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, 2022
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 28, 2022, there were 56,561,462 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, 2022

Table of Contents

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.) 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 increased reimbursement and patient access challenges we face as a result of declining 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 regulatory approval for tradipitant from the U.S. Food and Drug Administration (FDA);
- the impact of the novel coronavirus (COVID-19) on our business and operations, including our revenue, our supply chain, our commercial activities, our ongoing and planned clinical trial 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 level of success in commercializing HETLIOZ® and Fanapt® in new markets;
- our ability to obtain approval from the FDA for HETLIOZ® beyond the currently approved indications;
- our ability to obtain approval from the FDA for Fanapt® 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 written and verbal forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained throughout this report. We caution you not to rely too heavily on the

forward-looking statements we make or that are made on our behalf. 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 for the fiscal year ended December 31, 2021, 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, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 58,226	$ 52,071
Marketable securities	382,632	380,742
Accounts receivable, net	28,805	32,467
Inventory	1,496	1,025
Prepaid expenses and other current assets	25,736	11,996
Total current assets	496,895	478,301
Property and equipment, net	2,746	3,113
Operating lease right-of-use assets	8,603	9,272
Intangible assets, net	19,323	20,081
Deferred tax assets	72,687	74,878
Non-current inventory and other	8,848	8,147
Total assets	$ 609,102	$ 593,792
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 50,236	$ 34,438
Product revenue allowances	38,164	39,981
Total current liabilities	88,400	74,419
Operating lease non-current liabilities	9,286	10,055
Other non-current liabilities	2,867	4,390
Total liabilities	100,553	88,864
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, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized; 56,552,462 and 55,900,855 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	57	56
Additional paid-in capital	677,955	669,223
Accumulated other comprehensive loss	(1,431)	(175)
Accumulated deficit	(168,032)	(164,176)
Total stockholders' equity	508,549	504,928
Total liabilities and stockholders' equity	$ 609,102	$ 593,792

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, 2022	June 30, 2021	June 30, 2022	June 30, 2021
Revenues:				
Net product sales	$ 64,390	$ 67,899	$ 124,582	$ 130,568
Total revenues	64,390	67,899	124,582	130,568
Operating expenses:				
Cost of goods sold excluding amortization	6,059	6,566	11,724	12,596
Research and development	21,490	20,248	42,459	36,379
Selling, general and administrative	33,001	28,347	73,849	58,144
Intangible asset amortization	379	369	758	739
Total operating expenses	60,929	55,530	128,790	107,858
Income (loss) from operations	3,461	12,369	(4,208)	22,710
Other income	329	235	434	322
Income (loss) before income taxes	3,790	12,604	(3,774)	23,032
Provision for income taxes	1,216	2,951	82	4,729
Net income (loss)	$ 2,574	$ 9,653	$ (3,856)	$ 18,303
Net income (loss) per share:				
Basic	$ 0.05	$ 0.17	$ (0.07)	$ 0.33
Diluted	$ 0.05	$ 0.17	$ (0.07)	$ 0.32
Weighted average shares outstanding:				
Basic	56,508,533	55,582,916	56,307,999	55,365,558
Diluted	56,821,024	56,903,340	56,307,999	56,705,419

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, 2022	June 30, 2021	June 30, 2022	June 30, 2021
Net income (loss)	$ 2,574	$ 9,653	$ (3,856)	$ 18,303
Other comprehensive income (loss):				
Net foreign currency translation gain (loss)	(30)	16	(46)	(31)
Change in net unrealized loss on marketable securities	(95)	(136)	(1,570)	(135)
Tax benefit on other comprehensive income (loss)	22	31	360	30
Other comprehensive loss, net of tax	(103)	(89)	(1,256)	(136)
Comprehensive income (loss)	$ 2,471	$ 9,564	$ (5,112)	$ 18,167

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, 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

(in thousands, except for share amounts)	Common Stock Shares	Common Stock Par Value	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
Balances at December 31, 2020	54,865,092	$ 55	$ 650,300	$ 239	$ (197,328)	$ 453,266
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	695,122	1	1,848	—	—	1,849
Stock-based compensation expense	—	—	3,909	—	—	3,909
Net income	—	—	—	—	8,650	8,650
Other comprehensive loss, net of tax	—	—	—	(47)	—	(47)
Balances at March 31, 2021	55,560,214	$ 56	$ 656,057	$ 192	$ (188,678)	$ 467,627
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	67,452	—	289	—	—	289
Stock-based compensation expense	—	—	3,740	—	—	3,740
Net income	—	—	—	—	9,653	9,653
Other comprehensive loss, net of tax	—	—	—	(89)	—	(89)
Balances at June 30, 2021	55,627,666	$ 56	$ 660,086	$ 103	$ (179,025)	$ 481,220

