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 March 31, 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	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 April 29, 2022, there were 56,489,712 shares of the registrant's common stock issued and outstanding.

Vanda Pharmaceuticals Inc.

Quarterly Report on Form 10-Q
For the Quarter Ended March 31, 2022

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- our ability to continue to commercialize HETLIOZ® (tasimelteon) capsules for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in the United States (U.S.) 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® for the treatment of jet lag disorder;
- 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)	March 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 66,927	$ 52,071
Marketable securities	368,249	380,742
Accounts receivable, net	30,497	32,467
Inventory	1,290	1,025
Prepaid expenses and other current assets	25,305	11,996
Total current assets	492,268	478,301
Property and equipment, net	2,917	3,113
Operating lease right-of-use assets	8,945	9,272
Intangible assets, net	19,702	20,081
Deferred tax assets	70,798	74,878
Non-current inventory and other	8,928	8,147
Total assets	$ 603,558	$ 593,792
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 51,394	$ 34,438
Product revenue allowances	39,348	39,981
Total current liabilities	90,742	74,419
Operating lease non-current liabilities	9,660	10,055
Other non-current liabilities	1,033	4,390
Total liabilities	101,435	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 March 31, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized; 56,486,712 and 55,900,855 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	56	56
Additional paid-in capital	674,001	669,223
Accumulated other comprehensive loss	(1,328)	(175)
Accumulated deficit	(170,606)	(164,176)
Total stockholders' equity	502,123	504,928
Total liabilities and stockholders' equity	$ 603,558	$ 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 March 31, 2022	Three Months Ended March 31, 2021
Revenues:		
Net product sales	$ 60,192	$ 62,669
Total revenues	60,192	62,669
Operating expenses:		
Cost of goods sold excluding amortization	5,665	6,030
Research and development	20,969	16,131
Selling, general and administrative	40,848	29,797
Intangible asset amortization	379	370
Total operating expenses	67,861	52,328
Income (loss) from operations	(7,669)	10,341
Other income	105	87
Income (loss) before income taxes	(7,564)	10,428
Provision (benefit) for income taxes	(1,134)	1,778
Net income (loss)	$ (6,430)	$ 8,650
Net income (loss) per share:		
Basic	$ (0.11)	$ 0.16
Diluted	$ (0.11)	$ 0.15
Weighted average shares outstanding:		
Basic	56,105,239	55,145,789
Diluted	56,105,239	56,505,087

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 March 31, 2022	Three Months Ended March 31, 2021
Net income (loss)	$ (6,430)	$ 8,650
Other comprehensive income (loss):		
Net foreign currency translation loss	(16)	(47)
Change in net unrealized gain (loss) on marketable securities	(1,475)	1
Tax benefit (provision) on other comprehensive income (loss)	338	(1)
Other comprehensive loss, net of tax	(1,153)	(47)
Comprehensive income (loss)	$ (7,583)	$ 8,603

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

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

(in thousands, except for share amounts)	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Par Value				
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

(in thousands, except for share amounts)	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Par Value				
Balances at December 31, 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

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)	Three Months Ended March 31, 2022	Three Months Ended March 31, 2021
Cash flows from operating activities		
Net income (loss)	$ (6,430)	$ 8,650
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation of property and equipment	323	345
Stock-based compensation	4,778	3,909
Amortization of premiums and accretion of discounts on marketable securities	77	490
Gain on sale of marketable securities	—	(12)
Intangible asset amortization	379	370
Deferred income taxes	4,417	1,160
Other non-cash adjustments, net	552	295
Changes in operating assets and liabilities:		
Accounts receivable	1,957	(1,483)
Prepaid expenses and other assets	(13,360)	50
Inventory	(1,179)	42
Accounts payable and other liabilities	13,426	(5,272)
Product revenue allowances	(894)	649
Net cash provided by operating activities	4,046	9,193
Cash flows from investing activities		
Purchases of property and equipment	(75)	(130)
Purchases of marketable securities	(79,134)	(93,060)
Sales and maturities of marketable securities	90,075	93,261
Net cash provided by investing activities	10,866	71
Cash flows from financing activities		
Proceeds from exercise of stock options	—	1,849
Net cash provided by financing activities	—	1,849
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(57)	(15)
Net change in cash, cash equivalents and restricted cash	14,855	11,098
Cash, cash equivalents and restricted cash		
Beginning of period	52,590	61,613
End of period	$ 67,445	$ 72,711

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, delayed sleep phase disorder (DSPD), symptoms of 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 includes 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 March 31, 2022 and for the three months ended March 31, 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)	March 31, 2022	March 31, 2021
Cash and cash equivalents	$ 66,927	$ 72,132
Restricted cash included in:		
Prepaid expenses and other current assets	—	57
Non-current inventory and other	518	522
Total cash, cash equivalents and restricted cash	$ 67,445	$ 72,711

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 months ended March 31, 2022 and 2021 were as follows:

	Three Months Ended	
(in thousands)	March 31, 2022	March 31, 2021
HETLIOZ® net product sales	$ 37,031	$ 39,343
Fanapt® net product sales	23,161	23,326
Total net product sales	$ 60,192	$ 62,669

