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

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2023
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 x No o

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 x No o

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	x	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. o

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

As of July 20, 2023, there were 57,508,663 shares of the registrant's common stock issued and outstanding.

Vanda Pharmaceuticals Inc.

Quarterly Report on Form 10-Q
For the Quarter Ended June 30, 2023

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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 continue to commercialize HETLIOZ® (tasimelteon) capsules for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in the United States (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 increase market awareness of Non-24 and SMS and market acceptance of HETLIOZ®;
- our ability to overcome the continued reimbursement and patient access challenges we face as a result of third-party payor coverage;
- our ability to continue to generate U.S. sales of Fanapt® (iloperidone) oral tablets for the treatment of schizophrenia;
- our ability to obtain approval from the FDA for Fanapt® beyond the currently approved indications;
- our ability to obtain regulatory approval for tradipitant from the U.S. Food and Drug Administration (FDA);
- 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 HETLIOZ®, HETLIOZ LQ®, and Fanapt® 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 ability to obtain approval from the FDA for HETLIOZ® beyond the currently approved indications;
- 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;
- the size and growth of the 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;
- the cost and effects of litigation;
- 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, 2022, 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)	June 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 150,031	$ 135,029
Marketable securities	339,320	331,830
Accounts receivable, net	33,621	33,512
Inventory	1,080	1,194
Prepaid expenses and other current assets	9,452	17,727
Total current assets	533,504	519,292
Property and equipment, net	2,164	2,573
Operating lease right-of-use assets	7,782	8,400
Intangible assets, net	17,808	18,565
Deferred tax assets	70,476	74,039
Non-current inventory and other	9,948	11,378
Total assets	$ 641,682	$ 634,247
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 31,929	$ 45,551
Product revenue allowances	55,468	45,885
Total current liabilities	87,397	91,436
Operating lease non-current liabilities	7,942	8,813
Other non-current liabilities	6,445	6,800
Total liabilities	101,784	107,049
Commitments and contingencies (Notes 8 and 13)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 20,000,000 shares authorized, and no shares issued or outstanding at June 30, 2023 and December 31, 2022	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized; 57,496,913 and 56,783,764 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	57	57
Additional paid-in capital	693,835	686,235
Accumulated other comprehensive loss	(865)	(1,193)
Accumulated deficit	(153,129)	(157,901)
Total stockholders' equity	539,898	527,198
Total liabilities and stockholders' equity	$ 641,682	$ 634,247

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		Six Months Ended	
	June 30, 2023	June 30, 2022	June 30, 2023	June 30, 2022
Revenues:				
Net product sales	$ 46,056	$ 64,390	$ 108,554	$ 124,582
Total revenues	46,056	64,390	108,554	124,582
Operating expenses:				
Cost of goods sold excluding amortization	3,499	6,059	8,273	11,724
Research and development	16,647	21,490	35,884	42,459
Selling, general and administrative	28,399	33,001	64,503	73,849
Intangible asset amortization	378	379	757	758
Total operating expenses	48,923	60,929	109,417	128,790
Income (loss) from operations	(2,867)	3,461	(863)	(4,208)
Other income	5,459	329	8,983	434
Income (loss) before income taxes	2,592	3,790	8,120	(3,774)
Provision for income taxes	1,072	1,216	3,348	82
Net income (loss)	$ 1,520	$ 2,574	$ 4,772	$ (3,856)
Net income (loss) per share:				
Basic	$ 0.03	$ 0.05	$ 0.08	$ (0.07)
Diluted	$ 0.03	$ 0.05	$ 0.08	$ (0.07)
Weighted average shares outstanding:				
Basic	57,453,916	56,508,533	57,233,878	56,307,999
Diluted	57,535,615	56,821,024	57,469,105	56,307,999

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

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

(in thousands)	Three Months Ended		Six Months Ended	
	June 30, 2023	June 30, 2022	June 30, 2023	June 30, 2022
Net income (loss)	$ 1,520	$ 2,574	$ 4,772	$ (3,856)
Other comprehensive income (loss):				
Net foreign currency translation gain (loss)	3	(30)	12	(46)
Change in net unrealized gain (loss) on marketable securities	(796)	(95)	410	(1,570)
Tax benefit (provision) on other comprehensive income (loss)	183	22	(94)	360
Other comprehensive income (loss), net of tax	(610)	(103)	328	(1,256)
Comprehensive income (loss)	$ 910	$ 2,471	$ 5,100	$ (5,112)

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 Shares	Common Stock Par Value	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
Balances at December 31, 2022	56,783,764	$ 57	$ 686,235	$ (1,193)	$ (157,901)	$ 527,198
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	657,228	—	—	—	—	—
Stock-based compensation expense	—	—	4,351	—	—	4,351
Net income	—	—	—	—	3,252	3,252
Other comprehensive income, net of tax	—	—	—	938	—	938
Balances at March 31, 2023	57,440,992	$ 57	$ 690,586	$ (255)	$ (154,649)	$ 535,739
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	55,921	—	—	—	—	—
Stock-based compensation expense	—	—	3,249	—	—	3,249
Net income	—	—	—	—	1,520	1,520
Other comprehensive loss, net of tax	—	—	—	(610)	—	(610)
Balances at June 30, 2023	57,496,913	$ 57	$ 693,835	$ (865)	$ (153,129)	$ 539,898

(in thousands, except for share amounts)	Common Stock Shares	Common Stock Par Value	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
Balances at December 31, 2021	55,900,855	$ 56	$ 669,223	$ (175)	$ (164,176)	$ 504,928
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	585,857	—	—	—	—	—
Stock-based compensation expense	—	—	4,778	—	—	4,778
Net loss	—	—	—	—	(6,430)	(6,430)
Other comprehensive loss, net of tax	—	—	—	(1,153)	—	(1,153)
Balances at March 31, 2022	56,486,712	$ 56	$ 674,001	$ (1,328)	$ (170,606)	$ 502,123
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	65,750	1	124	—	—	125
Stock-based compensation expense	—	—	3,830	—	—	3,830
Net income	—	—	—	—	2,574	2,574
Other comprehensive loss, net of tax	—	—	—	(103)	—	(103)
Balances at June 30, 2022	56,552,462	$ 57	$ 677,955	$ (1,431)	$ (168,032)	$ 508,549