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, 2022	Six Months Ended June 30, 2021
Cash flows from operating activities		
Net income (loss)	$ (3,856)	$ 18,303
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation of property and equipment	634	688
Stock-based compensation	8,608	7,649
Amortization of premiums and accretion of discounts on marketable securities	(2)	1,016
Gain on sale of marketable securities	—	(12)
Intangible asset amortization	758	739
Deferred income taxes	2,550	2,906
Other non-cash adjustments, net	975	666
Changes in operating assets and liabilities:		
Accounts receivable	3,575	(7,064)
Prepaid expenses and other assets	(13,691)	(1,554)
Inventory	(1,582)	(1,366)
Accounts payable and other liabilities	13,732	888
Product revenue allowances	(1,970)	5,351
Net cash provided by operating activities	9,731	28,210
Cash flows from investing activities		
Purchases of property and equipment	(268)	(428)
Purchases of marketable securities	(175,985)	(197,352)
Sales and maturities of marketable securities	172,527	163,670
Net cash used in investing activities	(3,726)	(34,110)
Cash flows from financing activities		
Proceeds from exercise of stock options	125	2,138
Net cash provided by financing activities	125	2,138
Effect of exchange rate changes on cash, cash equivalents and restricted cash	22	(29)
Net change in cash, cash equivalents and restricted cash	6,152	(3,791)
Cash, cash equivalents and restricted cash		
Beginning of period	52,590	61,613
End of period	$ 58,742	$ 57,822

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 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 BPO-27 for the treatment of secretory diarrhea disorders, including cholera;
- VQW-765, a small molecule nicotinic acetylcholine receptor partial agonist, with potential use for the treatment of psychiatric disorders; and
- VHX-896 (formerly P88), the active metabolite of iloperidone.

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, 2021. The financial information as of June 30, 2022 and for the three and six months ended June 30, 2022 and 2021 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, 2021 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 Statement of Cash Flows:

(in thousands)	June 30, 2022	June 30, 2021
Cash and cash equivalents	$ 58,226	$ 57,242
Restricted cash included in:		
Prepaid expenses and other current assets	—	57
Non-current inventory and other	516	523
Total cash, cash equivalents and restricted cash	$ 58,742	$ 57,822

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, 2022 and 2021 were as follows:

	Three Months Ended		Six Months Ended	
(in thousands)	June 30, 2022	June 30, 2021	June 30, 2022	June 30, 2021
HETLIOZ® net product sales	$ 41,188	$ 44,509	$ 78,219	$ 83,852
Fanapt® net product sales	23,202	23,390	46,363	46,716
Total net product sales	$ 64,390	$ 67,899	$ 124,582	$ 130,568

Major Customers

HETLIOZ® is available in the United States (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 89% of total revenues for the six months ended June 30, 2022. There were five major customers that each accounted for more than 10% of accounts receivable and, as a group, represented 84% of total accounts receivable at June 30, 2022. 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, 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	$ 200,247	$ —	$ (2,141)	$ 198,106
Corporate debt	184,222	494	(190)	184,526
Total marketable securities	$ 384,469	$ 494	$ (2,331)	$ 382,632

The following is a summary of the Company's available-for-sale marketable securities as of December 31, 2021, 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	$ 195,076	$ 1	$ (358)	$ 194,719
Corporate debt	185,933	113	(23)	186,023
Total marketable securities	$ 381,009	$ 114	$ (381)	$ 380,742

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, 2022 and December 31, 2021 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, corporate notes and asset-backed securities 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, 2022, as follows:

		Fair Value Measurement as of June 30, 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	$ 198,106	$ 198,106	$ —	$ —
Corporate debt	197,522	—	197,522	—
Total assets measured at fair value	$ 395,628	$ 198,106	$ 197,522	$ —

The Company held certain assets that are required to be measured at fair value on a recurring basis as of December 31, 2021, as follows:

		Fair Value Measurement as of December 31, 2021 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	$ 194,719	$ 194,719	$ —	$ —
Corporate debt	186,023	—	186,023	—
Total assets measured at fair value	$ 380,742	$ 194,719	$ 186,023	$ —

Total assets measured at fair value as of June 30, 2022 include $13.0 million of cash equivalents. Total assets measured at fair value as of December 31, 2021 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, 2022 and December 31, 2021:

(in thousands)	June 30, 2022	December 31, 2021
Current assets		
Work-in-process	$ —	$ 30
Finished goods	1,496	995
Total inventory, current	$ 1,496	$ 1,025
Non-Current assets		
Raw materials	$ 1,818	$ 2,143
Work-in-process	4,791	3,934
Finished goods	1,493	1,150
Total inventory, non-current	8,102	7,227
Total inventory	$ 9,598	$ 8,252

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. The $8.0 million is being amortized on a straight-line basis over the estimated economic useful life of the related product patents.

