as the labeling approved for the listed drug. The labeling and packaging for HETLIOZ® includes Braille, but Teva's generic version does not. On this basis, the Company believes that Teva's approved labeling does not comply with applicable requirements. The Company has asked the DC District Court to, among other things, vacate the FDA's approval of Teva's ANDA, declare that the approval of the ANDA was unlawful, arbitrary, and capricious and compel the FDA to order Teva to recall its generic HETLIOZ® product. In February 2023, Teva intervened in the lawsuit as a defendant. In September 2023, the Company amended its lawsuit to request that the DC District Court set aside the FDA's July 2023 denial of the Company's citizen petition, originally filed with the FDA in January 2023. In April 2024, the Company filed a motion for summary judgment. In February 2025, the DC District Court denied the Company's motion and granted the FDA and Teva's cross motions for summary judgment. In February 2025, the Company appealed to the U.S. Court of Appeals for the District of Columbia Circuit. In October 2025, the DC District Court granted the FDA's motion for a stay of the briefing schedule that it filed in October 2025 due to the government shutdown.

In September 2023, the Company filed a lawsuit in the DC District Court against the FDA challenging the FDA's approval of an ANDA filed by MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited (MSN) for its generic version of HETLIOZ® capsules under the APA, the FDCA, FDA regulations and the Appointments Clause of the U.S. Constitution. The Company believes that MSN's underlying approval data, particularly its bioequivalence studies, are faulty. On this basis, the Company asked the DC District Court to, among other things, vacate the FDA's approval of MSN's ANDA, declare that the approval of the ANDA was unlawful, arbitrary, and capricious, is unconstitutional under the Appointments Clause, and compel the FDA to order MSN to recall its generic HETLIOZ® product. In December 2023, the Company filed a motion for summary judgment. In January 2024, the FDA opposed the Company's motion and moved to waive the administrative record, following which the court held an oral argument on the cross-motions. The DC District Court issued an order compelling the FDA to serve the administrative record and set deadlines for further proceedings. In April 2024, the Company filed a motion for summary judgment. In July 2024, the DC District Court held an oral argument on the motion to dismiss that the FDA filed in January 2024, which the Company opposed in February 2024. In September 2024, the DC District Court granted in part the FDA's motion to dismiss as to the Company's APA claims and denied the FDA's motion to dismiss as to the Company's claims under the Appointments Clause. In August 2025, the Company filed a motion for summary judgment based on its Appointments Clause claims, to which the FDA filed an opposition and cross-motion for summary judgment in September 2025. The Company's lawsuit remains pending.

In April 2024, the Company filed a lawsuit in the Delaware District Court against MSN and its commercial partner Amneal Pharmaceuticals, Inc. (Amneal), and Impax Laboratories LLC (Impax) alleging claims for false advertising in violation of the Lanham Act and unfair competition under several state laws as well as claims for breach of express representation and fraudulent inducement of a license agreement. In July 2024, the defendants filed a motion to dismiss and in September 2024, the Company opposed the motion, to which the defendants replied in October 2024. In July 2025, the Delaware District Court issued its report and recommendation to deny the defendants' motion to dismiss as to standing but granted their motion to dismiss the Lanham Act claims, to which the Company objected in August 2025. In September 2025, the Delaware District Court overruled the Company's objections. In October 2025, the Company appealed the Delaware District Court's decision.

In December 2024, the Company filed a lawsuit in the Delaware District Court against each of Teva and Apotex asserting U.S. Patent No. 11,918,556 ('556 Patent), a method of administration patent that was not litigated in the prior Delaware District Court cases, will be infringed by Teva's and Apotex's generic versions of HETLIOZ®, each of which was approved by the FDA. The Company has asked the Delaware District Court to, among other things, order that the effective date of the FDA's approval of Teva's and Apotex' generic versions of HETLIOZ® be a date that is no earlier than the expiration of the '556 Patent, or such later date that the Delaware District Court may determine, and enjoin each of Teva and Apotex from the commercial manufacture, use, import, offer for sale and/or sale of their generic versions of HETLIOZ® until the expiration of the '556 Patent, or such later date that the Delaware District Court may determine. In March 2025, Teva filed its answer and asserted counterclaims against the Company, including, among other things, for alleged violation of the antitrust laws and inequitable conduct, which the Company opposed in May 2025. The Delaware District Court declined to consolidate this action with the Company's case alleging Lanham Act violations against Teva but consolidated this action with the Company's action relating to the '129 Patent. The Company's lawsuit remains pending, and a trial is scheduled to begin on August 3, 2026.

HETLIOZ LQ®. In July 2024, the Company filed a Hatch-Waxman lawsuit against MSN in the Delaware District Court asserting that U.S. Patent Nos. 10,179,119, 11,266,622, 11,285,129, 11,850,229, 10,610,510, 10,980,770, and 11,759,446 (together, the Asserted Patents) will be infringed by MSN's generic version of HETLIOZ LQ® for which MSN is seeking FDA approval. The Company has asked the Delaware District Court to, among other things, enter judgment that MSN has infringed at least one claim of each of the Asserted Patents by submitting or causing to be submitted its ANDA to obtain FDA approval for the commercial manufacture, use, import, offer for sale and/or sale in the U.S. of its generic version of HETLIOZ LQ®

before the expiration of each of the Asserted Patents, enter judgment that the use of MSN's generic version of HETLIOZ LQ® in the U.S. before the expiration of each of the Asserted Patents will directly infringe at least one claim of each of the Asserted Patents, order that the effective date of any approval by the FDA of MSN's generic version of HETLIOZ LQ® be a date that is no earlier than the expiration of the last expiring Asserted Patent(s), or such later date as the Court may determine, enjoin MSN from the commercial manufacture, use, import, offer for sale and/or sale of its generic version of HETLIOZ LQ® until the expiration of each of the Asserted Patents or such later date as the Court may determine, and award monetary damages, to the extent applicable. The Company's lawsuit remains pending, and a trial that was scheduled to begin on June 15, 2026 has been rescheduled to begin on September 14, 2026.

Other Matters. From April 2022 to July 2024, the Company filed eighteen lawsuits in the DC District Court against the FDA to compel the FDA to produce records under the Freedom of Information Act (FOIA) regarding, among other matters: the FDA's denial of the Company's supplemental New Drug Application (sNDA) for HETLIOZ® in the treatment of jet lag disorder; cases in which the FDA waived its putative requirement of a 9-month non-rodent toxicity study before drugs can be tested on human patients for extended durations; communications external to and within the FDA relating to tradipitant, HETLIOZ® and Fanapt®; a warning letter that the FDA sent to the Company concerning its webpages for HETLIOZ® and Fanapt®; the FDA's removal of a clinical trials design presentation from its website; discipline reviews relating to the FDA's evaluations of the Company's sNDA for HETLIOZ® and a third-party sNDA for jet lag; internal standard operating procedures or guidance relating to the FDA's processing of incoming FOIA requests; and bioequivalence and other study reports submitted relating to the FDA's consideration of tasimelteon ANDAs. Nine of these lawsuits have since been resolved in the Company's favor and the other nine remain outstanding. The FDA has failed to respond and provide the requested documents within the statutory timeframe with respect to each of these ten outstanding cases. The Company has asked the DC District Court to, among other things, compel the FDA to comply with its obligations and declare that its lack of compliance violates FOIA.

In May 2022, the Company filed a lawsuit in the DC District Court against the FDA challenging the FDA's denial of Fast Track designation for tradipitant. In October 2021, the Company submitted to the FDA a request for Fast Track designation for tradipitant under the Food and Drug Administration Modernization Act of 1997 (FDAMA). The FDAMA provides for expedited development and review of drugs that receive Fast Track designation from the FDA. Under the FDAMA, the FDA must designate a drug as a Fast Track product if it both (1) is intended to treat a serious or life-threatening disease or condition and (2) demonstrates the potential to address unmet medical needs for such disease or condition. Although Fast Track designation is non-discretionary when the criteria are satisfied, the FDA denied the Company's request for Fast Track designation. The Company does not believe that the FDA based its decision on the relevant criteria. Therefore, among other reasons, the Company maintains that the FDA's denial is unlawful. The Company has asked the DC District Court to, among other things, set aside and vacate the FDA's denial. An oral argument was held in January 2023. In August 2023, the DC District Court ruled against the Company. In September 2023, the Company appealed the ruling to the U.S. Court of Appeals for the District of Columbia Circuit and in September 2024, the Court of Appeals held an oral argument. In December 2024, the Court of Appeals affirmed the DC District Court's ruling. In May 2025, the Company filed a petition for a writ of certiorari with the U.S. Supreme Court to review the Court of Appeals' decision, to which the FDA filed an opposition in October 2025. The Company's lawsuit remains pending.