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)	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022
Cash flows from operating activities		
Net income (loss)	$ 4,772	$ (3,856)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation of property and equipment	515	634
Stock-based compensation	7,600	8,608
Amortization of premiums and accretion of discounts on marketable securities	(4,241)	(2)
Loss on sale of marketable securities	655	—
Intangible asset amortization	757	758
Deferred income taxes	3,469	2,550
Other non-cash adjustments, net	1,844	975
Changes in operating assets and liabilities:		
Accounts receivable	(199)	3,575
Prepaid expenses and other assets	8,527	(13,691)
Inventory	210	(1,582)
Accounts payable and other liabilities	(14,035)	13,732
Product revenue allowances	8,709	(1,970)
Net cash provided by operating activities	18,583	9,731
Cash flows from investing activities		
Purchases of property and equipment	(106)	(268)
Purchases of marketable securities	(410,979)	(175,985)
Sales and maturities of marketable securities	407,485	172,527
Net cash used in investing activities	(3,600)	(3,726)
Cash flows from financing activities		
Proceeds from exercise of stock options	—	125
Net cash provided by financing activities	—	125
Effect of exchange rate changes on cash, cash equivalents and restricted cash	19	22
Net change in cash, cash equivalents and restricted cash	15,002	6,152
Cash, cash equivalents and restricted cash		
Beginning of period	135,498	52,590
End of period	$ 150,500	$ 58,742

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) 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 and operates in one reporting segment.

The Company's commercial portfolio is currently comprised of two products, HETLIOZ® for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) and nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) and Fanapt® for the treatment of schizophrenia. HETLIOZ® is the first product approved by the United States Food and Drug Administration (FDA) for patients with Non-24 and patients with SMS. In addition, the Company has a number of drugs in development, including:

- HETLIOZ® (tasimelteon) for the treatment of jet lag disorder, insomnia, delayed sleep phase disorder (DSPD), sleep disturbances in autism spectrum disorder (ASD) and pediatric Non-24;
- Fanapt® (iloperidone) for the treatment of bipolar I disorder and Parkinson's disease psychosis and a long acting injectable (LAI) formulation for the treatment of schizophrenia;
- Tradipitant (VLY-686), a small molecule neurokinin-1 (NK-1) receptor antagonist, for the treatment of gastroparesis, motion sickness, atopic dermatitis, and COVID-19 pneumonia;
- VTR-297, a small molecule histone deacetylase (HDAC) inhibitor for the treatment of 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 performance anxiety and psychiatric disorders;
- VHX-896, the active metabolite of iloperidone; and
- Antisense oligonucleotide (ASO) molecules.

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, 2022. The financial information as of June 30, 2023 and for the three and six months ended June 30, 2023 and 2022 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, 2022 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 at the date of the financial statements, disclosure of contingent assets and liabilities, and the reported amounts of revenue and expenses during the reporting period. Management continually re-evaluates its

estimates, judgments and assumptions, and management's evaluation could change. Actual results could differ from those estimates.

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 leases for office space 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:

(in thousands)	June 30, 2023	June 30, 2022
Cash and cash equivalents	$ 150,031	$ 58,226
Restricted cash included in non-current inventory and other	469	516
Total cash, cash equivalents and restricted cash	$ 150,500	$ 58,742

Revenue from Net Product Sales

The Company's net product sales consist of sales of HETLIOZ® and Fanapt®. Net sales by product for the three and six months ended June 30, 2023 and 2022 were as follows:

	Three Months Ended		Six Months Ended	
(in thousands)	June 30, 2023	June 30, 2022	June 30, 2023	June 30, 2022
HETLIOZ® net product sales	$ 21,979	$ 41,188	$ 61,595	$ 78,219
Fanapt® net product sales	24,077	23,202	46,959	46,363
Total net product sales	$ 46,056	$ 64,390	$ 108,554	$ 124,582

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 and June 30, 2023. HETLIOZ® net product sales during the three months ended June 30, 2023 reflect lower unit sales as a result of the reduction of the elevated inventory levels at specialty pharmacy customers at March 31, 2023 and as a result of continued generic competition. HETLIOZ® net product sales will likely decline in future periods, potentially significantly, as a result of continued reduction of the elevated inventory levels at specialty pharmacy customers absent removal of generic HETLIOZ® products from the United States (U.S.) market. Additionally, the Company constrained HETLIOZ® net product sales for the three and six months ended June 30, 2023 to an amount not probable of significant revenue reversal. The Company recognized $4.8 million of net product sales during the three months ended June 30, 2023 related to a change in estimate on revenue constrained during the first quarter of 2023. HETLIOZ® net product sales could experience variability in future periods as the remaining uncertainties associated with variable consideration related to the significant increase of inventory stocking by specialty pharmacy customers during the three months ended March 31, 2023 are resolved.

Major Customers

HETLIOZ® is available in the U.S. for distribution through a limited number of specialty pharmacies and is not available in retail pharmacies. Fanapt® is available in the U.S. for distribution through a limited number of wholesalers and is available in retail pharmacies. The Company invoices and records revenue when its customers, specialty pharmacies and wholesalers, receive product from the third-party logistics warehouse, which is the point at which control is transferred to the customer. There were five major customers that each accounted for more than 10% of total revenues and, as a group, represented 80% of total revenues for the six months ended June 30, 2023. There were five major customers that each accounted for more than 10% of accounts receivable and, as a group, represented 94% of total accounts receivable at June 30, 2023. 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

There are no recent accounting pronouncements that are expected to have a material impact on the Company's condensed consolidated financial statements or related disclosures.