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. The $25.0 million, which was capitalized as an intangible asset in the first quarter of 2015, was determined to be additional consideration for the acquisition of the HETLIOZ® intangible asset and is 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, 2022:

		June 30, 2022		
(in thousands)	Estimated Useful Life	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	March 2035	$ 33,000	$ 13,677	$ 19,323

The following is a summary of the Company's intangible assets as of December 31, 2021:

(in thousands)	Estimated Useful Life	December 31, 2021 Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	July 2035	$ 33,000	$ 12,919	$ 20,081

As of June 30, 2022 and December 31, 2021, 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, 2022 and 2021. Amortization expense was $0.8 million and $0.7 million for the six months ended June 30, 2022 and 2021, respectively. The following is a summary of the future intangible asset amortization schedule as of June 30, 2022:

(in thousands)	Total	2022	2023	2024	2025	2026	Thereafter
HETLIOZ®	$ 19,323	$ 758	$ 1,516	$ 1,516	$ 1,516	$ 1,516	$ 12,501

7. Accounts Payable and Accrued Liabilities

The following is a summary of the Company's accounts payable and accrued liabilities as of June 30, 2022 and December 31, 2021:

(in thousands)	June 30, 2022	December 31, 2021
Research and development expenses	$ 12,500	$ 10,082
Consulting and other professional fees	8,820	8,732
Royalties payable	5,549	5,873
Compensation and employee benefits	4,710	6,515
Operating lease liabilities	2,245	2,311
Accounts payable and other accrued liabilities	16,412	925
Total accounts payable and accrued liabilities	$ 50,236	$ 34,438

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, 2022, 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 current royalty on net sales is 10%. This royalty will drop to 5% in December 2022 and 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 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, 2022, the Company has paid Lilly $3.0 million in upfront fees and development milestones. The 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, 2022, the Company has paid UCSF $1.6 million in upfront fees and development milestones. The 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. As a result of completion of the first clinical study initiated by the Company for VSJ-110, the Company made a $350,000 development milestone payment to UCSF in the fourth quarter of 2021. The likelihood of achieving this milestone was determined to be probable during 2020 and the obligation of $350,000 tied to such milestone was recorded as research and development expense in the Condensed Consolidated Statements of Operations during the year ended December 31, 2020.

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.

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 primarily relate to commitments for data services and 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, 2022 and December 31, 2021:

(in thousands)	June 30, 2022	December 31, 2021
Foreign currency translation	$ (14)	$ 32
Unrealized loss on marketable securities	(1,417)	(207)
Accumulated other comprehensive loss	$ (1,431)	$ (175)

10. Stock-Based Compensation

As of June 30, 2022, there were 6,442,978 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 11,890,000 shares of common stock authorized for issuance under the 2016 Plan, 4,207,145 shares of which remained available for future grant as of June 30, 2022.

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. Certain service option awards granted to employees and executive officers provide for partial acceleration of vesting if the employee or executive officer is subject to an involuntary termination, and full acceleration of vesting if the employee or executive officer 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, 2022, $9.3 million of unrecognized compensation costs related to unvested service option awards are expected to be recognized over a weighted average period of 1.4 years. No option awards are classified as a liability as of June 30, 2022.

A summary of option activity under the Plans for the six months ended June 30, 2022 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, 2021	3,721,148	$ 14.16	5.77	$ 11,327
Granted	745,028	11.10		
Exercised	(30,000)	4.15		172
Outstanding at June 30, 2022	4,436,176	13.72	6.05	2,640
Exercisable at June 30, 2022	2,975,219	13.53	4.64	2,486
Vested and expected to vest at June 30, 2022	4,198,438	13.75	5.87	2,615

The weighted average grant-date fair value of options granted was $5.18 and $8.91 per share for the six months ended June 30, 2022 and 2021, respectively. Proceeds from the exercise of stock options amounted to $0.1 million and $2.1 million for the six months ended June 30, 2022 and 2021, respectively.

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 vest in four equal annual installments provided that the employee remains employed with the Company. Certain service RSUs granted to employees and executive officers provide for accelerated vesting if the employee or executive officer is subject to an involuntary termination within 24 months after a change in control. Annual service RSUs granted to directors vest on the first anniversary of the grant date and provide for accelerated vesting if there is a change in control of the Company.

As of June 30, 2022, $25.4 million of unrecognized compensation costs related to unvested service RSUs are expected to be recognized over a weighted average period of 1.8 years. No RSUs are classified as a liability as of June 30, 2022.

A summary of RSU activity under the Plans for the six months ended June 30, 2022 follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2021	1,764,740	$ 17.27
Granted	897,374	11.26
Forfeited	(33,205)	14.44
Vested	(622,107)	17.55
Unvested at June 30, 2022	2,006,802	14.54

The grant date fair value for the 622,107 shares underlying RSUs that vested during the six months ended June 30, 2022 was $10.9 million.