In September 2022, the Company filed a lawsuit in the DC District Court against the FDA to compel the FDA to comply with two separate non-discretionary obligations under the FDCA and its implementing regulations: an obligation to publish a notice of an opportunity for a hearing on the Company's sNDA for HETLIOZ® in the treatment of jet lag disorder in the Federal Register within 180 days of the filing of the sNDA, and a separate obligation to publish the same notice within 60 days of the request for a hearing. The FDA published the notice of an opportunity for a hearing on October 11, 2022. The Company has asked the DC District Court to, among other things, compel the FDA to comply with its obligations and declare that its lack of compliance violates the FDCA and the FDA regulations. In January 2024, the DC District Court held an oral argument on dispositive cross-motions, following which the DC District Court granted in part the Company's motion for summary judgment. The DC District Court ruled that the FDA violated the statute and ordered the FDA to either finally resolve the Company's application or commence a hearing on or before March 5, 2024. In March 2024, the Company and the FDA filed a consent motion for entry of final judgment in the Company's favor on its APA claim for the FDA's unreasonable delay in resolving the hearing request, following which the FDA refused to hold a hearing or approve the Company's sNDA for HETLIOZ® in the treatment of jet lag disorder. The Company subsequently filed a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit (DC Circuit). Under the FDCA, the FDA has an obligation to either approve an sNDA or to hold a hearing on the application's approvability. The Company's petition asks the DC Circuit to set aside the FDA's order refusing to hold a hearing and refusing approval. In January 2025, the DC Circuit held an oral argument. In August 2025, the DC Circuit issued a decision in favor of the Company against the FDA, setting aside the FDA's refusal to hold a hearing on the Company's sNDA for HETLIOZ® in the treatment of jet lag disorder and remanding the case back to the FDA.

In May 2023, the Company filed a lawsuit in the U.S. Court of Federal Claims (Federal Claims Court) against the federal government for the uncompensated taking and misuse of the Company's trade secrets and confidential information. The Company believes that the FDA violated the Fifth Amendment's due process clause by improperly providing confidential details from the Company's drug master files for HETLIOZ® and Fanapt® to generic drug manufacturers during the FDA's review of the manufacturers' ANDAs. The Company has asked the Federal Claims Court to, among other things, declare that the FDA's disclosure of the Company's confidential commercial information constitutes a taking for purposes of the Fifth Amendment and award just compensation. The federal government filed a motion to dismiss the complaint, which the Company opposed. In January 2024, the Federal Claims Court held an oral argument on the motion to dismiss, following which the Federal Claims Court issued a decision denying in part the government's motion, allowing the Company's takings claim to proceed. In April 2024, the government filed a judgment on the pleadings, to which the Company opposed in July 2024 and the government replied in August 2024. In December 2024, the Federal Claims Court held an oral argument on the motion for judgment on the pleadings and in January 2025, the Federal Claims Court ruled against the Company. In February 2025, the Company appealed the ruling to the U.S. Court of Appeals for the Federal Circuit. The Company's appeal remains pending.

In February 2024, the Company filed a lawsuit in the DC District Court against the FDA to compel the FDA to comply with its statutory obligations under the FDCA and its implementing regulations, and to challenge the FDA's complete response letter and 60-day filing regulations, which the Company believes do not absolve the FDA of its statutory responsibilities. Under the FDCA, the FDA has an obligation to either approve the Company's sNDA for HETLIOZ® in the treatment of insomnia characterized by difficulties with sleep initiation within 180 days of the filing of the sNDA or give the Company a notice of an opportunity for a hearing. The Company submitted the sNDA on May 4, 2023. The Company has asked the DC District Court to, among other things, compel the FDA to comply with its obligations, declare that its lack of compliance violates the FDCA and the FDA regulations and declare the FDA's complete response letter and 60-day filing regulations unlawful. In June 2024, the Company filed a motion for summary judgment and the FDA published a notice of opportunity for a hearing. In July 2024, the FDA opposed the Company's motion for summary judgment. In September 2024, the DC District Court held an oral argument on the dispositive cross motions. In March and April 2025, the parties provided supplemental briefing. In May 2025, the DC District Court held a further hearing on the supplemental briefings. In September 2025, the Company filed a motion to stay proceedings in the case until January 2026 pursuant to an agreement between the Company and the FDA (FDA Agreement). The Company's lawsuit remains pending subject to the stay.

On April 22, 2024, a purported stockholder of the Company filed a lawsuit in the Court of Chancery of the State of Delaware (Delaware Chancery Court) against the members of the Company's board of directors and the Rights Agent, along with the Company as nominal defendant (collectively, the Defendants), captioned *Steamfitters Local 449 Pension Fund v. Mihael H. Polymeropoulos, et al., CA No. 2024-0416-KSJM*. The lawsuit contended, among other things, that the members of the Company's board of directors breached their fiduciary duties in adopting the Rights Agreement. The lawsuit sought relief declaring, in part, that provisions of the Rights Agreement be deemed unenforceable and sought to enjoin the use of such provisions as well as damages, costs, and other remedies, and also sought to enjoin for 30 days the Company's 2024 Annual Meeting of Stockholders (the Annual Meeting) that was held on May 17, 2024. At a hearing on May 7, 2024, the Delaware Chancery Court denied the plaintiff's request to enjoin the Annual Meeting. A three-day trial in the case was scheduled to begin on November 4, 2024. On August 7, 2024, the Company amended the Rights Agreement to, among other things, clarify certain of the provisions that were the subject of the lawsuit. On August 12, 2024, the parties filed with the Delaware Chancery Court a stipulation and order dismissing the lawsuit with prejudice, pursuant to which, the plaintiff agreed that the amendment to the Rights Agreement mooted the plaintiff's claims. The plaintiff filed a petition in the Delaware Chancery Court seeking an award of attorney's fees and expenses, which the Company opposed. In February 2025, the Delaware Chancery Court held a hearing, and on July 3, 2025, issued a bench ruling, awarding the plaintiff $2.0 million for attorney's fees and expenses.

In August 2024, the Company filed a lawsuit against the FDA in the DC District Court challenging FDA decisionmakers' authority under the Appointments Clause of the U.S. Constitution to render a decision on the Company's new drug application for tradipitant to treat symptoms of gastroparesis. In September 2024, the Company filed a motion for a preliminary injunction to enjoin the FDA from subjecting the Company's NDA for tradipitant for the treatment of symptoms of gastroparesis to a final decision prior to the PDUFA target date of September 18, 2024. In September 2024, the DC District Court denied the motion. The Company filed a motion for summary judgment in December 2024, and in January 2025, the FDA opposed the motion and cross-moved to dismiss and for summary judgment. In February 2025, the Company filed its reply and opposition, to which the FDA replied in March 2025. The Company's lawsuit remains pending.

In January 2025, the Company and a co-plaintiff filed a lawsuit against the FDA in the U.S. District Court for the Middle District of Florida (Florida District Court) challenging the FDA's partial clinical hold preventing the Company from studying the effects of tradipitant for the prevention of motion sickness for more than 90 total doses per patient over a period of two years. The FDA based its partial clinical hold on the Company's refusal to perform a repeat-dose toxicity study in a non-rodent species of at least a 6-month duration. However, under the FDA Modernization Act 2.0, nonclinical studies may include non-

animal alternatives. The Company believes that the FDA's basis for the partial clinical hold is contrary to law and in excess of the FDA's statutory authority. The Company and co-plaintiff have asked the Florida District Court to, among other things, set aside the FDA's partial clinical hold and declare the FDA's partial clinical hold as unlawful. In March 2025, the FDA moved to dismiss the lawsuit and subsequently moved to stay summary judgment briefing in April 2025. The Company subsequently opposed the FDA's motion to stay, following which the Florida District Court granted the FDA's motion. In October 2025, the Company dismissed the case pursuant to the FDA Agreement.