3. Marketable Securities

The following is a summary of the Company's available-for-sale marketable securities as of June 30, 2023, 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	$ 236,097	$ 18	$ (1,058)	$ 235,057
Corporate debt	104,351	13	(101)	104,263
Total marketable securities	$ 340,448	$ 31	$ (1,159)	$ 339,320

The following is a summary of the Company's available-for-sale marketable securities as of December 31, 2022, 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	$ 178,351	$ —	$ (1,181)	$ 177,170
Corporate debt	155,017	14	(371)	154,660
Total marketable securities	$ 333,368	$ 14	$ (1,552)	$ 331,830

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 June 30, 2023 and December 31, 2022 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 June 30, 2023, as follows:

		Fair Value Measurement as of June 30, 2023 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	$ 235,057	$ 235,057	$ —	$ —
Corporate debt	149,847	—	149,847	—
Total assets measured at fair value	$ 384,904	$ 235,057	$ 149,847	$ —

The Company held certain assets that are required to be measured at fair value on a recurring basis as of December 31, 2022, as follows:

		Fair Value Measurement as of December 31, 2022 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	$ 177,170	$ 177,170	$ —	$ —
Corporate debt	154,660	—	154,660	—
Total assets measured at fair value	$ 331,830	$ 177,170	$ 154,660	$ —

Total assets measured at fair value as of June 30, 2023 include $45.6 million of cash equivalents. Total assets measured at fair value as of December 31, 2022 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 June 30, 2023 and December 31, 2022:

(in thousands)	June 30, 2023	December 31, 2022
Current assets		
Work-in-process	$ —	$ 23
Finished goods	1,080	1,171
Total inventory, current	$ 1,080	$ 1,194
Non-Current assets		
Raw materials	$ 1,043	$ 1,043
Work-in-process	7,260	8,212
Finished goods	798	1,041
Total inventory, non-current	9,101	10,296
Total inventory	$ 10,181	$ 11,490

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. 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 $7.1 million and $8.0 million of HETLIOZ® product and $3.0 million and $3.4 million of Fanapt® product as of June 30, 2023 and December 31, 2022, respectively.

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.

The following is a summary of the Company's intangible assets as of June 30, 2023:

(in thousands)	Estimated Useful Life	June 30, 2023 Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	March 2035	$ 33,000	$ 15,192	$ 17,808

The following is a summary of the Company's intangible assets as of December 31, 2022:

(in thousands)	Estimated Useful Life	December 31, 2022 Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	March 2035	$ 33,000	$ 14,435	$ 18,565

As of June 30, 2023 and December 31, 2022, 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 $0.4 million for each of the three months ended June 30, 2023 and 2022. Amortization expense was $0.8 million for each of the six months ended June 30, 2023 and 2022. The following is a summary of the future intangible asset amortization schedule as of June 30, 2023:

(in thousands)	Total	2023	2024	2025	2026	2027	Thereafter
HETLIOZ®	$ 17,808	$ 759	$ 1,516	$ 1,516	$ 1,516	$ 1,516	$ 10,985

7. Accounts Payable and Accrued Liabilities

The following is a summary of the Company's accounts payable and accrued liabilities as of June 30, 2023 and December 31, 2022:

(in thousands)	June 30, 2023	December 31, 2022
Research and development expenses	$ 13,277	$ 9,474
Consulting and other professional fees	7,061	9,241
Compensation and employee benefits	4,319	6,839
Royalties payable	2,736	4,979
Operating lease liabilities	2,366	2,328
Accounts payable and other accrued liabilities	2,170	12,690
Total accounts payable and accrued liabilities	$ 31,929	$ 45,551

As of December 31, 2022, the prepaid expenses and other current assets and accounts payable and accrued liabilities balances included $11.5 million related to the case *Gordon v. Vanda Pharmaceuticals Inc.* In January 2023, the settlement related to the case was fully and finally approved. As a result, the Company removed the associated prepaid and liability balances. (See Note 16, *Legal Matters*, in Part II, Item 8 of the Annual Report for additional information.)

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.

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 June 30, 2023, 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 in the U.S. decreased from 10% to 5% in December 2022. This U.S. royalty will end 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®.

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 (NCE) 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.

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 June 30, 2023, the Company has paid Lilly $3.0 million in upfront fees and development milestones. As of June 30, 2023, remaining milestone obligations include a $2.0 million development milestone due upon the filing of the first application for marketing authorization for tradipitant in either the U.S. or European Union (E.U.), $10.0 million and $5.0 million 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.

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 under the license agreement, 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 June 30, 2023, the Company has paid UCSF $1.6 million in upfront fees and development milestones. As of June 30, 2023, 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 but 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; however, Novartis is eligible to receive tiered-royalties on net sales at percentage rates up to the mid-teens.

Other Agreements

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 during the year ended December 31, 2022. The Company is funding the research and development activities and has the option to license jointly developed intellectual property upon successful development.

Purchase Commitments

In the 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 longer than one year are not material. 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.

9. Accumulated Other Comprehensive Loss

The accumulated balances related to each component of other comprehensive loss, net of taxes, were as follows as of June 30, 2023 and December 31, 2022:

(in thousands)	June 30, 2023	December 31, 2022
Foreign currency translation	$ 5	$ (7)
Unrealized loss on marketable securities	(870)	(1,186)
Accumulated other comprehensive loss	$ (865)	$ (1,193)

10. Stock-Based Compensation

As of June 30, 2023, there were 7,047,240 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. Each of the amendments to the 2016 Plan was approved by the Company's stockholders. There is a total of 13,790,000 shares of common stock authorized for issuance under the 2016 Plan, 4,479,515 shares of which remained available for future grant as of June 30, 2023.

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 June 30, 2023, $8.1 million of unrecognized compensation costs related to unvested service option awards are expected to be recognized over a weighted average period of 1.3 years. No option awards are classified as a liability as of June 30, 2023.

A summary of option activity under the Plans for the six months ended June 30, 2023 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, 2022	4,232,210	$ 14.19	5.81	$ —
Granted	944,776	6.92		
Expired	(130,417)	12.38		
Outstanding at June 30, 2023	5,046,569	12.88	6.20	26
Exercisable at June 30, 2023	3,321,471	14.26	4.76	—
Vested and expected to vest at June 30, 2023	4,763,321	13.15	6.01	20

The weighted average grant date fair value of options granted was $3.53 and $5.18 per share for the six months ended June 30, 2023 and 2022, respectively. There were no proceeds from the exercise of stock options for the six months ended June 30, 2023. Proceeds from the exercise of stock options amounted to $0.1 million for the six months ended June 30, 2022.

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 June 30, 2023, $19.0 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 June 30, 2023.

A summary of RSU activity for the Plans for the six months ended June 30, 2023 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2022	1,915,546	$ 14.41
Granted	852,243	6.97
Forfeited	(53,969)	13.13
Vested	(713,149)	15.10
Unvested at June 30, 2023	2,000,671	11.03

The grant date fair value for the 713,149 shares underlying RSUs that vested during the six months ended June 30, 2023 was $10.8 million.