Stock-Based Compensation Expense

Stock-based compensation expense recognized for the three and six months ended June 30, 2022 and 2021 was comprised of the following:

	Three Months Ended		Six Months Ended	
(in thousands)	June 30, 2022	June 30, 2021	June 30, 2022	June 30, 2021
Research and development	$ 899	$ 957	$ 2,059	$ 2,077
Selling, general and administrative	2,931	2,783	6,549	5,572
Total stock-based compensation expense	$ 3,830	$ 3,740	$ 8,608	$ 7,649

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, 2022 and 2021 were as follows:

	Six Months Ended	
	June 30, 2022	June 30, 2021
Expected dividend yield	0 %	0 %
Weighted average expected volatility	46 %	46 %
Weighted average expected term (years)	6.05	5.98
Weighted average risk-free rate	2.03 %	0.75 %

11. Income Taxes

For the three months ended June 30, 2022 and 2021, the Company recorded income tax expense of $1.2 million and $3.0 million, respectively. The income tax expense for each of the three months ended June 30, 2022 and 2021 was primarily driven by the estimated effective tax rate for the year, as well as discrete income tax expense of $0.3 million.

For the six months ended June 30, 2022 and 2021, the Company recorded income tax expense of $0.1 million and $4.7 million, respectively. The income tax expense for the six months ended June 30, 2022 and 2021 was primarily driven by the estimated effective tax rate for the year, as well as discrete income tax expense of $1.4 million and $0.1 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, 2022 and 2021:

	Three Months Ended		Six Months Ended	
(in thousands, except for share and per share amounts)	June 30, 2022	June 30, 2021	June 30, 2022	June 30, 2021
Numerator:				
Net income (loss)	$ 2,574	$ 9,653	$ (3,856)	$ 18,303
Denominator:				
Weighted average shares outstanding, basic	56,508,533	55,582,916	56,307,999	55,365,558
Effect of dilutive securities	312,491	1,320,424	—	1,339,861
Weighted average shares outstanding, diluted	56,821,024	56,903,340	56,307,999	56,705,419
Net income (loss) per share, basic and diluted:				
Basic	$ 0.05	$ 0.17	$ (0.07)	$ 0.33
Diluted	$ 0.05	$ 0.17	$ (0.07)	$ 0.32
Antidilutive securities excluded from calculations of diluted net income (loss) per share	5,389,183	2,212,724	4,982,824	2,174,917

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

Fanapt®. In 2014 and 2015, Roxane Laboratories, Inc. (Roxane) and its affiliates, West-Ward Pharmaceuticals International Limited and West-Ward Pharmaceuticals Corp (West-Ward), Inventia Healthcare Pvt. Ltd. (Inventia), Lupin Ltd. and Lupin Pharmaceuticals, Inc. (Lupin), Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd. (Taro), and Apotex Inc. and Apotex Corp. (Apotex) (collectively, the Fanapt® Defendants) each submitted an Abbreviated New Drug Applications (ANDA) to the FDA seeking approval to market generic versions of Fanapt® prior to the expiration of certain of the Company's patents covering Fanapt®, including U.S. Patent No. 8,586,610 ('610 Patent) and U.S. Patent No. 9,138,432 ('432 Patent). In response, the Company filed separate lawsuits in 2014 and 2015 against each of the Fanapt® Defendants in the U.S. District Court for the District of Delaware (Delaware District Court) for patent infringement.

In August 2016, the Delaware District Court ruled in the Company's favor, permanently enjoining Roxane from manufacturing, using, selling, offering to sell, distributing or importing any generic iloperidone product described in Roxane's ANDA until the expiration of the '610 Patent in November 2027, or May 2028 if the Company obtains pediatric exclusivity. This ruling was affirmed on appeal by the Federal Circuit Court of Appeals in April 2018. West-Ward, having replaced Roxane as defendant following the acquisition of Roxane by West-Ward's parent company, Hikma Pharmaceuticals PLC (Hikma), petitioned the U.S. Supreme Court for a writ of certiorari, which was denied in January 2020. The Company's lawsuit against Hikma regarding the '432 Patent remains pending.

The Company entered into separate license agreements with each of Taro, Apotex and Lupin resolving these lawsuits in October 2016, December 2016 and July 2020, respectively. The license agreements grant Taro, Apotex and Lupin non-exclusive licenses to manufacture and commercialize a version of Fanapt® in the U.S. effective as of the expiration of the '610 Patent or earlier under certain limited circumstances. The Company entered into a confidential stipulation with Inventia regarding any potential launch of its generic versions of Fanapt®, but the Company's lawsuit against Inventia regarding the '610 and '432 Patents remains pending.