In February 2025, the Company filed a lawsuit in the DC District Court against the FDA to compel the FDA to comply with its statutory obligations under the FDCA and its implementing regulations and to challenge the FDA's reliance on PDUFA deadlines and its complete response letter and 60-day filing regulations, which the Company believes do not absolve the FDA of its statutory responsibilities. Under the FDCA, the FDA has an obligation to either approve the Company's NDA for tradipitant to prevent vomiting induced by motion within 180 days of the filing of the NDA or give the Company a notice of an opportunity for a hearing. The Company submitted the NDA on December 30, 2024. The Company has asked the DC District Court to, among other things, compel the FDA to comply with its obligations, declare that its lack of compliance violates the FDCA and the FDA regulations and declare the FDA's complete response letter and 60-day filing regulations and adherence to PDUFA deadlines unlawful. Separately, under the FDCA, the FDA has an obligation to commence a hearing on the Company's NDA for tradipitant in gastroparesis within 120 days of a timely accepted notice of opportunity for a hearing, which the FDA issued on January 7, 2025. In April 2025, the Company filed a motion for summary judgment regarding its motion sickness NDA and requested to file summary judgment regarding its gastroparesis NDA. In May 2025, the DC District Court held a hearing on the motion regarding the motion sickness NDA. The Center for Drug Evaluation and Research issued a proposed order denying a hearing on the gastroparesis NDA in July 2025. In September 2025, the Company filed a motion to stay proceedings in the DC District Court regarding the gastroparesis NDA until January 2026 pursuant to the FDA Agreement. The Company's lawsuit remains pending subject to the stay.

In April 2025, the Company filed a petition for review in the U.S. Court of Appeals for the DC Circuit seeking review of the FDA's final order refusing to hold a hearing or to approve the Company's sNDA for HETLIOZ® in the treatment of insomnia associated with difficulties with sleep initiation. Under the FDCA, the FDA has an obligation to either approve an sNDA or to hold a hearing on the application's approvability. The Company's petition asks the DC Circuit to set aside the FDA's order refusing to hold a hearing and refusing approval. The Company's petition for review remains pending.

In April 2025, the Company and two co-plaintiffs filed a lawsuit against the FDA in the U.S. District Court for the Southern District of Texas (Texas District Court) challenging the FDA's prohibition of the Company's proposal to disclose truthful, non-misleading information to prescribers and patients, including the co-plaintiffs, about the off-label use of HETLIOZ® to treat jet lag disorder. The Company believes that the FDA's prohibition of truthful, non-misleading speech promoting off-label uses of drugs is content-based speech regulation and unconstitutional under the First Amendment. The Company has asked the Texas District Court to, among other things, declare that the Company has a right under the First Amendment to engage in truthful, non-misleading speech regarding the potential use of HETLIOZ® as a treatment for jet lag disorder and enjoin the FDA from taking adverse action against the Company relating to such communications. In July 2025, the FDA moved to stay case deadlines pending resolution of a forthcoming motion that it will file to dismiss or transfer the case. In October 2025, the Company dismissed the case pursuant to the FDA Agreement.

ITEM 2 Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview

Vanda Pharmaceuticals Inc. (we, our, us or Vanda) is a leading global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high unmet medical needs and improve the lives of patients.

We strive to advance novel approaches to bring important new medicines to market through responsible innovation. We are committed to the use of technologies that support sound science, including genetics and genomics, in drug discovery, clinical trials and the commercial positioning of our products.

Our commercial portfolio is currently comprised of three products: Fanapt® for the acute treatment of manic or mixed episodes associated with bipolar I disorder and the treatment of schizophrenia, HETLIOZ® for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) and for the treatment of nighttime sleep disturbances in Smith-Magenis syndrome (SMS) and PONVORY® for the treatment of relapsing forms of multiple sclerosis (RMS) including clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease. HETLIOZ® is the first product approved by the United States Food and Drug Administration (FDA) for patients with Non-24 and for patients with SMS. In addition, we have a number of drugs and/or additional indications for current products in development, including:

- Fanapt® (iloperidone) long acting injectable (LAI) formulation for the treatment of schizophrenia;
- Bysanti™ (milsaperidone), the active metabolite of Fanapt®, for the acute treatment of manic or mixed episodes associated with bipolar I disorder and for the treatment of schizophrenia and major depressive disorder (MDD);
- HETLIOZ® (tasimelteon) for the treatment of jet lag disorder, insomnia, pediatric insomnia, delayed sleep phase disorder (DSPD) and pediatric Non-24;
- PONVORY® (ponesimod) for the treatment of psoriasis and ulcerative colitis;
- Tradipitant (VLY-686), a small molecule neurokinin-1 (NK-1) receptor antagonist, for the treatment of gastroparesis, motion sickness and atopic dermatitis;
- Imsidolimab, an IL-36R antagonist, for the treatment of generalized pustular psoriasis (GPP);
- VTR-297, a small molecule histone deacetylase (HDAC) inhibitor for the treatment of onychomycosis and hematologic malignancies and with potential use as a treatment for several oncology indications;
- Portfolio of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) activators and inhibitors, including VSJ-110 for the treatment of dry eye and ocular inflammation and VPO-227 for the treatment of secretory diarrhea disorders, including cholera;
- VQW-765, a small molecule nicotinic acetylcholine receptor partial agonist, for the treatment of social/performance anxiety and psychiatric disorders; and
- Antisense oligonucleotide (ASO) molecules, including VCA-894A for the treatment of Charcot-Marie-Tooth Disease, Type 2S (CMT2S), caused by cryptic slice site variants within the IGHMBP2 gene and VGT-1849A for the treatment of polycythemia vera (PV), a form of a rare hematologic malignancy.

Operational Highlights

Key Operational Highlights – Commercial

- Fanapt® experienced significant growth, with total prescriptions (TRx) increasing by 35% and Fanapt® net product sales increasing by 31% in the third quarter of 2025 as compared to the third quarter of 2024.
- During the first nine months of 2025, our direct-to-consumer campaign, launched in the first quarter, continued to drive meaningful gains in brand awareness for our company and our products, Fanapt® and PONVORY®. We maintained strategic investments in our commercial infrastructure, including increased brand visibility through targeted sponsorships, with the goal of supporting long-term market leadership and future commercial launches.

Key Operational Highlights – Regulatory & Clinical Development

- A clinical study of tradipitant in the prevention of vomiting induced by a GLP-1 analog, Wegovy® (semaglutide), is now complete. Results are expected in the fourth quarter of 2025.

- On October 1, 2025, we announced that we had agreed on a collaborative framework with the FDA for the resolution of certain disputes regarding HETLIOZ® and tradipitant. Pursuant to the agreement:
    - The FDA will conduct an expedited re-review of the partial clinical hold preventing long term clinical studies of tradipitant for the treatment of motion sickness by November 26, 2025. The FDA will continue its review of our New Drug Application (NDA) for this indication, with the existing Prescription Drug User Fee Act (PDUFA) target action date of December 30, 2025.
    - The FDA will conduct an expedited re-review of our supplemental New Drug Application (sNDA) for HETLIOZ® for the treatment of jet lag disorder by January 7, 2026, including consideration of alternative or narrowed indications focusing on the sleep-related aspects of jet lag disorder.
- Bysanti™ NDA for bipolar I disorder and schizophrenia is under review by the FDA with a PDUFA target action date of February 21, 2026.
- Tradipitant NDA for motion sickness is under review by the FDA with a PDUFA target action date of December 30, 2025.
- A Bysanti™ Phase III clinical study for use as a once-daily adjunctive treatment for MDD is enrolling patients and results are expected in 2026.
- Imsidolimab Biologics License Application (BLA) in GPP expected to be submitted to the FDA in the fourth quarter of 2025.
- The Phase III study of the long acting injectable formulation of iloperidone in the treatment of schizophrenia in relapse-prevention is enrolling patients.
- A clinical study of the long acting injectable formulation of iloperidone in people with treatment-resistant hypertension is ongoing and we plan to begin enrolling patients soon.