Stock-Based Compensation Expense

Stock-based compensation expense recognized for the three and six months ended June 30, 2023 and 2022 was comprised of the following:

	Three Months Ended		Six Months Ended	
(in thousands)	June 30, 2023	June 30, 2022	June 30, 2023	June 30, 2022
Research and development	$ 733	$ 899	$ 1,799	$ 2,059
Selling, general and administrative	2,516	2,931	5,801	6,549
Total stock-based compensation expense	$ 3,249	$ 3,830	$ 7,600	$ 8,608

The fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton option pricing model that uses the assumptions noted in the following table. 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. Assumptions used in the Black-Scholes-Merton option pricing model for employee and director stock options granted during the six months ended June 30, 2023 and 2022 were as follows:

	Six Months Ended	
	June 30, 2023	June 30, 2022
Expected dividend yield	0 %	0 %
Weighted average expected volatility	47 %	46 %
Weighted average expected term (years)	6.16	6.05
Weighted average risk-free rate	3.89 %	2.03 %

11. Income Taxes

For the three months ended June 30, 2023 and 2022, the Company recorded a provision for income taxes of $1.1 million and $1.2 million, respectively. The income tax expense for the three months ended June 30, 2023 and 2022 was primarily driven by the estimated effective tax rate for the year, as well as discrete income tax expense of $0.8 million and $0.3 million, respectively.

For the six months ended June 30, 2023 and 2022, the Company recorded a provision for income taxes of $3.3 million and $0.1 million, respectively. The income tax expense for the six months ended June 30, 2023 and 2022 was primarily driven by the estimated effective tax rate for the year, as well as discrete income tax expense of $1.8 million and $1.4 million, respectively.

12. Earnings per Share

Basic earnings per share (EPS) is calculated by dividing the net income (loss) by the weighted average number of shares of common stock outstanding. Diluted EPS is computed by dividing the net income (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.

The following table presents the calculation of basic and diluted net income (loss) per share of common stock for the three and six months ended June 30, 2023 and 2022:

	Three Months Ended		Six Months Ended	
(in thousands, except for share and per share amounts)	June 30, 2023	June 30, 2022	June 30, 2023	June 30, 2022
Numerator:				
Net income (loss)	$ 1,520	$ 2,574	$ 4,772	$ (3,856)
Denominator:				
Weighted average shares outstanding, basic	57,453,916	56,508,533	57,233,878	56,307,999
Effect of dilutive securities	81,699	312,491	235,227	—
Weighted average shares outstanding, diluted	57,535,615	56,821,024	57,469,105	56,307,999
Net income (loss) per share, basic and diluted:				
Basic	$ 0.03	$ 0.05	$ 0.08	$ (0.07)
Diluted	$ 0.03	$ 0.05	$ 0.08	$ (0.07)
Antidilutive securities excluded from calculations of diluted net income (loss) per share	6,722,509	5,389,183	6,427,780	4,982,824

The Company incurred a net loss for the six months ended June 30, 2022 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. Legal Matters

HETLIOZ®. Between April 2018 and March 2021, the Company filed numerous Hatch-Waxman lawsuits in the U.S. District Court for the District of Delaware (Delaware District Court) against Teva Pharmaceuticals USA, Inc. (Teva), MSN

Pharmaceuticals Inc. and MSN Laboratories Private Limited (MSN) and Apotex Inc. and Apotex Corp. (Apotex, and collectively with Teva and MSN, the HETLIOZ® Defendants) asserting that U.S. Patent Nos. RE46,604 ('604 Patent), 9,060,995, 9,539,234, 9,549,913, 9,730,910 ('910 Patent), 9,844,241, 10,071,977, 10,149,829 ('829 Patent), 10,376,487 ('487 Patent), 10,449,176, 10,610,510, 10,610,511, 10,829,465, and 10,611,744 will be infringed by the HETLIOZ® Defendants' generic versions of HETLIOZ® for which they were seeking FDA approval. As initially disclosed in the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 14, 2022, in January 2022, the Company entered into a license agreement with MSN and Impax Laboratories LLC (Impax) resolving the lawsuits against MSN (the MSN/Impax License Agreement). The MSN/Impax License Agreement grants MSN and Impax a non-exclusive license to manufacture and commercialize MSN's generic version of HETLIOZ® in the U.S. effective as of March 13, 2035, unless prior to that date the Company obtains pediatric exclusivity for HETLIOZ®, in which case the license will be effective as of July 27, 2035. The MSN/Impax License Agreement also provides that MSN and Impax may launch a generic version of HETLIOZ® earlier under certain limited circumstances. The consolidated lawsuits against the remaining HETLIOZ® Defendants were tried in March 2022.

On December 13, 2022, the Delaware District Court ruled that Teva and Apotex did not infringe the '604 Patent, and that the asserted claims of the '604, '910, '829 and '487 Patents were invalid. In December 2022, the Company appealed the Delaware District Court's decision to the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) and an oral argument for the appeal was held in March 2023. On May 10, 2023, a three-judge panel of the Federal Circuit affirmed the Delaware District Court's ruling, and on June 9, 2023, the Company requested a rehearing or rehearing en banc from the Federal Circuit. On July 18, 2023, the Federal Circuit requested a response from Teva and Apotex, due August 1, 2023.

On December 27, 2022, the Company filed patent infringement lawsuits, including Hatch-Waxman Act claims, against each of Teva and 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, a method of administration patent that was not litigated in the Delaware District Court cases ('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 Delaware District Court, where it is now pending.

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 March 2023, Teva filed a motion to dismiss or to transfer the case to the Delaware District Court, which motion 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, 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; additionally, the generic drug must have the same conditions of use as the listed drug. The labeling and packaging for HETLIOZ® includes Braille, but Teva's generic tasimelteon 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 shipments or sales of its generic HETLIOZ® product. In February 2023, Teva intervened in the lawsuit as a defendant. The Company's lawsuit remains pending.