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 91% of total revenues for the three months ended March 31, 2022. There were five major customers that each accounted for more than 10% of accounts receivable and, as a group, represented 89% of total accounts receivable at March 31, 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 March 31, 2022, which all have contractual maturities of less than two years:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
U.S. Treasury and government agencies	$ 206,413	$ —	$ (1,578)	$ 204,835
Corporate debt	163,578	5	(169)	163,414
Total marketable securities	$ 369,991	$ 5	$ (1,747)	$ 368,249

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 March 31, 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 March 31, 2022, as follows:

		Fair Value Measurement as of March 31, 2022 Using		
(in thousands)	Total Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
U.S. Treasury and government agencies	$ 204,835	$ 204,835	$ —	$ —
Corporate debt	181,397	—	181,397	—
Total assets measured at fair value	$ 386,232	$ 204,835	$ 181,397	$ —

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 March 31, 2022 include $18.0 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 March 31, 2022 and December 31, 2021:

(in thousands)	March 31, 2022	December 31, 2021
Current assets		
Work-in-process	$ —	$ 30
Finished goods	1,290	995
Total inventory, current	$ 1,290	$ 1,025
Non-Current assets		
Raw materials	$ 1,954	$ 2,143
Work-in-process	4,546	3,934
Finished goods	1,485	1,150
Total inventory, non-current	7,985	7,227
Total inventory	$ 9,275	$ 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 March 31, 2022:

		March 31, 2022		
(in thousands)	Estimated Useful Life	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	March 2035	$ 33,000	$ 13,298	$ 19,702

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 March 31, 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 March 31, 2022 and 2021. The following is a summary of the future intangible asset amortization schedule as of March 31, 2022:

(in thousands)	Total	2022	2023	2024	2025	2026	Thereafter
HETLIOZ®	$ 19,702	$ 1,137	$ 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 March 31, 2022 and December 31, 2021:

(in thousands)	March 31, 2022	December 31, 2021
Consulting and other professional fees	$ 13,416	$ 8,732
Research and development expenses	13,123	10,082
Royalties payable	5,099	5,873
Compensation and employee benefits	3,132	6,515
Operating lease liabilities	2,297	2,311
Accounts payable and other accrued liabilities	14,327	925
Total accounts payable and accrued liabilities	$ 51,394	$ 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 March 31, 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 NCE patent has expired or was not issued. The Company is obligated to pay this 6% royalty on net sales in the U.S. through November 2026.

Tradipitant. In April 2012, the Company entered into a license agreement with Eli Lilly and Company (Lilly) pursuant to which the Company acquired an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize an NK-1 receptor antagonist, tradipitant, for all human indications. Lilly is eligible to receive future payments based upon achievement of specified development, regulatory approval and commercialization milestones as well as tiered-royalties on net sales at percentage rates up to the low double digits. As of March 31, 2022, the Company has paid Lilly $3.0 million in upfront fees and development milestones. As of March 31, 2022, remaining milestone obligations include a $2.0 million development milestone due upon the filing of the first 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 a 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 March 31, 2022, the Company has paid UCSF $1.6 million in upfront fees and development milestones. As of March 31, 2022, 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 March 31, 2022 and December 31, 2021:

(in thousands)	March 31, 2022	December 31, 2021
Foreign currency translation	$ 16	$ 32
Unrealized loss on marketable securities	(1,344)	(207)
Accumulated other comprehensive loss	$ (1,328)	$ (175)

10. Stock-Based Compensation

As of March 31, 2022, there were 6,386,142 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 10,790,000 shares of common stock authorized for issuance under the 2016 Plan, 3,230,231 shares of which remained available for future grant as of March 31, 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 March 31, 2022, $10.0 million of unrecognized compensation costs related to unvested service option awards are expected to be recognized over a weighted average period of 1.5 years. No option awards are classified as a liability as of March 31, 2022.

A summary of option activity under the Plans for the three months ended March 31, 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	646,200	11.36		
Outstanding at March 31, 2022	4,367,348	13.75	6.17	3,029
Exercisable at March 31, 2022	2,852,580	13.20	4.65	3,004
Vested and expected to vest at March 31, 2022	4,080,448	13.77	5.94	3,027

The weighted average grant-date fair value of options granted was $5.28 and $8.95 per share for the three months ended March 31, 2022 and 2021, respectively. There were no proceeds from the exercise of stock options for the three months ended March 31, 2022. Proceeds from the exercise of stock options amounted to $1.8 million for the three months ended March 31, 2021.

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 March 31, 2022, $28.0 million of unrecognized compensation costs related to unvested service RSUs are expected to be recognized over a weighted average period of 1.9 years. No RSUs are classified as a liability as of March 31, 2022.

A summary of RSU activity under the Plans for the three months ended March 31, 2022 follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2021	1,764,740	$ 17.27
Granted	848,350	11.37
Forfeited	(8,439)	14.68
Vested	(585,857)	17.51
Unvested at March 31, 2022	2,018,794	14.73

The grant date fair value for the 585,857 shares underlying RSUs that vested during the three months ended March 31, 2022 was $10.3 million.