Since we began operations, we have devoted substantially all of our resources to the in-licensing, clinical development and commercialization of our products. Our ability to generate meaningful product sales and achieve profitability largely depends on our level of success in commercializing Fanapt® in the United States (U.S.), HETLIOZ® in the U.S. and Europe and PONVORY® in the U.S. and Canada, on our ability, alone or with others, to complete the development of our products, and to obtain the regulatory approvals for and to manufacture, market and sell our products. The results of our operations will vary significantly from year-to-year and quarter-to-quarter and depend on a number of factors, including risks related to our business, risks related to our industry, and other risks that are detailed in Part I, Item 1A, *Risk Factors*, of our annual report on Form 10-K (Annual Report) for the year ended December 31, 2024 and Item 1A, *Risk Factors*, of any Quarterly Report filed subsequent to our Annual Report.

Critical Accounting Policies and Estimates

The preparation of our 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 our financial statements, as well as the reported revenues and expenses during the reported periods. We base our estimates on 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 apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no significant changes in our critical accounting policies including estimates, assumptions and judgments from those described in Part II, Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations*, included in the Annual Report. A summary of our significant accounting policies appears in the notes to our audited consolidated financial statements included in the Annual Report. However, we believe that the following accounting policies are important to understanding and evaluating our reported financial results as they involve the most significant judgments and estimates used in the preparation of our condensed consolidated financial statements, and we have accordingly included them in this discussion.

Revenue from net product sales. We account for a contract when it has approval and commitment from both parties, the rights of the parties are identified, payment terms are identified, the contract has commercial substance and collectability of consideration is probable. We recognize revenue when control of the product is transferred to the customer in an amount that reflects the consideration we expect to be entitled to in exchange for those product sales, which is typically once the product physically arrives at the customer. Sales tax, value-added taxes and usage-based taxes are excluded from revenues.

Fanapt® is available in the U.S. for distribution through a limited number of wholesalers and is available in retail pharmacies. HETLIOZ® is available in the U.S. for distribution through a limited number of specialty pharmacies and is not available in retail pharmacies. PONVORY® is available in the U.S. for distribution primarily through a limited number of specialty distributors and specialty pharmacies. We invoice and record revenue when our customers, wholesalers, specialty pharmacies and specialty distributors, receive product from the third-party logistics warehouse, which is the point at which control is transferred to the customer. Revenues and accounts receivable are concentrated with these customers. Outside the U.S., we have a distribution agreement for the commercialization of Fanapt® in Israel and sell HETLIOZ® in Germany. Receivables are carried at transaction price, net of allowance for credit losses. Allowance for credit losses is measured using historical loss rates based on the aging of receivables and incorporating current conditions and forward-looking estimates.

The transaction price is determined based upon the consideration to which we will be entitled in exchange for transferring product to the customer. Our product sales are recorded net of applicable product revenue allowances for which reserves are established and include discounts, rebates, chargebacks, service fees, co-pay assistance and product returns that are applicable for various government and commercial payors. Where appropriate, our estimates of variable consideration included in the transaction price consider a range of possible outcomes. Allowances for rebates, chargebacks and co-pay assistance are based upon the insurance benefits of the end customer, which are estimated using historical activity and, where available, actual and pending prescriptions for which we have validated the insurance benefits. Variable consideration may be constrained and is included in the transaction price if, in our judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the respective underlying contracts. If actual results in the future vary from our estimates, we adjust our estimate in the period identified, which would affect net product sales in the period such variances become known. During the nine months ended September 30, 2025 and 2024, we constrained the variable consideration for HETLIOZ® net product sales. The constrained revenue relates to the uncertainties of payor utilization, patient demand and chargeback and rebate amounts, including Medicaid, related to the elevated levels of inventory on hand at the specialty pharmacies.

Reserves for variable consideration are classified as product revenue allowances on the Condensed Consolidated Balance Sheets, with the exception of prompt-pay discounts, which are classified as reductions of accounts receivable. The reserve for product returns for which the product may not be returned for a period of greater than one year from the balance sheet date is included as a component of other non-current liabilities in the Condensed Consolidated Balance Sheets. Uncertainties related to variable consideration are generally resolved in the quarter subsequent to period end, with the exception of Medicaid rebates, which are dependent upon the timing of when states submit reimbursement claims, Medicare inflationary rebates, which are billed on an annual basis beginning in 2025, and product returns that are resolved during the product expiry period specified in the customer contract. Due to increased inventory stocking of HETLIOZ® at specialty pharmacy customers in 2025 and 2024, the time it takes to resolve these uncertainties could be longer than we have experienced prior to the entrance of generic competition. We currently record sales allowances for the following:

- *Prompt-pay:* Wholesalers, specialty pharmacies and specialty distributors, our direct customers, are generally offered discounts for prompt payment. We expect that these direct customers will earn prompt payment discounts and, therefore, we deduct the full amount of these discounts from total product sales when revenues are recognized.
- *Rebates:* Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program as well as contracted rebate programs with other payors, including the Medicare Part D inflationary rebate effective October 1, 2022. Rebate amounts owed after the final dispensing of the product to a benefit plan participant are based upon contractual agreements or legal requirements with public sector benefit providers, such as Medicaid and Medicare. The allowances for rebates are based on statutory or contracted discount rates and estimated patient utilization.
- *Chargebacks:* Chargebacks are discounts that occur when contracted indirect customers purchase directly from wholesalers, specialty pharmacies and specialty distributors. Contracted indirect customers, which currently consist primarily of Public Health Service institutions and federal government entities purchasing via the Federal Supply Schedule, generally purchase the product at a discounted price. The wholesaler, specialty pharmacy or specialty distributor, in turn, charges back the difference between the price initially paid by the wholesaler, specialty pharmacy or specialty distributor and the discounted price paid to the wholesaler, specialty pharmacy or specialty distributor by the contracted customer.
- *Medicare Part D rebates:* Prior to January 1, 2025, the Medicare Part D prescription drug benefit required manufacturers to fund approximately 70% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients for applicable drugs. We account for the Medicare Part D coverage gap using a point of sale model. Estimates for expected Medicare Part D rebates are based, in part, on historical activity and, where available, actual and pending prescriptions when we have validated the insurance benefits. Beginning January 1, 2025, the Medicare Part D coverage gap discount program was replaced with a new discounting program under the Inflation Reduction Act of 2022. The Medicare Part D benefit redesign is expected to result in higher discounts for our

Medicare payor segment relative to the previous Medicare Part D prescription drug coverage gap discount program. Under the redesigned Medicare Part D program, applicable drugs dispensed to applicable beneficiaries will be subject to manufacturer discounts of 10% during the initial coverage phase and 20% during the catastrophic coverage phase. Under the Medicare Part D benefit redesign, we are a specified manufacturer whose applicable drugs for applicable beneficiaries who are Low Income Subsidy eligible under section 1860D-14(a) of the Social Security Act will be subject to lower applicable discounts during the phase-in period.

- *Service fees:* We receive sales order management, data and distribution services from certain customers, for which we are assessed fees. These fees are based on contracted terms and are known amounts. We accrue service fees at the time of revenue recognition, resulting in a reduction of product sales and the recognition of an accrued liability, unless it is a payment for a distinct good or service from the customer in which case the fair value of those distinct goods or services are recorded as selling, general and administrative expense.
- *Co-pay assistance:* Patients who have commercial insurance and meet certain eligibility requirements may receive co-pay assistance. Co-pay assistance utilization is based on information provided by our third-party administrator.
- *Product returns:* We generally offer direct customers a limited right to return as contractually defined with our customers. We consider several factors in the estimation process, including expiration dates of product shipped to customers, inventory levels within the distribution channel, product shelf life, historical return activity, including activity for product sold for which the return period has past, prescription trends and other relevant factors. We do not expect returned products to be resalable. There was no right of return asset as of September 30, 2025 or December 31, 2024.