Other Matters. From April 2022 to June 2023, the Company filed eight lawsuits in the DC District Court against the FDA to compel the FDA to produce records under the Freedom of Information Act (FOIA). The first lawsuit, filed in April 2022, requested certain records relating to its denial of the Company's supplemental NDA for HETLIOZ® in the treatment of jet lag disorder. The Company had repeatedly attempted to obtain these records from the FDA pursuant to a FOIA request submitted by the Company in December of 2019, but the FDA refused to provide them, claiming an exemption under FOIA. In March 2023, the DC District Court ruled in the Company's favor, rejecting the FDA's claim that the exemption applied to the records requested. The second lawsuit, filed in May 2022, requested certain records regarding 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. The Company attempted to obtain these records from the FDA pursuant to a FOIA request submitted by the Company in January of 2020, but the FDA failed to respond to the request. In response to litigation, the FDA provided these

records to the Company. On June 20, 2023, the Company and the FDA filed a stipulation of dismissal to the action. The remaining lawsuits, which relate to requests for communications external to and within the FDA relating to tradipitant, communications external to and within the FDA relating to HETLIOZ®, communications external to and within the FDA relating to a warning letter that the FDA sent to Vanda concerning Vanda's webpages for HETLIOZ® and Fanapt®, and communications relating to the FDA's removal of a clinical trials design presentation from its website, are ongoing. The FDA has failed to respond and disclose the requested documents within the statutory timeframe with respect to each of these requests. 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 April 2022, the Company filed a lawsuit in the U.S. District Court for the District of Maryland (the MD District Court) against the Centers for Medicare & Medicaid Services (CMS) and the Administrator of CMS challenging CMS' rule broadly interpreting the defined terms "line extension" and "new formulation" under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (ACA), which went into effect in January 2022 (the Rule). The Company believes that the Rule is unlawful and contrary to the intent of Congress when it passed the ACA. Under the Rule, certain of the Company's products would be treated as line extensions and new formulations subject to enhanced rebates, despite the statutory text and CMS' own long-standing practice, under which such products would not constitute line extensions or new formulations. In March 2023, the MD District Court ruled that CMS' interpretation of the terms was reasonable and consistent with Congress' intent. In April 2023, the Company appealed the ruling to the U.S. Court of Appeals for the Fourth Circuit.

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 September 2022, the Company filed a lawsuit in the DC District Court against the FDA to compel the FDA to comply with two separate nondiscretionary obligations under the FDCA and its implementing regulations: an obligation to publish a notice of an opportunity for a hearing on the Company's supplemental New Drug Application (sNDA) 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 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.

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

Overview

Vanda Pharmaceuticals Inc. (we, our 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 two products, HETLIOZ® for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) and nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) and Fanapt® for the treatment of schizophrenia. HETLIOZ® is the first product approved by the U.S. Food and Drug Administration (FDA) for patients with Non-24 and patients with SMS. In addition, we have a number of drugs in development, including:

- HETLIOZ® (tasimelteon) for the treatment of jet lag disorder, insomnia, delayed sleep phase disorder (DSPD), sleep disturbances in autism spectrum disorder (ASD) and pediatric Non-24;
- Fanapt® (iloperidone) for the treatment of bipolar I disorder and Parkinson's disease psychosis and a long acting injectable (LAI) formulation for the treatment of schizophrenia;
- Tradipitant (VLY-686), a small molecule neurokinin-1 (NK-1) receptor antagonist, for the treatment of gastroparesis, motion sickness, atopic dermatitis, and COVID-19 pneumonia;
- VTR-297, a small molecule histone deacetylase (HDAC) inhibitor for the treatment of 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 performance anxiety and psychiatric disorders;
- VHX-896, the active metabolite of iloperidone; and
- Antisense oligonucleotide (ASO) molecules.

Operational Highlights

Fanapt®

- We previously announced positive results in the Phase III clinical study of Fanapt® in acute manic and mixed episodes associated with bipolar I disorder in adults. We continue to pursue FDA approval of a supplemental New Drug Application (sNDA) for Fanapt® in bipolar I disorder.

HETLIOZ®

- We are continuing to pursue FDA approvals for HETLIOZ® in the indications of insomnia and jet lag disorder.
- In May 2023, the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit) affirmed the lower court ruling in favor of Teva Pharmaceuticals USA, Inc. (Teva), Apotex Inc. and Apotex Corp. (Apotex) in the HETLIOZ® Abbreviated New Drug Applications litigation. We disagree with the Federal Circuit's ruling, and in June 2023, we requested a rehearing from the Federal Circuit. On July 18, 2023, the Federal Circuit requested a response from Teva and Apotex, which is due August 1, 2023.

Tradipitant

- We continue to pursue FDA approval of a New Drug Application (NDA) for tradipitant for patients with gastroparesis.
- We announced positive results in the Phase III study of tradipitant in motion sickness. We plan to continue the motion sickness clinical program and pursue FDA approval upon completion of additional efficacy and safety studies.

Early-Stage Programs

- We announced that the FDA had granted Orphan Drug Designation for VCA-894A for the treatment of Charcot-Marie-Tooth disease, axonal, type 2S (CMT2S), caused by cryptic splice site variants within IGHMBP2.

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 HETLIOZ® and Fanapt® in the U.S. and Europe, 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, 2022.

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.

HETLIOZ® is available in the U.S. for distribution through a limited number of specialty pharmacies and is not available in retail pharmacies. Fanapt® is available in the U.S. for distribution through a limited number of wholesalers and is available in retail pharmacies. We invoice and record revenue when customers, specialty pharmacies and wholesalers, 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 sell HETLIOZ® in Germany and have a distribution agreement with Megapharm Ltd. for the commercialization of Fanapt® in Israel. 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 six months ended June 30, 2023, we constrained the variable consideration for HETLIOZ® net product sales. The constrained revenue relates to the uncertainties of payor utilization 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, and product returns that are resolved during the product expiry period specified in the customer contract. Due to increased inventory stocking at specialty pharmacy customers of HETLIOZ® in the first quarter of 2023, the time for these uncertainties to be resolved could be longer than we have historically experienced. We currently record sales allowances for the following:

Prompt-pay: Specialty pharmacies and wholesalers are generally offered discounts for prompt payment. We expect that the specialty pharmacies and wholesalers will earn prompt payment discounts and, therefore, 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 new 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 specialty pharmacies and wholesalers. 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 specialty pharmacy or wholesaler, in turn, charges back the difference between the price initially paid by the specialty pharmacy or wholesaler and the discounted price paid to the specialty pharmacy or wholesaler by the contracted customer.