Stock-Based Compensation Expense

Stock-based compensation expense recognized for the three months ended March 31, 2022 and 2021 was comprised of the following:

	Three Months Ended	
(in thousands)	March 31, 2022	March 31, 2021
Research and development	$ 1,160	$ 1,120
Selling, general and administrative	3,618	2,789
Total stock-based compensation expense	$ 4,778	$ 3,909

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 three months ended March 31, 2022 and 2021 were as follows:

	Three Months Ended	
	March 31, 2022	March 31, 2021
Expected dividend yield	0 %	0 %
Weighted average expected volatility	47 %	46 %
Weighted average expected term (years)	6.05	5.98
Weighted average risk-free rate	1.86 %	0.73 %

11. Income Taxes

The Company recorded income tax benefit of $1.1 million and a provision for income taxes of $1.8 million for the three months ended March 31, 2022 and 2021, respectively. The income tax expense (benefit) for the three months ended March 31, 2022 and 2021 was primarily driven by the estimated effective tax rate for the year, as well as discrete income tax expense of $1.1 million and discrete income tax benefit of $0.3 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 months ended March 31, 2022 and 2021:

	Three Months Ended	
(in thousands, except for share and per share amounts)	**March 31, 2022**	**March 31, 2021**
Numerator:		
Net income (loss)	$ (6,430)	$ 8,650
Denominator:		
Weighted average shares outstanding, basic	56,105,239	55,145,789
Effect of dilutive securities	—	1,359,298
Weighted average shares outstanding, diluted	56,105,239	56,505,087
Net income (loss) per share, basic and diluted:		
Basic	$ (0.11)	$ 0.16
Diluted	$ (0.11)	$ 0.15
Antidilutive securities excluded from calculations of diluted net income (loss) per share	4,263,975	2,137,110

The company incurred a net loss for the three months ended March 31, 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 qui tam action filed against the Company under seal in March 2017 was unsealed by order of the U.S. District Court for the District of Columbia (DC District Court). The qui tam action was brought by a former Company employee on behalf of the U.S., 28 states and the District of Columbia (collectively, the Plaintiff States) and the policyholders of certain insurance companies under the Federal False Claims Act and state law equivalents to the Federal False Claims Act and related state laws. The complaint alleged that the Company violated these laws through the promotion and marketing of its products Fanapt® and HETLIOZ® and sought, among other things, treble damages, civil penalties for each alleged false claim, and attorneys’ fees and costs. The DOJ and the Plaintiff States elected not to intervene in the qui tam action, but the plaintiff continued to litigate the complaint. In March 2022, the DC District Court dismissed the plaintiff's complaint in its entirety, without prejudice.

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 court approval. Payment of the settlement award 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 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.

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, delayed sleep phase disorder (DSPD), symptoms of 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 symptoms of ASD are currently enrolling patients..
- 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 nighttime sleep disturbances in SMS.
- In January 2022, we settled our HETLIOZ® patent litigation against one of the defendants. The trial for the consolidated lawsuit against the remaining defendants was held in March 2022. A decision is expected from the court in the second half of 2022.

Tradipitant

- We are continuing to conduct an open-label study of safety for tradipitant in gastroparesis and continue to receive requests from patients reaching out to gain access to tradipitant through the Expanded Access program which has multiple patients continuing to take tradipitant for more than a year.
- We have scheduled a pre-NDA meeting with the FDA to discuss the planned New Drug Application submission for tradipitant in the short-term treatment of nausea in gastroparesis.
- The Phase III study of tradipitant in the treatment of motion sickness has restarted enrollment and is already over 15% enrolled. A prior Phase II study of tradipitant in the treatment of motion sickness observed a significantly lower incidence of vomiting in tradipitant-treated patients as compared to placebo-treated patients.

Fanapt®

- A Phase III study of Fanapt® in acute manic episodes in patients with bipolar disorder is over 75% enrolled and expected to complete enrollment 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 payment discounts and, therefore, deduct the full amount of these discounts from total product sales when revenues are recognized.

Rebates: Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program as well as contracted rebate programs with other payors. 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-payment assistance: Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment 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 March 31, 2022 or December 31, 2021.

The following table summarizes sales discounts and allowance activity as of and for the three months ended March 31, 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	20,576	7,587	28,163
Adjustments for prior period sales	(922)	(163)	(1,085)
Credits/payments made	(20,419)	(7,593)	(28,012)
Balances at March 31, 2022	$ 31,089	$ 9,432	$ 40,521

The provision of $20.6 million for rebates and chargebacks for the three months ended March 31, 2022 primarily represents Medicaid rebates applicable to sales of Fanapt® and HETLIOZ®. The provision of $7.6 million for discounts, returns and other for the three months ended March 31, 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 March 31, 2022 compared to three months ended March 31, 2021

Revenues. Total revenues decreased by $2.5 million, or 4%, to $60.2 million for the three months ended March 31, 2022 compared to $62.7 million for the three months ended March 31, 2021. Revenues were as follows:

	Three Months Ended			
(in thousands)	March 31, 2022	March 31, 2021	Net Change	Percent
HETLIOZ® net product sales	$ 37,031	$ 39,343	$ (2,312)	(6)%
Fanapt® net product sales	23,161	23,326	(165)	(1)%
Total net product sales	$ 60,192	$ 62,669	$ (2,477)	(4)%

HETLIOZ® net product sales decreased by $2.3 million, or 6%, to $37.0 million for the three months ended March 31, 2022 compared to $39.3 million for the three months ended March 31, 2021. The decrease to net product sales was attributable to a decrease in volume, partially offset by an increase in price net of deductions. We have experienced an increase in the rate at which third-party payors refuse to cover or reimburse prescriptions written for HETLIOZ®, which has contributed to the decrease in volume.