HETLIOZ®. Between April 2018 and March 2021, the Company filed numerous Hatch-Waxman lawsuits in the Delaware District Court against Teva Pharmaceuticals USA, Inc. (Teva), MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited (MSN) and Apotex (collectively the HETLIOZ® Defendants) asserting that U.S. Patent Nos. RE46,604, 9,060,995, 9,539,234, 9,549,913, 9,730,910, 9,844,241, 10,071,977, 10,149,829, 10,376,487, 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 are seeking FDA approval. In January 2022, the Company entered into a license agreement with MSN and Impax Laboratories LLC (Impax) resolving the lawsuits against MSN. The license agreement, which is subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice (the DOJ), grants MSN and Impax a non-exclusive license to manufacture and commercialize MSN's 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. MSN and Impax may enter the market earlier under certain limited circumstances. The consolidated lawsuits against the remaining HETLIOZ® Defendants were tried in March 2022. The Company expects the Delaware District Court to render its opinion in the second half of 2022.

Other Matters. In February 2019, a securities class action, *Gordon v. Vanda Pharmaceuticals Inc.*, was filed in the U.S. District Court for the Eastern District of New York naming the Company and certain of its officers as defendants. An amended complaint was filed in July 2019. The amended complaint, filed on behalf of a purported stockholder, asserts claims on behalf of a putative class of all persons who purchased the Company's publicly traded securities between November 4, 2015 and February 11, 2019, for alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder. The amended complaint alleges that the defendants made false and misleading statements and/or omissions regarding Fanapt®, HETLIOZ® and the Company's interactions with the FDA regarding tradipitant between November 3, 2015 and February 11, 2019. In March 2020, the Company filed a motion to dismiss the complaint. In March 2021, the motion to dismiss was granted in part and denied in part. In May 2022, the parties executed a stipulation of settlement to resolve the claims asserted with no admission of wrongdoing by any defendant. The executed stipulation of settlement is subject to court approval. Payment of the settlement amount will be made by the Company's insurers. The settlement is not expected to have a material adverse effect on the Company's business, results of operations or financial condition.

In April 2022, the Company filed a lawsuit in the U.S District Court for the District of Columbia (DC District Court) against the FDA to compel the FDA to produce, as required by the Freedom of Information Act (FOIA), certain records relating to its denial of the Company's supplemental NDA for HETLIOZ® in the treatment of jet lag disorder. The Company has 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 has refused to provide them, claiming an exemption under FOIA. The Company does not believe that the exemption claimed by the FDA applies to the records requested.

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. The Company seeks to, among other things, have the MD District Court set aside the definitions of "line extension" and "new formulation" in the Rule, declare the Rule unlawful and void and enjoin CMS from enforcing, applying, or implementing the Rule as applied to require the Company to treat these products as line extensions.

In May 2022, the Company filed a lawsuit in the DC District Court against the FDA to compel the FDA to produce, as required by FOIA, certain records relating to 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 has failed to respond to the request.

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.

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 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 BPO-27 for the treatment of secretory diarrhea disorders, including cholera;
- VQW-765, a small molecule nicotinic acetylcholine receptor partial agonist, with potential use for the treatment of psychiatric disorders; and
- VHX-896 (formerly P88), the active metabolite of iloperidone.

Operational Highlights

HETLIOZ®

- Clinical trials for HETLIOZ® in DSPD and sleep disturbances in ASD are currently enrolling patients.
- We are preparing for the submission of a supplemental New Drug Application for HETLIOZ® in the treatment of insomnia.
- Since November 2021, more than 15 states have revised or agreed to revise their Medicaid prior authorization criteria to broaden access to HETLIOZ® for patients with Non-24 and patients with nighttime sleep disturbances in SMS.
- In July 2022, an Administrative Law Judge struck down a Medicare Part D plan policy that blocked HETLIOZ® coverage for sighted Non-24 patients. We intend to advocate with other Part D plans to challenge similar policies and improve HETLIOZ® access for Non-24 patients.
- In January 2022, we settled our HETLIOZ® patent litigation against one of the Abbreviated New Drug Application (ANDA) defendants. The trial for the consolidated lawsuit against the remaining defendants was held in March 2022. A decision is expected from the court by the end of 2022.

Tradipitant

- We are continuing to conduct an open-label safety study for tradipitant in gastroparesis and continue to receive requests from patients seeking access to tradipitant through the Expanded Access program that has multiple patients who have taken tradipitant for more than a year.
- We recently held a pre-NDA meeting with the FDA to discuss the planned New Drug Application (NDA) submission for tradipitant in the short-term treatment of nausea in gastroparesis. We are preparing for the submission of the NDA for this indication.

- The Phase III study of tradipitant in the treatment of motion sickness is approximately 30% enrolled.