Medicare Part D coverage gap: The Medicare Part D prescription drug benefit requires 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 coverage gap are based in part on historical activity and, where available, actual and pending prescriptions when we have validated the insurance benefits.

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 goods to be resalable. There was no right of return asset as of June 30, 2023 or December 31, 2022.

The following table summarizes sales discounts and allowance activity as of and for the six months ended June 30, 2023:

(in thousands)	Rebates & Chargebacks	Discounts, Returns and Other	Total
Balances at December 31, 2022	$ 37,459	$ 10,024	$ 47,483
Provision related to current period sales	52,103	14,819	66,922
Adjustments for prior period sales	491	26	517
Credits/payments made	(44,521)	(14,350)	(58,871)
Balances at June 30, 2023	$ 45,532	$ 10,519	$ 56,051

The provision of $52.1 million for rebates and chargebacks for the six months ended June 30, 2023 primarily represents Medicaid rebates applicable to sales of HETLIOZ® and Fanapt®. The provision of $14.8 million for discounts, returns and other for the six months ended June 30, 2023 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 both HETLIOZ® and Fanapt®.

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 often are 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. 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.

As a result of the unfavorable events and subsequent developments in the fourth quarter of 2022 and second quarter of 2023 related to the HETLIOZ® patent litigation (see Note 13, *Legal Matters*, in Part I of this Quarterly Report) we performed impairment reviews for our HETLIOZ® asset group and determined, based upon our review of undiscounted cash flows, that the carrying value of our HETLIOZ® asset group, inclusive of the intangible asset, is recoverable. Accordingly, we did not record an intangible asset impairment charge for the periods ended June 30, 2023 and December 31, 2022. The litigation and subsequent developments do not affect the sale of HETLIOZ® in the E.U. and there is no generic litigation pending outside of the U.S. with respect to HETLIOZ®. Furthermore, the litigation and subsequent events do not relate to the HETLIOZ LQ® oral suspension formulation. Our expected cash flows continue to support our estimated useful economic life of the intangible asset through March 2035.

Income taxes. We assess the need for a valuation allowance against our 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 of the deferred tax assets will not be realized. The analysis is highly dependent upon historical and projected taxable income. Projected taxable income includes significant assumptions related to revenue, commercial expenses and research and development activities, which could be affected by the HETLIOZ® generic competition, amongst other factors. 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 on Form 10-Q (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, 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. In December 2022, the U.S. District Court for the District of Delaware ruled in favor of Teva Pharmaceuticals USA, Inc. (Teva) and Apotex Inc. and Apotex Corp. (Apotex) in our patent litigation relating to their filing of Abbreviated New Drug Applications (ANDAs) for generic versions of HETLIOZ® in the U.S., and in May 2023, the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) affirmed this ruling. We disagree with the Federal Circuit's ruling and on June 9, 2023, we requested a rehearing or rehearing en banc from the Federal Circuit. On July 18, 2023, the Federal Circuit requested a response from Teva and Apotex, due August 1, 2023. The FDA approved Teva's ANDA in December 2022, and Teva has since launched its generic version of HETLIOZ® at risk in the U.S. The FDA has also approved the ANDAs for Apotex and MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited (MSN), and HETLIOZ® could face even more competition from generic companies in the U.S. in the near term in light of the patent litigation rulings against us. The license agreement that we entered into when we settled our litigation with MSN (MSN/Impax License Agreement) grants MSN and Impax Laboratories LLC (Impax) a non-exclusive license to manufacture and commercialize MSN's generic version of HETLIOZ® in the U.S. effective as of March 13, 2035, unless prior to that date we obtain pediatric exclusivity for HETLIOZ®, in which case the license will be effective as of July 27, 2035. The MSN/Impax License Agreement also provides that MSN and Impax may launch a generic version of HETLIOZ® earlier under certain limited circumstances. MSN and its commercial partner, Amneal Pharmaceuticals, Inc., have informed us of their belief that such circumstances have occurred. We disagree with this position and intend to aggressively defend our legal rights to exclusivity for HETLIOZ®. Sales of generic versions of HETLIOZ® could result in a significant reduction in the demand for HETLIOZ® and/or the price at which we can sell it and/or create volatility in net product sales in future periods, which would have a material and adverse impact on our revenues and results of operations. Unless and until we are able to successfully enforce our legal rights to exclusivity, we may reduce the amount we spend with the intention of retaining the capability to ramp-up promptly.

Three months ended June 30, 2023 compared to three months ended June 30, 2022

Revenues. Total revenues decreased by $18.3 million, or 28%, to $46.1 million for the three months ended June 30, 2023 compared to $64.4 million for the three months ended June 30, 2022. Revenues were as follows:

	Three Months Ended			
(in thousands)	**June 30, 2023**	**June 30, 2022**	**Net Change**	**Percent**
HETLIOZ® net product sales	$ 21,979	$ 41,188	$ (19,209)	(47)%
Fanapt® net product sales	24,077	23,202	875	4 %
Total net product sales	$ 46,056	$ 64,390	$ (18,334)	(28)%

HETLIOZ® net product sales decreased by $19.2 million, or 47%, to $22.0 million for the three months ended June 30, 2023 compared to $41.2 million for the three months ended June 30, 2022. The decrease to net product sales was attributable to a decrease in volume and a decrease in price net of deductions, partially offset by the recognition of $4.8 million of net product sales related to a change in estimate on revenue constrained during the first quarter of 2023. 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 and June 30, 2023. HETLIOZ® net product sales during the three months ended June 30, 2023 reflect lower unit sales as a result of the reduction of the elevated inventory levels at specialty pharmacy customers at March 31, 2023 and as a result of continued generic competition. HETLIOZ® net product sales will likely decline in future periods, potentially significantly, as a result of continued reduction of the elevated inventory levels at specialty pharmacy customers absent removal of generic HETLIOZ® products from the U.S. market. Additionally, we constrained HETLIOZ® net product sales for the three and six months ended June 30, 2023 to an amount not probable of significant revenue reversal. HETLIOZ® net product sales could experience variability in future periods as the remaining uncertainties associated with variable consideration related to the significant increase of inventory stocking by specialty pharmacy customers during the three months ended March 31, 2023 are resolved.