Fanapt® net product sales decreased by $0.2 million, or 1%, to $23.2 million for the three months ended March 31, 2022 compared to $23.3 million for the three months ended March 31, 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 $0.4 million, or 6%, to $5.7 million for the three months ended March 31, 2022 compared to $6.0 million for the three months ended March 31, 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 $4.8 million, or 30%, to $21.0 million for the three months ended March 31, 2022 compared to $16.1 million for the three months ended March 31, 2021. The increase in research and development expenses was associated with our Fanapt® development program, partially offset by a decrease in expenses associated with our tradipitant development program.

The following table summarizes the costs of our product development initiatives for the three months ended March 31, 2022 and 2021:

(in thousands)	Three Months Ended March 31, 2022	March 31, 2021
Direct project costs (1)		
HETLIOZ®	$ 3,084	$ 2,691
Fanapt®	8,600	2,690
Tradipitant	4,755	6,544
VTR-297	415	233
CFTR	332	1,022
VQW-765	933	347
Other	715	397
Total direct project costs	18,834	13,924
Indirect project costs (1)		
Stock-based compensation	1,160	1,120
Other indirect overhead	975	1,087
Total indirect project costs	2,135	2,207
Total research and development expense	$ 20,969	$ 16,131

(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 $11.1 million, or 37%, to $40.8 million for the three months ended March 31, 2022 compared to $29.8 million for the three months ended March 31, 2021. The increase in selling, general and administrative expenses was primarily the result of an increase in spending on ongoing litigation, HETLIOZ® commercial support and other corporate activities as well as marketing activities for our commercial products.

Intangible asset amortization. Intangible asset amortization was $0.4 million for each of the three months ended March 31, 2022 and 2021.

Other income. Other income was $0.1 million for each of the three months ended March 31, 2022 and 2021. Other income primarily consists of investment income on our marketable securities.

Provision (benefit) for income taxes. An income tax benefit of $1.1 million and a provision for income taxes of $1.8 million was recorded for the three months ended March 31, 2022 and 2021, respectively. The income tax expense (benefit) for the three months ended March 31, 2022 and 2021 was primarily driven by the estimated effective tax rate for the year, as well as discrete income tax expense of $1.1 million and income tax benefit of $0.3 million, respectively.

Liquidity and Capital Resources

As of March 31, 2022, our total cash and cash equivalents and marketable securities were $435.2 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 March 31, 2022 and December 31, 2021 are summarized as follows:

(in thousands)	March 31, 2022	December 31, 2021
Cash and cash equivalents	$ 66,927	$ 52,071
Marketable securities:		
U.S. Treasury and government agencies	204,835	194,719
Corporate debt	163,414	186,023
Total marketable securities	368,249	380,742
Total cash, cash equivalents and marketable securities	$ 435,176	$ 432,813

As of March 31, 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 three months ended March 31, 2022 and 2021:

(in thousands)	Three Months Ended March 31, 2022	March 31, 2021	Net Change
Net cash provided by:			
Operating activities:			
Net income (loss)	$ (6,430)	$ 8,650	$ (15,080)
Non-cash charges	10,526	6,557	3,969
Net change in operating assets and liabilities	(50)	(6,014)	5,964
Operating activities	4,046	9,193	(5,147)
Investing activities:			
Purchases of property and equipment	(75)	(130)	55
Net purchases, sales and maturities of marketable securities	10,941	201	10,740
Investing activities	10,866	71	10,795
Financing activities:			
Proceeds from the exercise of stock options	—	1,849	(1,849)
Financing activities	—	1,849	(1,849)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(57)	(15)	(42)
Net change in cash, cash equivalents and restricted cash	$ 14,855	$ 11,098	$ 3,757

Operating Activities: Cash flows provided by operating activities during the three months ended March 31, 2022 were $4.0 million, a decrease of $5.1 million compared to cash flows provided by operating activities of $9.2 million for the three months ended March 31, 2021. The decrease reflects a decrease of $15.1 million in net income partially offset by an increase of $4.0 million in non-cash charges, primarily due to the change in our deferred tax assets, and an increase of $6.0 million from the net change in operating assets and liabilities. The increase of $6.0 million from the net change in operating assets and liabilities primarily relates to an increase in accounts payable and accrued liabilities, partially offset by an increase in prepaid expenses and other assets.

Investing Activities: Cash flows provided by investing activities during the three months ended March 31, 2022 were $10.9 million, an increase of $10.8 million compared to cash flows provided by investing activities of $0.1 million for the three months ended March 31, 2021. Investing activities primarily include purchases, sales and maturities of marketable securities.

Financing Activities: There were no cash flows from financing activities during the three months ended March 31, 2022, a decrease of $1.8 million compared to cash flows provided by financing activities of $1.8 million for the three months ended March 31, 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 March 31, 2022. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of March 31, 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 first 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

Approval of Amendment to Amended and Restated 2016 Equity Incentive Plan

On March 17, 2022 our Board of Directors approved, subject to stockholder approval, an amendment to our Amended and Restated 2016 Equity Incentive Plan, as amended (the 2016 Plan). The amendment to the 2016 Plan, if approved by the stockholders, will increase the aggregate number of shares of common stock that may be issued by us pursuant to awards under the 2016 Plan by 1,100,000 shares.