The following table summarizes sales discounts and allowance activity as of and for the nine months ended September 30, 2025:

(in thousands)	Rebates & Chargebacks	Discounts, Returns and Other	Total
Balances at December 31, 2024	$ 49,939	$ 12,391	$ 62,330
Provision related to current period sales	75,398	32,778	108,176
Adjustments for prior period sales	(5,252)	(586)	(5,838)
Credits/payments made	(62,176)	(29,856)	(92,032)
Balances at September 30, 2025	$ 57,909	$ 14,727	$ 72,636

The provision of $75.4 million for rebates and chargebacks for the nine months ended September 30, 2025 and its ending balance at September 30, 2025 primarily represents Medicaid rebates applicable to sales of Fanapt® and, to a lesser extent, HETLIOZ®. The provision of $32.8 million for discounts, returns and other for the nine months ended September 30, 2025 primarily represents wholesaler distribution fees applicable to sales of Fanapt® and estimated product returns of Fanapt®, and co-pay assistance costs and prompt-pay discounts applicable to the sales of all of our commercial products.

Stock-based compensation. Compensation costs for all stock-based awards to employees and directors are measured based on the grant date fair value of those awards and recognized over the period during which the employee or director is required to perform service in exchange for the award. We use the Black-Scholes-Merton option pricing model to determine the fair value of stock options. The determination of the fair value of stock options on the date of grant using an option pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include the expected stock price volatility over the expected term of the awards, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends. Expected volatility rates are based on the historical volatility of our publicly traded common stock and other factors. The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. We have never paid cash dividends to our stockholders and do not plan to pay dividends in the foreseeable future. As stock-based compensation expense recognized in the Condensed Consolidated Statements of Operations is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Research and development expenses. Research and development expenses consist primarily of fees for services provided by third parties in connection with the clinical trials, costs of contract manufacturing services for clinical trial use, milestone payments made under licensing agreements prior to regulatory approval, costs of materials used in clinical trials and research and development, costs for regulatory consultants and filings, depreciation of capital resources used to develop products, related facilities costs, and salaries, other employee-related costs and stock-based compensation for research and development personnel. We expense research and development costs as they are incurred for products in the development stage, including

manufacturing costs and milestone payments made under license agreements prior to FDA approval. Upon and subsequent to FDA approval, manufacturing and milestone payments made under license agreements are capitalized. Milestone payments are accrued when it is deemed probable that the milestone event will be achieved. Costs related to the acquisition of intellectual property are expensed as incurred if the underlying technology is developed in connection with our research and development efforts and has no alternative future use.

Clinical trials are inherently complex, often involve multiple service providers and can include payments made to investigator physicians at study sites. Because billing for services often lags delivery of service by a substantial amount of time, we are often required to estimate a significant portion of our accrued clinical expenses. Our assessments include, but are not limited to: (i) an evaluation by the project manager of the work that has been completed during the period, (ii) measurement of progress prepared internally and/or provided by the third-party service provider, (iii) analyses of data that justify the progress, and (iv) management's judgment. In the event that we do not identify certain costs that have begun to be incurred or we under- or over-estimate the level of services performed or the costs of such services, our reported expenses for such period would be too low or too high.

Intangible assets and impairment of long-lived assets. Our intangible assets consist of capitalized license costs for products approved by the FDA or costs to acquire already commercialized products. We amortize our intangible assets on a straight-line basis over the estimated useful economic life of the related product patents. We assess the impairment of intangible assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors we consider important that could trigger an impairment review include significant underperformance relative to expected historical or projected future operating results, a significant adverse change in legal or regulatory factors that could affect the value or patent life, including our ability to defend and enforce patent claims and other intellectual property rights and significant negative industry or economic trends. When we determine that the carrying value of our intangible assets may not be recoverable based upon the existence of one or more of the indicators of impairment, we measure any impairment based on the amount that carrying value exceeds fair value.

Income taxes. We assess the need for a valuation allowance against our deferred tax assets each quarter through the review of all available positive and negative evidence. Deferred tax assets are reduced by a tax valuation allowance when, in the opinion of management, it is more likely than not that some portion of the deferred tax assets will not be realized. The analysis is highly dependent upon historical and projected pretax income. In 2024, we generated our first full year pretax loss since 2017, largely due to expenditures on the commercial launches of Fanapt® in bipolar I disorder and PONVORY® in RMS. Projected taxable income includes significant assumptions related to revenue, which could be affected by the success of the commercial launches of Fanapt® in bipolar I disorder and PONVORY® in RMS and HETLIOZ® generic competition, commercial and research and development activities, and our ability to obtain regulatory approval from the FDA for products or new indications in development, among other factors. As of September 30, 2025, after considering all available positive and negative evidence, we concluded, consistent with prior periods, that it was more likely than not that substantially all of our deferred tax assets in the U.S. are realizable in future periods. We maintain a valuation allowance against certain state net deferred tax assets. If our results are not in line with our projections or if our projections change, or if there are meaningful changes to our business operations, the conclusion about the appropriateness of the valuation allowance could change in a future period. An increase in the valuation allowance would result in a non-cash income tax expense during the period of change. Any such adjustment could have a material impact on our results of operations.

Tax benefits are recognized from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax benefit recognized in the financial statements for a particular tax position is based on the largest benefit that is more likely than not to be realized upon settlement.

Recent Accounting Pronouncements

See Note 2, *Summary of Significant Accounting Policies,* to the condensed consolidated financial statements included in Part I of this Quarterly Report for information on recent accounting pronouncements.

Results of Operations

We anticipate that our results of operations will fluctuate for the foreseeable future due to several factors, including our and our partners' ability to continue to successfully commercialize our products, including activities related to Fanapt® for the acute treatment of manic or mixed episodes associated with bipolar I disorder in adults, which was approved in April 2024, and PONVORY® for the treatment of RMS, the impact of the Medicare Part D benefit redesign effective January 1, 2025 under the

Inflation Reduction Act of 2022, any possible payments made or received pursuant to license agreements, progress of our research and development efforts, the timing and outcome of clinical trials and related possible regulatory approvals and the status of existing and future potential litigation involving our products and intellectual property. See Note 14, *Legal Matters*, to the condensed consolidated financial statements included in Part I of this Quarterly Report for information on material legal matters.

Three months ended September 30, 2025 compared to three months ended September 30, 2024

Revenues. Total revenues increased by $8.6 million, or 18%, to $56.3 million for the three months ended September 30, 2025 compared to $47.7 million for the three months ended September 30, 2024. Revenues may decline in future periods, potentially significantly, as a result of the Medicare Part D program benefit redesign. Revenue from net product sales was as follows:

	Three Months Ended			
(in thousands)	September 30, 2025	September 30, 2024	Net Change	Percent
Fanapt® net product sales	$ 31,245	$ 23,919	$ 7,326	31 %
HETLIOZ® net product sales	17,978	17,870	108	1 %
PONVORY® net product sales	7,035	5,862	1,173	20 %
Total net product sales	$ 56,258	$ 47,651	$ 8,607	18 %

Fanapt® net product sales increased by $7.3 million, or 31%, to $31.2 million for the three months ended September 30, 2025 compared to $23.9 million for the three months ended September 30, 2024. The increase to net product sales was attributable to an increase in volume, partially offset by a decrease in price net of deductions. We initiated the commercial launch of Fanapt® for bipolar I disorder in adults in the third quarter of 2024.

HETLIOZ® net product sales increased by $0.1 million, or 1%, to $18.0 million for the three months ended September 30, 2025 compared to $17.9 million for the three months ended September 30, 2024. The increase to net product sales was attributable to an increase in volume, partially offset by a decrease in price net of deductions. Our HETLIOZ® net product sales as reported for the three months ended March 31, 2023 reflected higher unit sales as compared to recent prior periods. The higher unit sales during the three months ended March 31, 2023 resulted in a significant increase of inventory stocking at specialty pharmacy customers at March 31, 2023. During the remainder of 2023, although there was continued destocking at specialty pharmacy customers, inventory levels remained elevated relative to inventory levels prior to the entrance of generic competition and remained elevated throughout 2024 and 2025. Going forward, HETLIOZ® net product sales may reflect lower unit sales as a result of the reduction of elevated levels at specialty pharmacy customers or may be variable depending on when specialty pharmacy customers need to purchase again. Further, HETLIOZ® net product sales may decline in future periods, potentially significantly, related to continued generic competition in the U.S. We constrained HETLIOZ® net product sales for the three months ended September 30, 2025 and 2024 to an amount not probable of significant revenue reversal. The amount of revenue recognized during the three months ended September 30, 2025 and 2024 related to changes in estimates on revenue constrained during prior periods was $1.2 million and $0.8 million, respectively. HETLIOZ® net product sales could experience variability in future periods as the remaining uncertainties associated with variable consideration related to inventory stocking by specialty pharmacy customers are resolved.