Fanapt®

- Enrollment of the Phase III clinical study of Fanapt® in acute manic episodes in patients with bipolar disorder is close to being fully enrolled. The study is a placebo controlled four-week evaluation of approximately 400 patients at sites in the U.S. and Europe. Results are expected by the end of 2022.

VQW-765

- The Phase II clinical study of a single-dose treatment of VQW-765 to alleviate social/performance anxiety is fully enrolled. Results are expected by the end of 2022.

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, 2021.

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 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.

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, and product returns that are resolved during the product expiry period specified in the customer contract. We currently record sales allowances for the following:

Prompt-pay: Specialty pharmacies and wholesalers are offered discounts for prompt payment. We expect that the specialty pharmacies and wholesalers will earn prompt-pay 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. 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. The allowance for rebates is 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, 2022 or December 31, 2021.

The following table summarizes sales discounts and allowance activity as of and for the six months ended June 30, 2022:

(in thousands)	Rebates & Chargebacks	Discounts, Returns and Other	Total
Balances at December 31, 2021	$ 31,854	$ 9,601	$ 41,455
Provision related to current period sales	41,131	15,015	56,146
Adjustments for prior period sales	(1,580)	(82)	(1,662)
Credits/payments made	(41,183)	(15,346)	(56,529)
Balances at June 30, 2022	$ 30,222	$ 9,188	$ 39,410

The provision of $41.1 million for rebates and chargebacks for the six months ended June 30, 2022 primarily represents Medicaid rebates applicable to sales of Fanapt® and HETLIOZ®. The provision of $15.0 million for discounts, returns and other for the six months ended June 30, 2022 represents wholesaler distribution fees applicable to sales of Fanapt® and, to a lesser extent, 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. 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. No impairments have been recognized on our intangible assets.

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. 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 impact of the COVID-19 pandemic.

Three months ended June 30, 2022 compared to three months ended June 30, 2021

Revenues. Total revenues decreased by $3.5 million, or 5%, to $64.4 million for the three months ended June 30, 2022 compared to $67.9 million for the three months ended June 30, 2021. Revenues were as follows:

	Three Months Ended			
(in thousands)	June 30, 2022	June 30, 2021	Net Change	Percent
HETLIOZ® net product sales	$ 41,188	$ 44,509	$ (3,321)	(7)%
Fanapt® net product sales	23,202	23,390	(188)	(1)%
Total net product sales	$ 64,390	$ 67,899	$ (3,509)	(5)%

HETLIOZ® net product sales decreased by $3.3 million, or 7%, to $41.2 million for the three months ended June 30, 2022 compared to $44.5 million for the three months ended June 30, 2021. The decrease to net product sales was attributable to a decrease in volume, due in part to continued reimbursement challenges for prescriptions for patients with Non-24.

Fanapt® net product sales decreased by $0.2 million, or 1%, to $23.2 million for the three months ended June 30, 2022 compared to $23.4 million for the three months ended June 30, 2021. The decrease to net product sales was attributable to a decrease in volume, partially offset by an increase in price net of deductions.

Cost of goods sold. Cost of goods sold decreased by $0.5 million, or 8%, to $6.1 million for the three months ended June 30, 2022 compared to $6.6 million for the three months ended June 30, 2021. 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 10% and 5% of HETLIOZ® net product sales in the U.S. and Germany, respectively, and 6% of Fanapt® net product sales. Third-party royalty costs on HETLIOZ® net product sales in the U.S. will decrease to 5% in December 2022.

In addition to third-party royalty costs, HETLIOZ® and Fanapt® cost of goods sold as a percentage of revenue depends upon our cost to manufacture inventory at normalized production levels with our third-party manufacturers. We expect that, in the future, total HETLIOZ® manufacturing costs included in cost of goods sold will continue to be less than 2% of HETLIOZ® net product sales. We expect that, in the future, total Fanapt® manufacturing costs included in cost of goods sold will continue to be less than 3% of Fanapt® net product sales.

Research and development expenses. Research and development expenses increased by $1.2 million, or 6%, to $21.5 million for the three months ended June 30, 2022 compared to $20.2 million for the three months ended June 30, 2021. The increase in research and development expenses is due to the net changes in the costs of our various product development programs.

The following table summarizes the costs of our product development initiatives for the three months ended June 30, 2022 and 2021:

(in thousands)	Three Months Ended June 30, 2022	June 30, 2021
Direct project costs (1)		
HETLIOZ®	$ 3,183	$ 2,690
Fanapt®	7,788	6,723
Tradipitant	5,760	6,523
VTR-297	522	672
CFTR	254	1,052
VQW-765	1,290	436
Other	910	366
Total direct project costs	19,707	18,462
Indirect project costs (1)		
Stock-based compensation	899	957
Other indirect overhead	884	829
Total indirect project costs	1,783	1,786
Total research and development expense	$ 21,490	$ 20,248

(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 increased by $4.7 million, or 16%, to $33.0 million for the three months ended June 30, 2022 compared to $28.3 million for the three months ended June 30, 2021. The increase in selling, general and administrative expenses was primarily the result of an increase in spending on sales, marketing, and commercial support activities for our commercial products.