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).
10.1‡*	License Agreement, dated January 13, 2022, by and among MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, Impax Laboratories LLC and the registrant.
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 March 31, 2022 formatted in Inline Extensible Business Reporting Language (iXBRL) and filed electronically herewith: (i) Condensed Consolidated Balance Sheets as of March 31, 2022 and December 31, 2021; (ii) Condensed Consolidated Statements of Operations for the three months ended March 31, 2022 and 2021; (iii) Condensed Consolidated Statements of Comprehensive Income (Loss) for the three months ended March 31, 2022 and 2021; (iv) Condensed Consolidated Statements of Changes in Stockholders' Equity for the three months ended March 31, 2022 and 2021; (v) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2022 and 2021; and (vi) Notes to Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).
‡	Portions of this exhibit have been omitted under rules of the Securities and Exchange Commission permitting the confidential treatment of select information.
*	Filed herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Vanda Pharmaceuticals Inc.

May 6, 2022 /s/ Mihael H. Polymeropoulos, M.D.

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

May 6, 2022 /s/ Kevin Moran

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

EXHIBIT 10.1

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS OF THE TYPE THAT VANDA TREATS AS PRIVATE OR CONFIDENTIAL. SUCH EXCLUDED INFORMATION HAS BEEN MARKED WITH "[***]."

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this "**Agreement**") dated as of January 13, 2022 (the "**Effective Date**") is entered into between Vanda Pharmaceuticals Inc., a Delaware corporation with an address at 2200 Pennsylvania Avenue, N.W., 300E, Washington, DC 20037, on behalf of itself and its Affiliates (collectively, "**Vanda**"), MSN Pharmaceuticals Inc., a corporation organized and existing under the laws of Delaware, with a place of business at 20 Duke Road, Piscataway, New Jersey 08854, and MSN Laboratories Private Limited, a corporation organized and existing under the laws of India, with a place of business at MSN House, Sy No: 10 & 11 Whitefields, HITEC City, Hyderabad, Telangana, India 500081, on behalf of themselves and each of their Affiliates (collectively, "**MSN**"), and Impax Laboratories LLC (f.k.a. Impax Pharmaceuticals, Inc.), a limited liability company organized and existing under the laws of Delaware, with a place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, NJ 08807, on behalf of itself and its Affiliates (collectively "**Impax"**).

WHEREAS Vanda is the owner of the Patent Rights (as the term is defined below) and has sued MSN in the actions captioned *Vanda Pharmaceuticals Inc. v. MSN Pharmaceuticals Inc. et al.*, Case Nos. 1:18-cv-690 (CFC), 1:19-cv-926 (CFC), 1:20-cv-235 (CFC), 1:20-cv-318 (CFC), 1:20-cv-1334 (CFC), and 1:21-cv-00283 (CFC) (the "**Litigation**") which is pending in the United States District Court, District of Delaware (the "**Court**"), in which Vanda alleges that MSN's filings of Abbreviated New Drug Application ("ANDA") No. 211654 infringes U.S. Patent Nos. RE46,604, 9,060,995, 9,539,234, 9,549,913, 9,730,910, 9,855,241, 10,149,829, 10,071,977, 10,376,487, 10,449,176, 10,610,510, 10,610,511, 10,829,465, and 10,611,744 ("the asserted patents");

WHEREAS Impax and MSN are Parties to a certain Finished Dosage Development, Commercial Supply and Distribution Agreement dated as of February 12, 2018 (the "**Supply Agreement**"), which grants to Impax an exclusive license to use, import, offer for sale, sell and have sold Generic Product under MSN's ANDA No. 211654;

WHEREAS the Supply Agreement grants Impax the authority to control the Litigation, negotiate settlement terms and settle the Litigation; and

WHEREAS the parties desire to settle the Litigation and MSN and Impax desire to receive, and Vanda desires to grant to MSN and Impax, a non-exclusive, [***] license under the Patent Rights to make, use, sell, offer for sale and import Generic Product (as the term is defined below), all on the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. DEFINITIONS.

1.1 "**Affiliate**" means, with respect to any entity, any other entity that directly or indirectly controls, is controlled by, or is under common control with, such entity. An entity shall be regarded as in control of another entity if it owns, or directly or indirectly controls, at least fifty percent (50%) of the voting stock or other ownership interest of the other entity, or if it directly or indirectly possesses the power to direct or cause the direction of the management and policies of the other entity by any means whatsoever.

1.2 "**[***]**" shall mean [***] (as defined below).

1.3 "**Authorized Generic**" shall mean any product that is sold, offered for sale or distributed in the United States pursuant to NDA No. [***] but not under the Hetlioz® tradename or another trademark or tradename owned by Vanda or its Affiliates.

1.4 "**Business Day**" shall mean any day other than a Saturday, a Sunday or a day on which the state or federal courts located in the State of Delaware are authorized or obligated by law or executive order to be closed.

1.5 "**Confidential Information**" means all non-public materials, information and data concerning the disclosing party and its operations that is disclosed by the disclosing party to the receiving party pursuant to this Agreement, orally or in written, electronic or tangible form, or otherwise obtained by the receiving party through observation or examination of the disclosing party's operations. Confidential Information includes, but is not limited to, information about the disclosing party's financial condition and projections; business, marketing or strategic plans; sales information; customer lists; price lists; databases; trade secrets; product prototypes and designs; techniques, formulae, algorithms and other non-public process information. Notwithstanding the foregoing, Confidential Information of a party shall not include that portion of such materials, information and data that, and only to the extent, that the recipient can establish by written documentation: (a) is known to the recipient as evidenced by its written records before receipt thereof from the disclosing party, (b) is disclosed to the recipient free of confidentiality obligations by a Third Party who has the right to make such disclosure without obligations of confidentiality, (c) is or becomes part of the public domain through no fault of the recipient, or (d) the recipient can reasonably establish is independently developed by persons on behalf of recipient without the use of the information disclosed by the disclosing party.