Fanapt® net product sales increased by $0.9 million, or 4%, to $24.1 million for the three months ended June 30, 2023 compared to $23.2 million for the three months ended June 30, 2022. The increase to net product sales was attributable to an increase in price net of deductions.

Cost of goods sold. Cost of goods sold decreased by $2.6 million, or 42%, to $3.5 million for the three months ended June 30, 2023 compared to $6.1 million for the three months ended June 30, 2022. 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 5% of HETLIOZ® net product sales in Germany and 6% of Fanapt® net product sales. Third-party royalty costs on HETLIOZ® net product sales in the U.S. decreased from 10% to 5% in December 2022 and are expected to end in the second quarter of 2024. 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 $7.1 million and $8.0 million of HETLIOZ® product and $3.0 million and $3.4 million of Fanapt® product as of June 30, 2023 and December 31, 2022, respectively.

Research and development expenses. Research and development expenses decreased by $4.8 million, or 23%, to $16.6 million for the three months ended June 30, 2023 compared to $21.5 million for the three months ended June 30, 2022. The decrease was primarily due to a decrease in clinical trial expenses associated with our Fanapt® and VQW-765 development programs, partially offset by an increase in clinical trial expenses associated with our other development programs, which include expenses incurred on product discovery.

The following table summarizes the costs of our product development initiatives for the three months ended June 30, 2023 and 2022:

	Three Months Ended	
(in thousands)	**June 30, 2023**	**June 30, 2022**
Direct project costs (1)		
HETLIOZ®	$ 2,450	$ 3,183
Fanapt®	2,588	7,788
Tradipitant	6,027	5,760
VTR-297	369	522
CFTR	378	254
VQW-765	278	1,290
Other	2,701	910
Total direct project costs	14,791	19,707
Indirect project costs (1)		
Stock-based compensation	733	899
Other indirect overhead	1,123	884
Total indirect project costs	1,856	1,783
Total research and development expense	$ 16,647	$ 21,490

(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. In addition, we expect to incur licensing costs in the future that could be substantial, as we continue our efforts to expand our product pipeline.

Selling, general and administrative expenses. Selling, general and administrative expenses decreased by $4.6 million, or 14%, to $28.4 million for the three months ended June 30, 2023 compared to $33.0 million for the three months ended June 30, 2022. The decrease in selling, general and administrative expenses was primarily the result of a decrease in spending on marketing and sales activities.

Intangible asset amortization. Intangible asset amortization was $0.4 million for each of the three months ended June 30, 2023 and 2022.

Other income. Other income was $5.5 million for the three months ended June 30, 2023 compared to $0.3 million for the three months ended June 30, 2022. Other income primarily consists of investment income on our marketable securities, which increased in 2023 as a result of higher yields on our marketable securities.

Provision for income taxes. A provision for income taxes of $1.1 million and $1.2 million was recorded for the three months ended June 30, 2023 and 2022, respectively. The income tax expense for each of the three months ended June 30, 2023 and 2022 was primarily driven by the estimated effective tax rate for the year as well as discrete income tax expense of $0.8 million and $0.3 million, respectively.

Six months ended June 30, 2023 compared to six months ended June 30, 2022

Revenues. Total revenues decreased by $16.0 million, or 13%, to $108.6 million for the six months ended June 30, 2023 compared to $124.6 million for the six months ended June 30, 2022. Revenues were as follows:

	Six Months Ended			
(in thousands)	**June 30, 2023**	**June 30, 2022**	**Net Change**	**Percent**
HETLIOZ® net product sales	$ 61,595	$ 78,219	$ (16,624)	(21)%
Fanapt® net product sales	46,959	46,363	596	1 %
Total net product sales	$ 108,554	$ 124,582	$ (16,028)	(13)%

HETLIOZ® net product sales decreased by $16.6 million, or 21%, to $61.6 million for the six months ended June 30, 2023 compared to $78.2 million for the six months ended June 30, 2022. The decrease to net product sales was attributable to a decrease in price net of deductions, partially offset by an increase in volume. Our HETLIOZ® net product sales for the three months ended March 31, 2023 reflected higher unit sales as compared to recent prior periods and resulted in a significant increase of inventory stocking at specialty pharmacy customers at March 31, 2023 and June 30, 2023. HETLIOZ® net product sales will likely decline in future periods, potentially significantly, as a result of continued reduction of the elevated inventory levels at specialty pharmacy customers absent removal of generic HETLIOZ® products from the U.S. market. Additionally, we constrained HETLIOZ® net product sales for the three and six months ended June 30, 2023 to an amount not probable of significant revenue reversal. HETLIOZ® net product sales could experience variability in future periods as the remaining uncertainties associated with variable consideration related to the significant increase of inventory stocking by specialty pharmacy customers during the three months ended March 31, 2023 are resolved.

Fanapt® net product sales increased by $0.6 million, or 1%, to $47.0 million for the six months ended June 30, 2023 compared to $46.4 million for the six months ended June 30, 2022. The increase to net product sales was attributable to an increase in price net of deductions, partially offset by a decrease in volume.

Cost of goods sold. Cost of goods sold decreased by $3.5 million, or 29%, to $8.3 million for the six months ended June 30, 2023 compared to $11.7 million for the six months ended June 30, 2022. 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 on HETLIOZ® net product sales in the U.S. decreased from 10% to 5% in December 2022 and are expected to end in the second quarter of 2024. 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 $7.1 million and $8.0 million of HETLIOZ® product and $3.0 million and $3.4 million of Fanapt® product as of June 30, 2023 and December 31, 2022, respectively.

Research and development expenses. Research and development expenses decreased by $6.6 million, or 15%, to $35.9 million for the six months ended June 30, 2023 compared to $42.5 million for the six months ended June 30, 2022. The decrease in research and development expenses was associated with our Fanapt® development program and VQW-765 development program, partially offset by an increase in clinical trial expenses associated with our tradipitant development program and our other development programs, which include expenses incurred on product discovery.