Intangible asset amortization. Intangible asset amortization was $0.4 million for each of the three months ended June 30, 2022 and 2021.

Other income. Other income was $0.3 million for the three months ended June 30, 2022 compared to $0.2 million for the three months ended June 30, 2021. Other income primarily consists of investment income on our marketable securities.

Provision for income taxes. We recorded a provision for income taxes of $1.2 million and $3.0 million for the three months ended June 30, 2022 and 2021, respectively. The income tax expense for each of the three months ended June 30, 2022 and 2021 was primarily driven by the estimated effective tax rate for the year as well as discrete income tax expense of $0.3 million.

Six months ended June 30, 2022 compared to six months ended June 30, 2021

Revenues. Total revenues decreased by $6.0 million, or 5%, to $124.6 million for the six months ended June 30, 2022 compared to $130.6 million for the six months ended June 30, 2021. Revenues were as follows:

(in thousands)	Six Months Ended June 30, 2022	June 30, 2021	Net Change	Percent
HETLIOZ® net product sales	$ 78,219	$ 83,852	$ (5,633)	(7)%
Fanapt® net product sales	46,363	46,716	(353)	(1)%
Total net product sales	$ 124,582	$ 130,568	$ (5,986)	(5)%

HETLIOZ® net product sales decreased by $5.6 million, or 7%, to $78.2 million for the six months ended June 30, 2022 compared to $83.9 million for the six months ended June 30, 2021. The decrease to net product sales was attributable to a decrease in volume, partially offset by an increase in price net of deductions. The decrease in volume was due in part to continued reimbursement challenges for prescriptions for patients with Non-24.

Fanapt® net product sales decreased by $0.4 million, or 1%, to $46.4 million for the six months ended June 30, 2022 compared to $46.7 million for the six months ended June 30, 2021. The decrease to net product sales was attributable to a decrease in volume partially offset by an increase in price net of deductions.

Cost of goods sold. Cost of goods sold decreased by $0.9 million, or 7%, to $11.7 million for the six months ended June 30, 2022 compared to $12.6 million for the six months ended June 30, 2021. 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 10% and 5% of HETLIOZ® net product sales in the U.S. and Germany, respectively, and 6% of Fanapt® net product sales. Third-party royalty costs on HETLIOZ® net product sales in the U.S. will decrease to 5% in December 2022.

In addition to third-party royalty costs, HETLIOZ® and Fanapt® cost of goods sold as a percentage of revenue depends upon our cost to manufacture inventory at normalized production levels with our third-party manufacturers. We expect that, in the future, total HETLIOZ® manufacturing costs included in cost of goods sold will continue to be less than 2% of HETLIOZ® net product sales. We expect that, in the future, total Fanapt® manufacturing costs included in cost of goods sold will continue to be less than 3% of Fanapt® net product sales.

Research and development expenses. Research and development expenses increased by $6.1 million, or 17%, to $42.5 million for the six months ended June 30, 2022 compared to $36.4 million for the six months ended June 30, 2021. The increase in research and development expenses was associated with our Fanapt® development program, partially offset by a decrease in expenses for our tradipitant development program.

The following table summarizes the costs of our product development initiatives for the six months ended June 30, 2022 and 2021:

(in thousands)	Six Months Ended June 30, 2022	June 30, 2021
Direct project costs (1)		
HETLIOZ®	$ 6,267	$ 5,381
Fanapt®	16,388	9,413
Tradipitant	10,515	13,067
VTR-297	937	905
CFTR	586	2,074
VQW-765	2,223	783
Other	1,625	763
Total direct project costs	38,541	32,386
Indirect project costs (1)		
Stock-based compensation	2,059	2,077
Other indirect overhead	1,859	1,916
Total indirect project costs	3,918	3,993
Total research and development expense	$ 42,459	$ 36,379

(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 increased by $15.7 million, or 27%, to $73.8 million for the six months ended June 30, 2022 compared to $58.1 million for the six months ended June 30, 2021. The increase in selling, general and administrative expenses was primarily the result of an increase in spending on ongoing litigation and other corporate activities, as well as marketing, sales and commercial support activities for our commercial products.

Intangible asset amortization. Intangible asset amortization was $0.8 million and $0.7 million for the six months ended June 30, 2022 and 2021, respectively.

Other income. Other income was $0.4 million for the six months ended June 30, 2022 compared to $0.3 million for the six months ended June 30, 2021. Other income primarily consists of investment income on our marketable securities.