1.6 "**Hetlioz Product**" means the form, formulation, and dosage of the current FDA-approved Hetlioz® capsule product listed on Exhibit A. For the avoidance of doubt, the Hetlioz Product shall not include [***].

1.7 "**FDA**" means the United States Food and Drug Administration or any successor entity thereto.

1.8 **"Generic Product"** means—regardless of whether a product is considered generic, branded, private-labeled or otherwise—a product for which FDA approval is sought as, or that has been deemed by FDA to be, bioequivalent to the Hetlioz Product and has the same strength and dosage form as the Hetlioz Product. For the avoidance of doubt, "Generic Product" does not include the Hetlioz Product itself but does include any Authorized Generic.

1.9 "**Orange Book**" means the current edition (in electronic or hard copy form) of the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, as may be amended from time to time, and any successor publication thereto.

1.10 "**Patent Rights**" means (a) the patents listed on Exhibit B to this Agreement and the patent applications giving rise thereto, (b) all provisional applications, divisionals, continuations, continuations-in-part, reissues and renewals that claim priority to, or common priority with, any patent application that resulted in the patents described in clause (a) above, and all patents granted thereon, (c) all patents that have issued or in the future issue from any of the foregoing patent applications, including utility, model and design patents and certificates of invention, together with any reexamination certificates (including any amended claims from an *inter partes* review or post-grant review proceeding), reissues, renewals, extensions, and extended exclusivities or restorations by existing or future extension or restoration mechanisms, or additions thereto, and (d) all other relevant patents and patent applications, if any, that cover the Hetlioz Product or an approved use of the Hetlioz Product.

1.11 "**Third Party**" means any person or entity other than Vanda, MSN or Impax or their respective Affiliates.

1.12 **"Trigger Date"** means, with respect to a Generic Product for which MSN has an approved ANDA, on a Generic-Product-by-Generic-Product basis, the earliest of:

(a) March 13, 2035; provided however, that if Vanda obtains pediatric exclusivity pursuant to 21 U.S.C. § 355A, then the date for purposes of this subsection 1.12(a) shall be July 27, 2035;

(b) the date on which (i) a final decision by a court from which no appeal can be taken, other than a petition for a writ of certiorari, is entered such that all of the then-asserted claims within the Patent Rights as to such Generic Product are finally held to be unpatentable or invalid or unenforceable or not infringed by the applicable Generic Product or have lapsed (for the avoidance of doubt, a court of appeals' judgment or order is not "final" until issuance of the mandate); (ii) the last to expire patent containing a then-asserted claim within the Patent Rights as to such Generic Product, which claim has not been finally held to be unpatentable or invalid or unenforceable or not infringed by the applicable Generic Product, expires or lapses; or (iii) a final decision by the U.S. Patent and Trademark Office, from which no appeal can be taken, is entered such that all of the claims within the Patent Rights as to such Generic Product are finally held to be unpatentable or invalid or unenforceable or have lapsed (for the avoidance of doubt, a court of appeals' judgment or order is not "final" until issuance of the mandate);

(c) the date on which such Generic Product is first sold in the United States by a Third Party that holds or is otherwise licensed under an approved ANDA to manufacture and/or sell such Generic Product in the United States ("**Third Party ANDA Holder**") after the Effective Date, provided that (i) [***] , and (ii) [***] either (A) [***] , or (B) [***], then in each case of clauses (A) and (B) [***];

(d) the first date when such Generic Product is licensed to be sold in the United States by a Third Party who is under authority or license of Vanda; and

(e) the first date an Authorized Generic is licensed to be sold in the United States.

[***] shall not constitute [***], provided that [***], if: (i) [***], (ii) [***], and (iii) [***].

If [***] with any [***] and such [***] in order to [***].

1.13 "**United States**" means the United States of America, including its territories and possessions.

1.14 "**Valid Claim**" means a claim in an issued patent within the Patent Rights that has not (a) expired; (b) been disclaimed (but, if terminally disclaimed, only after the patent to which the terminal disclaimer is tied has expired); (c) been declared invalid or unenforceable in a final decision of a court, or (d) been declared invalid or unenforceable in a final decision by the U.S. Patent and Trademark Office, from which no appeal can be taken (for the avoidance of doubt, a court of appeals' judgment or order is not "final" until issuance of the mandate).

1.15 "**Vanda NDA**" means the New Drug Application [***] and any supplements or amendments thereto.