PONVORY® net product sales increased by $1.2 million, or 20%, to $7.0 million for the three months ended September 30, 2025 compared to $5.9 million for the three months ended September 30, 2024. The increase in net product sales was attributable to an increase in volume. We initiated the commercial launch of PONVORY® in RMS in the third quarter of 2024.

Cost of goods sold. Cost of goods sold increased by $0.4 million, or 16%, to $3.0 million for the three months ended September 30, 2025 compared to $2.6 million for the three months ended September 30, 2024. Cost of goods sold includes third-party manufacturing costs of product sold, third-party royalty costs and distribution and other costs. Third-party royalty costs were 6% of Fanapt® net product sales and 5% of HETLIOZ® net product sales in Germany. Third-party royalty costs on HETLIOZ® net product sales in the U.S. decreased from 10% to 5% in December 2022 and ended in April 2024. Third-party royalty costs on HETLIOZ® net product sales in Germany will end in October 2026. There are no third-party royalty costs on net sales of PONVORY®. We evaluate the risk of excess inventory and product expiry by evaluating current and future product demand relative to product shelf life and build demand forecasts by considering factors such as, but not limited to, overall market potential, market share, market acceptance, patient usage, and generic competition. Our inventory balance consisted of $1.7 million of Fanapt® product, $8.0 million of HETLIOZ® product and $0.3 million of PONVORY® product as of September 30, 2025.

Research and development expenses. Research and development expenses increased by $5.8 million, or 34%, to $22.6 million for the three months ended September 30, 2025 compared to $16.8 million for the three months ended September 30, 2024. The increase was primarily due to an increase in expenses across many different development programs, including our Fanapt® development program.

The following table summarizes the costs of our product development initiatives for the three months ended September 30, 2025 and 2024:

	Three Months Ended	
(in thousands)	**September 30, 2025**	**September 30, 2024**
Direct project costs (1)		
Fanapt®	$ 3,767	$ 1,876
Bysanti™	2,977	2,864
HETLIOZ®	2,751	2,840
PONVORY®	2,514	1,027
Tradipitant	3,119	4,392
Imsidolimab	966	—
VTR-297	978	712
CFTR	2,165	806
VQW-765	1,112	194
Other	569	318
Total direct project costs	20,918	15,029
Indirect project costs (1)		
Stock-based compensation	458	703
Other indirect overhead	1,187	1,044
Total indirect project costs	1,645	1,747
Total research and development expense	$ 22,563	$ 16,776

(1) We record direct costs, including personnel costs and related benefits, on a project-by-project basis. Many of our research and development costs are not attributable to any individual project because we share resources across several development projects. We record indirect costs that support a number of our research and development activities in the aggregate, including stock-based compensation.

We expect to incur significant research and development expenses as we continue to develop our products and continue our efforts to expand our product pipeline.

Selling, general and administrative expenses. Selling, general and administrative expenses increased by $22.7 million, or 60%, to $60.3 million for the three months ended September 30, 2025 compared to $37.6 million for the three months ended September 30, 2024. The increase in selling, general and administrative expenses was primarily the result of an increase in spending on commercial activities related to our commercial launches of Fanapt® in bipolar disorder and PONVORY® in RMS. During 2024, we commenced a host of commercial activities as part of our commercial launches of Fanapt® in bipolar disorder and PONVORY® in RMS, including an expansion of our sales force and the development of prescriber awareness and comprehensive marketing programs. A direct-to-consumer campaign that started in the first quarter of 2025 continued in the second and third quarters of 2025, elevating brand awareness of the company and the key products Fanapt® and PONVORY®. Selling, general and administrative expenses may increase in future periods as a result of the ongoing commercial launches.

Intangible asset amortization. Intangible asset amortization was $1.8 million each for the three months ended September 30, 2025 and 2024.

Other income. Other income was $2.9 million for the three months ended September 30, 2025 compared to $4.8 million for the three months ended September 30, 2024. Other income primarily consists of investment income on our marketable securities.

Benefit for income taxes. An income tax benefit of $5.8 million and $0.9 million was recorded for the three months ended September 30, 2025 and 2024, respectively. The income tax benefit for each of the three months ended September 30, 2025 and 2024 was primarily driven by the estimated effective tax rate for the year as well as discrete income tax expense of $0.1 million and $0.2 million, respectively.

Nine months ended September 30, 2025 compared to nine months ended September 30, 2024

Revenues. Total revenues increased by $13.3 million, or 9%, to $158.9 million for the nine months ended September 30, 2025 compared to $145.6 million for the nine months ended September 30, 2024. Revenues were as follows:

	Nine Months Ended			
(in thousands)	September 30, 2025	September 30, 2024	Net Change	Percent
Fanapt® net product sales	$ 84,084	$ 67,648	$ 16,436	24 %
HETLIOZ® net product sales	55,042	56,631	(1,589)	(3)%
PONVORY® net product sales	19,763	21,308	(1,545)	(7)%
Total net product sales	$ 158,889	$ 145,587	$ 13,302	9 %

Fanapt® net product sales increased by $16.4 million, or 24%, to $84.1 million for the nine months ended September 30, 2025 compared to $67.6 million for the nine months ended September 30, 2024. The increase to net product sales was attributable to an increase in volume, partially offset by a decrease in price net of deductions. We initiated the commercial launch of Fanapt® for bipolar I disorder in adults in the third quarter of 2024.

HETLIOZ® net product sales decreased by $1.6 million, or 3%, to $55.0 million for the nine months ended September 30, 2025 compared to $56.6 million for the nine months ended September 30, 2024. The decrease to net product sales was attributable to a decrease in volume. Our HETLIOZ® net product sales as reported for the three months ended March 31, 2023 reflected higher unit sales as compared to recent prior periods. The higher unit sales during the three months ended March 31, 2023 resulted in a significant increase of inventory stocking at specialty pharmacy customers at March 31, 2023. During the remainder of 2023, although there was continued destocking at specialty pharmacy customers, inventory levels remained elevated relative to inventory levels prior to the entrance of generic competition and remained elevated throughout 2024 and 2025. Going forward, HETLIOZ® net product sales may reflect lower unit sales as a result of the reduction of elevated levels at specialty pharmacy customers or may be variable depending upon when specialty pharmacy customers need to purchase again. Further, HETLIOZ® net product sales may decline in future periods, potentially significantly, related to continued generic competition in the U.S. The Company constrained HETLIOZ® net product sales for the nine months ended September 30, 2025 and 2024 to an amount not probable of significant revenue reversal. The amount of revenue recognized during the nine months ended September 30, 2025 and 2024 related to changes in estimates on revenue constrained during prior periods was $0.8 million and $1.4 million, respectively. HETLIOZ® net product sales could experience variability in future periods as the remaining uncertainties associated with variable consideration related to inventory stocking by specialty pharmacy customers are resolved.

PONVORY® net product sales decreased by $1.5 million, or 7%, to $19.8 million for the nine months ended September 30, 2025 compared to $21.3 million for the nine months ended September 30, 2024. The decrease in net product sales was attributable to a decrease in price net of deductions. We initiated the commercial launch of PONVORY® in RMS in the third quarter of 2024. An amount of variable consideration related to PONVORY® net product sales is subject to dispute, of which approximately $3.0 million was recognized for the three months ended December 31, 2024.