Provision for income taxes. We recorded a provision for income taxes of $0.1 million and $4.7 million for the six months ended June 30, 2022 and 2021, respectively. The income tax expense for the six months ended June 30, 2022 and 2021 was primarily driven by the estimated effective tax rate for the year, as well as discrete income tax expense of $1.4 million and $0.1 million, respectively.

Liquidity and Capital Resources

As of June 30, 2022, our total cash and cash equivalents and marketable securities were $440.9 million compared to $432.8 million at December 31, 2021. 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, 2022 and December 31, 2021 are summarized as follows:

(in thousands)	June 30, 2022	December 31, 2021
Cash and cash equivalents	$ 58,226	$ 52,071
Marketable securities:		
U.S. Treasury and government agencies	198,106	194,719
Corporate debt	184,526	186,023
Total marketable securities	382,632	380,742
Total cash, cash equivalents and marketable securities	$ 440,858	$ 432,813

As of June 30, 2022, 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 primarily relate to commitments for data services and 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 and regulatory development of tradipitant and our other products, U.S. commercial activities for HETLIOZ® and Fanapt®, pursuit of market approval of HETLIOZ® and Fanapt® in other regions, 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, which consist primarily of 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, 2022 and 2021:

	Six Months Ended		
(in thousands)	June 30, 2022	June 30, 2021	Net Change
Net cash provided by (used in):			
Operating activities:			
Net income (loss)	$ (3,856)	$ 18,303	$ (22,159)
Non-cash charges	13,523	13,652	(129)
Net change in operating assets and liabilities	64	(3,745)	3,809
Operating activities	9,731	28,210	(18,479)
Investing activities:			
Purchases of property and equipment	(268)	(428)	160
Net purchases, sales and maturities of marketable securities	(3,458)	(33,682)	30,224
Investing activities	(3,726)	(34,110)	30,384
Financing activities:			
Proceeds from the exercise of stock options	125	2,138	(2,013)
Financing activities	125	2,138	(2,013)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	22	(29)	51
Net change in cash, cash equivalents and restricted cash	$ 6,152	$ (3,791)	$ 9,943

Operating Activities: Cash flows provided by operating activities during the six months ended June 30, 2022 were $9.7 million, a decrease of $18.5 million compared to cash flows provided by operating activities of $28.2 million for the six months ended June 30, 2021. The decrease reflects a decrease of $22.2 million in net income and a decrease of $0.1 million in non-cash charges, partially offset by an increase of $3.8 million from the net change in operating assets and liabilities. The increase of $3.8 million from the net change in operating assets and liabilities primarily relates to an increase in accounts payable and accrued liabilities and a decrease in accounts receivables, partially offset by an increase in prepaid expenses and other assets and a decrease in product revenue allowances.

Investing Activities: Cash flows used in investing activities during the six months ended June 30, 2022 were $3.7 million, a decrease of $30.4 million compared to cash flows used in investing activities of $34.1 million for the six months ended June 30, 2021. Investing activities primarily include purchases, sales and maturities of marketable securities.

Financing Activities: Cash flows provided by financing activities during the six months ended June 30, 2022 were $0.1 million, a decrease of $2.0 million compared to cash flows provided by financing activities of $2.1 million for the six months ended June 30, 2021. Financing activities include proceeds from exercises of stock options.

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 two years or less. 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 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, 2022. 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, 2022, the end of the period covered by this quarterly report, 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 2022 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, 2021, filed with the Securities and Exchange Commission on February 24, 2022, important factors which could affect our business, financial condition, results of operations and future operations under the heading *Risk Factors*. Our business, financial condition and operating results can be affected by a number of factors, whether currently known or unknown, including but not limited to those described as risk factors, any one or more of which could, directly or indirectly, cause our actual operating results and financial condition to vary materially from past, or anticipated future, operating results and financial condition. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, operating results and the price of our common stock. There have been no material changes in our risk factors subsequent to the filing of our Annual Report for the fiscal year ended December 31, 2021.

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, 2022 formatted in Inline Extensible Business Reporting Language (iXBRL) and filed electronically herewith: (i) Condensed Consolidated Balance Sheets as of June 30, 2022 and December 31, 2021; (ii) Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2022 and 2021; (iii) Condensed Consolidated Statements of Comprehensive Income (Loss) for the three and six months ended June 30, 2022 and 2021; (iv) Condensed Consolidated Statements of Changes in Stockholders' Equity for the three and six months ended June 30, 2022 and 2021; (v) Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2022 and 2021; and (vi) Notes to Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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.

August 4, 2022 /s/ Mihael H. Polymeropoulos, M.D.

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

August 4, 2022 /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.

August 4, 2022

/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.

August 4, 2022

/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, 2022 (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.

August 4, 2022

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

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

August 4, 2022

/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.