2. RELEASE; PATENT RIGHTS; COVENANTS.

2.1 Release. MSN and Impax, on their own behalves and on behalf of any person or entity within their respective control or with whom they contract in any way with respect to the ANDA and/or any Generic Product, represent and warrant that, as of the Effective Date, neither MSN nor Impax nor any person or entity within their control or with whom they have contracted with respect to the ANDA and/or Generic Product, has manufactured, used, sold, offered for sale, imported or distributed in the United States any Generic Product except for purposes that would not constitute infringement of the Patent Rights as a result of the application of 35 U.S.C. § 271(e)(1). In consideration for the covenants set forth in this Agreement, and in reliance on the representation and warranty in the preceding sentence, Vanda hereby as of the Effective Date fully, finally, and irrevocably releases MSN, Impax [***] (collectively, the "MSN Releasees") from all claims and other Losses (as that term is defined below) arising from the manufacture, use, sale, offer for sale, importation or distribution of MSN's Generic Product prior to the Effective Date (the "Released Claims").

2.2 Prior to Trigger Dates.

2.2.1 Commencing on the Effective Date and continuing until the Trigger Date, neither MSN nor Impax shall —directly or indirectly encourage or assist any Third Party to develop, make, use, sell, offer for sale, or import into the United States any Generic Product. Notwithstanding the foregoing, [***], in order to [***] (as that term is defined below), provided that such [***]. For the avoidance of doubt, and further notwithstanding the foregoing, [***]: (a) [***], (b) [***], and (c) [***], provided that [***].

2.2.2 If Vanda enters into any agreement allowing a Third Party ANDA Holder to engage in the activities identified in Section 2.2.1 earlier than MSN and Impax are authorized to engage in such activities, then this Agreement shall automatically be amended to authorize such earlier activities, and Vanda shall provide MSN or Impax with notice of any such earlier dates [***] after entering into any agreement providing for such earlier dates.

2.2.3 If any license or settlement agreement between Vanda and a Third Party allows or causes to allow a Third Party rights under the Patent Rights to sell Generic Product on a specific date that is earlier than the operative date under subsection 1.12(a), 1.12(b), 1.12(c), 1.12(e), and as to any entity under 1.12(d), above (each an "Earlier Trigger Date"), then Vanda shall notify MSN or Impax in writing of the Earlier Trigger Date within [***] of learning of or granting of the Earlier Trigger Date, including, but not limited to, within [***] of learning of the activation of a corresponding "trigger date" in a settlement agreement or license agreement with a Third Party or Affiliate of Vanda, and this Agreement shall automatically be amended to include such Earlier Trigger Date, and further providing that to the extent reasonably practicable, and without imposing any restrictions on Vanda's ability to settle any lawsuit with any Third Party ANDA Holder on such terms as Vanda chooses, notice shall be given to MSN or Impax no less than [***] before any such Earlier Trigger Date, if such Earlier Trigger Date is within Vanda's control.

2.2.4 Nothing in this Agreement shall be construed as prohibiting MSN or Impax from engaging in any activity that would not constitute infringement of the Patent Rights as a result of the application of 35 U.S.C. § 271(e)(1).

2.3 Validity of Vanda's Patents. MSN and Impax hereby admit that, solely with respect to its Generic Product, the claims of the Patent Rights are valid and enforceable. MSN and Impax hereby admit that, absent a license or applicable exemption under 21 U.S.C. § 271(e)(1), the commercial making, using, offering to sell, selling, and/or importation into the United States of a Generic Product is covered by one or more claims of the Patent Rights under 35 U.S.C. § 271. Within five days of the Effective Date, Vanda and MSN shall execute and cause to be filed with the Court in the Litigation a consent judgment in the form attached hereto as Exhibit C (the "**Consent Judgment and Injunction**"). The foregoing admissions and the Consent Judgment and Injunction shall be binding on MSN and Impax and admissible against MSN and Impax in any dispute or litigation between the parties regarding the Patent Rights, and MSN and Impax shall not challenge such admission. MSN and Impax shall not assist any Third Party in an action to invalidate or render unenforceable any Valid Claim, and MSN and Impax shall not disclose any of its proprietary or confidential information relating to the validity or enforceability of any Valid Claim, except to the extent required by court order or other applicable law. This paragraph is limited to (a) the claims of issued patents within the Patent Rights as they exist as of the Effective Date and (b) the claims of patent applications within the Patent Rights as such claims are drafted as of the Effective Date and the claims issuing therefrom to the extent such issued claims are the same as drafted as of the Effective Date. For the avoidance of doubt, MSN and Impax's admissions in this Section as to the Patent Rights are limited to its Generic Product, and MSN and Impax reserve all rights to challenge, petition, claim, or counterclaim against the Patent Rights for the non-infringement, invalidity, and/or unenforceability as to any drug product other than its Generic Product. Nothing herein shall prevent MSN from maintaining a "Paragraph IV Certification" pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (as amended or replaced) for its Generic Product with respect to the Patent Rights on the basis that any sale by MSN or Impax in accordance with this Agreement will be a licensed sale.

2.4 Vanda Covenants. Vanda, for itself and its Affiliates, hereby covenants as of the Effective Date of this Agreement and thereafter during the time that this Agreement is in effect:

a) Not to sue, not to assign to any other entity a right to sue, and not to authorize any other entity to sue, any MSN Releasee [***] on any Released Claims;

b) Not to assert, with respect to the sale of Generic Product on or after the Trigger Date in accordance with this Agreement, any patent remedies to which they would be entitled under 35 U.S.C. § 271(e)(4) or any other U.S. patent law if the Court had found that MSN infringed the asserted patents, and/or any patent claim with respect to the Patent Rights; and

c) Upon MSN's written request, to provide the FDA with written confirmation of the Trigger Date and the licenses, covenants, and waivers herein.