Cost of goods sold. Cost of goods sold increased by $0.5 million, or 6%, to $9.2 million for the nine months ended September 30, 2025 compared to $8.7 million for the nine months ended September 30, 2024. Cost of goods sold includes third-party manufacturing costs of product sold, third-party royalty costs and distribution and other costs. Third-party royalty costs were 6% of Fanapt® net product sales and 5% of HETLIOZ® net product sales in Germany. Third-party royalty costs on HETLIOZ® net product sales in the U.S. decreased from 10% to 5% in December 2022 and ended in April 2024. Third-party royalty costs on HETLIOZ® net product sales in Germany will end in October 2026. There are no third-party royalty costs on net sales of PONVORY®. We evaluate the risk of excess inventory and product expiry by evaluating current and future product demand relative to product shelf life and build demand forecasts by considering factors such as, but not limited to, overall market potential, market share, market acceptance, patient usage, and generic competition. Our inventory balance consisted of $1.7 million of Fanapt® product, $8.0 million of HETLIOZ® product and $0.3 million of PONVORY® product as of September 30, 2025.

Research and development expenses. Research and development expenses increased by $25.7 million, or 47%, to $80.3 million for the nine months ended September 30, 2025 compared to $54.6 million for the nine months ended September 30, 2024. The increase in research and development expenses was primarily due to an upfront payment to AnaptysBio, Inc. for the exclusive, global license to develop, manufacture, and commercialize imsidolimab and drug supply as well as an increase in expenses for our Fanapt® and Bysanti™ development programs, partially offset by a decrease in expenses for our tradipitant development program.

The following table summarizes the costs of our product development initiatives for the nine months ended September 30, 2025 and 2024:

(in thousands)	Nine Months Ended September 30, 2025	Nine Months Ended September 30, 2024
Direct project costs (1)		
Fanapt®	$ 11,002	$ 5,848
Bysanti™	9,376	4,390
HETLIOZ®	9,665	7,271
PONVORY®	6,404	4,052
Tradipitant	11,134	18,609
Imsidolimab	15,336	—
VTR-297	2,561	1,985
CFTR	5,552	4,927
VQW-765	1,762	564
Other	1,419	1,154
Total direct project costs	74,211	48,800
Indirect project costs (1)		
Stock-based compensation	1,819	2,241
Other indirect overhead	4,235	3,550
Total indirect project costs	6,054	5,791
Total research and development expense	$ 80,265	$ 54,591

(1) We record direct costs, including personnel costs and related benefits, on a project-by-project basis. Many of our research and development costs are not attributable to any individual project because we share resources across several development projects. We record indirect costs that support a number of our research and development activities in the aggregate, including stock-based compensation.

We expect to incur significant research and development expenses as we continue to develop our products and continue our efforts to expand our product pipeline.

Selling, general and administrative expenses. Selling, general and administrative expenses increased by $67.8 million, or 63%, to $175.0 million for the nine months ended September 30, 2025 compared to $107.1 million for the nine months ended September 30, 2024. The increase in selling, general and administrative expenses was primarily the result of an increase in spending on commercial activities related to our commercial launches of Fanapt® in bipolar disorder and PONVORY® in relapsing forms of MS. During 2024, we commenced a host of commercial activities as part of our commercial launches of Fanapt® in bipolar disorder and PONVORY® in RMS, including an expansion of our sales force and the development of prescriber awareness and comprehensive marketing programs. A direct-to-consumer campaign that started in the first quarter of 2025 continued in the second and third quarters of 2025, elevating brand awareness of the company and the key products Fanapt® and PONVORY®. Selling, general and administrative expenses may increase in future periods as a result of the ongoing commercial launches.

Intangible asset amortization. Intangible asset amortization was $5.3 million and $5.5 million for the nine months ended September 30, 2025 and 2024, respectively.

Other income. Other income was $10.2 million for the nine months ended September 30, 2025 compared to $14.0 million for the nine months ended September 30, 2024. Other income primarily consists of investment income on our marketable securities.

Benefit for income taxes. We recorded an income tax benefit of $21.4 million and $2.4 million for the nine months ended September 30, 2025 and 2024, respectively. The income tax benefit for the nine months ended September 30, 2025 and 2024 was primarily driven by the estimated effective tax rate for the year, as well as discrete income tax expense of $0.9 million and $1.0 million, respectively.

Liquidity and Capital Resources

As of September 30, 2025, our total cash and cash equivalents and marketable securities were $293.8 million compared to $374.6 million at December 31, 2024. Our cash and cash equivalents are deposits in operating accounts and highly liquid investments with an original maturity of 90 days or less at date of purchase and consist of investments in money market funds with commercial banks and financial institutions and commercial paper of high-quality corporate issuers. Our marketable securities consist of investments in government sponsored and corporate enterprises and commercial paper.

Our liquidity resources as of September 30, 2025 and December 31, 2024 are summarized as follows:

(in thousands)	September 30, 2025	December 31, 2024
Cash and cash equivalents	$ 70,022	$ 102,316
Marketable securities:		
U.S. Treasury and government agencies	179,586	227,830
Corporate debt	44,144	44,497
Total marketable securities	223,730	272,327
Total cash, cash equivalents and marketable securities	$ 293,752	$ 374,643

As of September 30, 2025, we maintained all of our cash, cash equivalents and marketable securities in two financial institutions. Deposits held with these institutions may exceed the amount of insurance provided on such deposits, but we do not anticipate any losses with respect to such deposits.

In the normal course of our business, we regularly enter into agreements with third-party vendors under fee service arrangements which generally may be terminated on 90 days' notice without incurring additional charges, other than charges for work completed or materials procured but not paid for through the effective date of termination and other costs incurred by our contractors in closing out work in progress as of the effective date of termination. Our non-cancellable purchase commitments for agreements with a remaining non-cancellable term longer than one year from September 30, 2025 primarily relate to commitments for data services and marketing activities. Various other long-term agreements entered into for services with other third-party vendors, such as inventory purchase commitments, are cancellable in nature or contain variable commitment terms within the agreement that are within our control. We also have long-term contractual obligations related to our leases and license agreements.

Other than as disclosed in Note 8, *Commitments and Contingencies*, to the condensed consolidated financial statements included in Part I of this Quarterly Report, there have been no material changes to our long-term contractual obligations as disclosed in Part II, Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations*, of our Annual Report. For further information regarding our long-term non-cancellable purchase commitments, leases and license agreements, see Note 8, *Commitments and Contingencies*.

We do not have any off-balance sheet arrangements.

Based on our current operating plans, which include costs and expenses in connection with our U.S. commercial activities, continued clinical development of tradipitant, Bysanti™ and our other products, pursuit of regulatory approval of tradipitant, Bysanti™ and imsidolimab, pursuit of further regulatory approvals for our currently approved products and payments due upon achievement of milestones under our license agreements, we believe that our cash, cash equivalents and marketable securities and cash received from product sales will be sufficient for at least the next 12 months. Our future cash requirements and the adequacy of our available funds will depend on many factors, primarily including a regulatory approval of tradipitant, Bysanti™ and imsidolimab, our ability to generate revenue, the scope and costs of our commercial, manufacturing and process development activities, the magnitude of our discovery, preclinical and clinical development programs, and potential costs to acquire or license the rights to additional products.

We may need or desire to obtain additional capital to finance our operations through debt, equity or alternative financing arrangements. We may also seek capital through collaborations or partnerships with other companies. The issuance of debt could require us to grant liens on certain of our assets that may limit our flexibility and debt securities may be convertible into common stock. If we raise additional capital by issuing equity securities, the terms and prices for these financings may be much more favorable to the new investors than the terms obtained by our existing stockholders. These financings may also significantly dilute the ownership of our existing stockholders. If we are unable to obtain additional financing, we may be required to reduce the scope of our future activities, which could harm our business, financial condition and operating results. There can be no assurance that any additional financing required in the future will be available on acceptable terms, if at all.