The following table summarizes the costs of our product development initiatives for the six months ended June 30, 2023 and 2022:

	Six Months Ended	
(in thousands)	**June 30, 2023**	**June 30, 2022**
Direct project costs (1)		
HETLIOZ®	$ 4,928	$ 6,267
Fanapt®	4,618	16,388
Tradipitant	14,366	10,515
VTR-297	813	937
CFTR	756	586
VQW-765	640	2,223
Other	5,515	1,625
Total direct project costs	31,636	38,541
Indirect project costs (1)		
Stock-based compensation	1,799	2,059
Other indirect overhead	2,449	1,859
Total indirect project costs	4,248	3,918
Total research and development expense	$ 35,884	$ 42,459

(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. In addition, we expect to incur licensing costs in the future that could be substantial, as we continue our efforts to expand our product pipeline.

Selling, general and administrative expenses. Selling, general and administrative expenses decreased by $9.3 million, or 13%, to $64.5 million for the six months ended June 30, 2023 compared to $73.8 million for the six months ended June 30, 2022. The decrease in selling, general and administrative expenses was primarily the result of a decrease in spending on marketing, sales and commercial support activities for our commercial products.

Intangible asset amortization. Intangible asset amortization was $0.8 million for each of the six months ended June 30, 2023 and 2022.

Other income. Other income was $9.0 million for the six months ended June 30, 2023 compared to $0.4 million for the six months ended June 30, 2022. Other income primarily consists of investment income on our marketable securities, which increased in 2023 as a result of higher yields on our marketable securities.

Provision for income taxes. We recorded a provision for income taxes of $3.3 million and $0.1 million for the six months ended June 30, 2023 and 2022, respectively. The income tax expense for the six months ended June 30, 2023 and 2022 was primarily driven by the estimated effective tax rate for the year, as well as discrete income tax expense of $1.8 million and $1.4 million, respectively.

Liquidity and Capital Resources

As of June 30, 2023, our total cash and cash equivalents and marketable securities were $489.4 million compared to $466.9 million at December 31, 2022. 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 June 30, 2023 and December 31, 2022 are summarized as follows:

(in thousands)	June 30, 2023	December 31, 2022
Cash and cash equivalents	$ 150,031	$ 135,029
Marketable securities:		
U.S. Treasury and government agencies	235,057	177,170
Corporate debt	104,263	154,660
Total marketable securities	339,320	331,830
Total cash, cash equivalents and marketable securities	$ 489,351	$ 466,859

As of June 30, 2023, 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 longer than one year are not material. Various other long-term agreements entered into for services with other third-party vendors, such as inventory purchase arrangements, 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 operating leases and license agreements. 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 license agreements, see Note 8, *Commitments and Contingencies*, to the condensed consolidated financial statements included in Part I of this Quarterly Report.

We do not have any off-balance sheet arrangements.

Based on our current operating plans, which include costs and expenses in connection with our continued clinical development of tradipitant and our other products, U.S. commercial activities for HETLIOZ® and Fanapt®, pursuit of regulatory approval of HETLIOZ® and Fanapt® in other regions and in other indications, 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 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 also may 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 six months ended June 30, 2023 and 2022:

(in thousands)	Six Months Ended June 30, 2023	June 30, 2022	Net Change
Net cash provided by (used in):			
Operating activities:			
Net income (loss)	$ 4,772	$ (3,856)	$ 8,628
Non-cash charges	10,599	13,523	(2,924)
Net change in operating assets and liabilities	3,212	64	3,148
Operating activities	18,583	9,731	8,852
Investing activities:			
Purchases of property and equipment	(106)	(268)	162
Net purchases, sales and maturities of marketable securities	(3,494)	(3,458)	(36)
Investing activities	(3,600)	(3,726)	126
Financing activities:			
Proceeds from the exercise of stock options	—	125	(125)
Financing activities	—	125	(125)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	19	22	(3)
Net change in cash, cash equivalents and restricted cash	$ 15,002	$ 6,152	$ 8,850

Operating Activities: Cash flows provided by operating activities during the six months ended June 30, 2023 were $18.6 million, an increase of $8.9 million compared to $9.7 million during the six months ended June 30, 2022. The increase reflects an increase of $8.6 million in net income and an increase of $3.1 million from the net change in operating assets and liabilities primarily due to an increase in our product revenue allowances as a result of increased inventory stocking of HETLIOZ® at specialty pharmacy customers in 2023, partially offset by a decrease of $2.9 million in non-cash charges primarily due to additional amortization of discounts on our marketable securities.

Investing Activities: Cash flows used in investing activities during the six months ended June 30, 2023 were $3.6 million, a decrease of $0.1 million compared to $3.7 million during the six months ended June 30, 2022. The change in investing activities reflects the timing of net reinvestment of available cash and cash equivalents in our portfolio of marketable securities.

Financing Activities: Financing activities include proceeds from exercises of stock options. Cash flows provided by financing activities during the six months ended June 30, 2022 were $0.1 million. There were no exercises of stock options during the six months ended June 30, 2023.

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 June 30, 2023. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of June 30, 2023, 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 second quarter of 2023 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 13, *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, 2022, filed with the Securities and Exchange Commission on February 9, 2023, 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. Other than as set forth below, there have been no material changes in our risk factors subsequent to the filing of our Annual Report for the fiscal year ended December 31, 2022.

Adverse developments affecting the financial services industry, including events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our business, financial condition or results of operations.

Events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. On March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial services industry or economy in general. These factors could include, among others,

events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our business, financial condition or results of operations.

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

None

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	Fourth Amended and Restated Bylaws of the registrant, as amended and restated on December 17, 2015 (filed as Exhibit 3.1 to the registrant's current report on Form 8-K (File No. 001-34186) on December 21, 2015 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 June 30, 2023 formatted in Inline Extensible Business Reporting Language (iXBRL) and filed electronically herewith: (i) Condensed Consolidated Balance Sheets as of June 30, 2023 and December 31, 2022; (ii) Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2023 and 2022; (iii) Condensed Consolidated Statements of Comprehensive Income (Loss) for the three and six months ended June 30, 2023 and 2022; (iv) Condensed Consolidated Statements of Changes in Stockholders' Equity for the three and six months ended June 30, 2023 and 2022; (v) Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2023 and 2022; and (vi) Notes to Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* Filed 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.

July 28, 2023 /s/ Mihael H. Polymeropoulos, M.D.

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

July 28, 2023 /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.

July 28, 2023

/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.

July 28, 2023

/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 June 30, 2023 (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.

July 28, 2023

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

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

July 28, 2023

/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.