Cash Flow

The following table summarizes our net cash flows from operating, investing and financing activities for the nine months ended September 30, 2025 and 2024:

(in thousands)	Nine Months Ended September 30, 2025	Nine Months Ended September 30, 2024	Net Change
Net cash provided by (used in):			
Operating activities:			
Net loss	$ (79,287)	$ (13,988)	$ (65,299)
Non-cash charges	(6,020)	7,324	(13,344)
Net change in operating assets and liabilities	5,282	(7,276)	12,558
Operating activities	(80,025)	(13,940)	(66,085)
Investing activities:			
Asset acquisition	—	(4,229)	4,229
Purchases of property and equipment	(896)	(276)	(620)
Net purchases, sales and maturities of marketable securities	50,890	(16,918)	67,808
Investing activities	49,994	(21,423)	71,417
Financing activities:			
Principal payments on finance leases	(1,351)	—	(1,351)
Tax obligations paid in connection with settlement of restricted stock units	(915)	—	(915)
Financing activities	(2,266)	—	(2,266)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	3	39	(36)
Net change in cash, cash equivalents and restricted cash	$ (32,294)	$ (35,324)	$ 3,030

Operating Activities: Cash flows used in operating activities during the nine months ended September 30, 2025 were $80.0 million, a decrease of $66.1 million compared to $13.9 million during the nine months ended September 30, 2024. The decrease primarily reflects a decrease of $65.3 million in net income, non-cash charges, including the change in deferred income taxes, as well as the net change in operating assets and liabilities. Our net loss for the nine months ended September 30, 2025 includes expenses associated with the $15.0 million payment related to the exclusive, global license agreement with Anaptys for the development and commercialization of imsidolimab. The decrease in net change in operating assets and liabilities is primarily due to timing of payments for product revenue allowances and receipt of cash for accounts receivable.

Investing Activities: Cash flows provided by investing activities during the nine months ended September 30, 2025 were $50.0 million, an increase of $71.4 million compared to $21.4 million cash used in investing activities during the nine months ended September 30, 2024. The change in investing activities primarily reflects the timing of reinvestment of available cash and cash equivalents and maturities of the investments in our portfolio of marketable securities. Additionally, the $4.2 million asset acquisition cash flow during the nine months ended September 30, 2024 relates to the payment of the remaining consideration for the PONVORY® acquisition that was accrued as of December 31, 2023.

Financing Activities: Financing activities include principal payments for our finance lease liabilities and tax obligations paid in connection with settlement of restricted stock units. Cash flows used in financing activities during the nine months ended September 30, 2025 were $2.3 million. There were no financing cash flows for the nine months ended September 30, 2024.

ITEM 3 Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk is currently confined to our cash and cash equivalents, marketable securities and restricted cash. We currently do not hedge interest rate exposure. We have not used derivative financial instruments for speculation or trading purposes.

We deposit our cash with financial institutions that we consider to be of high credit quality and purchase marketable securities that are generally investment grade, liquid, short-term fixed income securities and money-market instruments denominated in U.S. dollars. Our marketable securities consist of commercial paper, corporate notes and U.S. government agency notes and

have maturities of less than two years. We do not believe that an increase in market rates would have any significant impact on the realized value of our cash equivalents and marketable securities.

We are also exposed to risks related to changes in foreign currency exchange rates relating to our foreign operations. The functional currency of our international subsidiaries is the local currency. We are exposed to foreign currency risk to the extent that we enter into transactions denominated in currencies other than our subsidiaries' respective functional currencies. We are also exposed to unfavorable fluctuations of the U.S. dollar, which is our reporting currency, against the currencies of our operating subsidiaries when their respective financial statements are translated into U.S. dollars for inclusion in our condensed consolidated financial statements. We do not currently hedge our foreign currency exchange rate risk. Foreign currency has not had, nor do we believe that a decrease or increase in any foreign currency exchange rates would have, a material impact on our results of operations.

ITEM 4 Controls and Procedures

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (Exchange Act)) as of September 30, 2025. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of September 30, 2025, the end of the period covered by this quarterly report on Form 10-Q, to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the third quarter of 2025 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

Information with respect to this item may be found in Note 14, *Legal Matters,* to the condensed consolidated financial statements in Part I of this quarterly report on Form 10-Q, which is incorporated herein by reference.

ITEM 1A Risk Factors

We previously disclosed in Part I, Item 1A of our annual report on Form 10-K (Annual Report) for the year ended December 31, 2024, filed with the Securities and Exchange Commission on February 14, 2025, important factors which could affect our business, financial condition, results of operations and future operations under the heading Risk Factors. Our business, financial condition and operating results can be affected by a number of factors, whether currently known or unknown, including but not limited to those described as risk factors, any one or more of which could, directly or indirectly, cause our actual operating results and financial condition to vary materially from past, or anticipated future, operating results and financial condition. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, operating results and the price of our common stock. There have been no material changes to the risk factors disclosed in (i) our Annual Report for the fiscal year ended December 31, 2024 or (ii) any Quarterly Report on Form 10-Q filed subsequent to our Annual Report.

ITEM 2 Unregistered Sales of Equity Securities and Use of Proceeds

None.

ITEM 3 Defaults Upon Senior Securities

None.

ITEM 4 Mine Safety Disclosures

Not applicable.

ITEM 5 Other Information

During the fiscal quarter ended September 30, 2025, none of our directors or officers informed us of the adoption, modification or termination of a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Regulation S-K, Item 408. Furthermore, during the fiscal quarter ended September 30, 2025, we did not adopt or terminate a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Regulation S-K, Item 408.

ITEM 6 Exhibits

Exhibit Number	Description
3.1	Form of Amended and Restated Certificate of Incorporation of the registrant (filed as Exhibit 3.8 to Amendment No. 2 to the registrant's registration statement on Form S-1 (File No. 333-130759) on March 17, 2006 and incorporated herein by reference).
3.2	Amended and Restated Bylaws of the registrant, as amended and restated on October 2, 2024 (filed as Exhibit 3.1 to the registrant's current report on Form 8-K (File No. 001-34186) on October 3, 2024 and incorporated herein by reference).
3.3	Amended and Restated Certificate of Designation of Rights, Preferences and Privileges of Series A Junior Participating Preferred Stock of Vanda Pharmaceuticals Inc. (filed as Exhibit 3.1 to the registrant's current report on Form 8-K (File No. 001-34186) on April 17, 2024 and incorporated herein by reference).
31.1*	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of the Chief Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of the Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer), as required by Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from this quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2025 formatted in Inline Extensible Business Reporting Language (iXBRL) and filed electronically herewith: (i) Condensed Consolidated Balance Sheets as of September 30, 2025 and December 31, 2024; (ii) Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2025 and 2024; (iii) Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2025 and 2024; (iv) Condensed Consolidated Statements of Changes in Stockholders' Equity for the three and nine months ended September 30, 2025 and 2024; (v) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2025 and 2024; and (vi) Notes to Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* Filed herewith.

** Furnished herewith.

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.

Vanda Pharmaceuticals Inc.

October 30, 2025 /s/ Mihael H. Polymeropoulos, M.D.

Mihael H. Polymeropoulos, M.D.
President, Chief Executive Officer and Chairman of the Board
(Principal Executive Officer)

October 30, 2025 /s/ Kevin Moran

Kevin Moran
Senior Vice President, Chief Financial Officer and Treasurer
(Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mihael H. Polymeropoulos, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Vanda Pharmaceuticals 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) 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.

October 30, 2025

/s/ Mihael H. Polymeropoulos, M.D.

Mihael H. Polymeropoulos, M.D.
President, Chief Executive Officer and Chairman of the Board
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kevin Moran, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Vanda Pharmaceuticals 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) 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.

October 30, 2025

/s/ Kevin Moran

Kevin Moran
Senior Vice President, Chief Financial Officer and Treasurer
(Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Vanda Pharmaceuticals Inc. (the Company), does hereby certify, to the best of such officer's knowledge, that:

The Quarterly Report on Form 10-Q for the quarter ended September 30, 2025 (the Form 10-Q) of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and the information contained in the Form 10-Q fairly presents, in all material respects, the consolidated financial condition and results of operations of the Company.

October 30, 2025

/s/ Mihael H. Polymeropoulos, M.D.

Mihael H. Polymeropoulos, M.D.
President, Chief Executive Officer and Chairman of the Board
(Principal Executive Officer)

October 30, 2025

/s/ Kevin Moran

Kevin Moran
Senior Vice President, Chief Financial Officer and Treasurer
(Principal Financial Officer and Principal Accounting Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission (SEC) or its staff upon request. This certification "accompanies" the Form 10-Q to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Company 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 the Form 10-Q), irrespective of any general incorporation language contained in such filing.