2.5 MSN and Impax Covenants. Unless and until MSN or Impax submits an Abbreviated New Drug Application for a product in which tasimelteon is the active pharmaceutical ingredient but which is not a Generic Product, MSN and Impax, for themselves and their Affiliates, hereby covenants as of the Effective Date of this Agreement and thereafter during the time that this Agreement is in effect that MSN and Impax will not challenge the validity or patentability of any of the Patent Rights, or provide any support to a challenge to the validity patentability of any of the Patent Rights by any other entity before any court, tribunal, or administrative body, including but not limited to the United States Patent and Trademark Office. MSN and Impax, for themselves and their affiliates, further covenants as of the Effective Date of this Agreement and thereafter during the time that this Agreement is in effect that if MSN or Impax successfully challenge the validity or patentability of any patent listed in the Orange Book with respect to Hetlioz®, MSN and Impax will not rely on such challenge, or the legal result of such challenge, including for purposes of determining a Trigger Date under Section 1.12 of this Agreement, to develop, make, use, sell, offer for sale, or import into the United States any Generic Product. For avoidance of doubt, if MSN successfully challenges the validity or patentability of any patent listed in the Orange Book with respect to Hetlioz® as permitted under this Agreement, MSN and Impax may rely on such challenge, or the legal result of such challenge, in order to develop, make, use, sell, offer for sale, or import into the United States any product that is not a Generic Product.

3. LICENSE; EXCLUSIVITY WAIVER

3.1 License Grants. Subject to the terms and conditions of this Agreement, and effective on the Trigger Date, Vanda hereby grants to MSN and Impax a non-exclusive[***] license under the Patents Rights to make, have made, use, sell, offer for sale and import the applicable Generic Products and [***]. For the avoidance of doubt, the use or resale of a Generic Product by a supplier or customer of MSN or Impax following the Trigger Date, to the extent such Generic Product was first manufactured and sold by or on behalf of MSN or Impax within the scope of the foregoing license, shall not constitute an infringement of the Patent Rights as set forth in this Agreement.

3.2 Waiver of Exclusivities. With respect to the sale of Generic Product in accordance with this Agreement on or after the Trigger Dates provided for in Sections 1.12(a) and Sections 1.12(b), Vanda hereby grants to MSN a waiver of any and all statutory or regulatory exclusivities necessary to effectuate the licenses contained herein.

3.3 No Other Licenses. Except as otherwise provided herein, nothing in this Agreement shall be construed as: (a) an obligation to bring or prosecute actions or suits against Third Parties for infringement of any patent, whether within the Patent Rights or otherwise; (b) granting a license or conferring any right under any patent with respect to actions taken wholly after the expiration of such patent; (c) conferring a right to use in advertising, publicity, promotion or otherwise any of Vanda's trademarks, including in the trademark Hetlioz®, trade dresses, service marks, or other intellectual property other than the Patent Rights; or (d) granting by implication, estoppel or otherwise, any licenses or rights under the Patent Rights or any other patents.

3.4 Effect of an At-Risk Launch. For the avoidance of doubt, in the event that any entity other than Vanda or its Affiliates, or MSN or its Affiliates, or Impax or its Affiliates, sells an unlicensed Generic Product on a date prior to the Trigger Date (the "Unlicensed Launch Date"), then the terms of Section 1.12(c) shall apply.

4. TERM AND TERMINATION.

4.1 Term. Subject to Sections 4.2 and 4.3, this Agreement shall expire on the expiration of the last to expire of the Patent Rights; provided, however, that if there are no valid, issued patents within the Patent Rights, but there are at such time pending patent applications within the Patent Rights, then subject to the terms and conditions of this Agreement, the term of this Agreement shall continue for the pendency of such pending patent applications.

4.2 Termination for Cause. Either party may terminate this Agreement upon or after the material breach of any material provision of this Agreement by the other party if the other party has not cured such breach within [***] after receipt of express written notice thereof by the non-breaching party. If this Agreement is terminated as the result of a material breach by MSN or Impax prior to expiration of the last of the Patent Rights, then neither MSN nor Impax shall make, have made, use, sell, offer for sale, import or distribute the applicable Generic Product until (i) there are no Valid Claims covering the Generic Product, (ii) a final decision by a court from which no appeal can be taken is entered holding that all of the said applicable Patent Rights as to such Generic Product are unpatentable or invalid or unenforceable or not infringed by the applicable Generic Product (for the avoidance of doubt, a court of appeals' judgment or order is not "final" until issuance of the mandate); or (iii) a final decision by the U.S. Patent and Trademark Office, from which no appeal can be taken, is entered holding that all the said applicable Patent Rights as to such Generic Product are unpatentable, invalid or unenforceable (for the avoidance of doubt, a court of appeals' judgment or order is not "final" until issuance of the mandate).

4.3 Termination for Challenge. Vanda shall have the right to immediately terminate this Agreement at any time after the Effective Date in the event MSN or Impax contests or challenges, or supports or assists any Third Party to contest or challenge, with the U.S. Patent Office or any U.S. court, U.S. regulatory agency or other forum, Vanda's ownership of or rights in, or the validity, enforceability or scope of, any of the Patent Rights in connection with a Generic Product.

4.4 Effect of Expiration or Termination. Expiration or termination of this Agreement shall not relieve the parties of any obligation accruing prior to such expiration or termination, and the provisions of Sections 1, 2.1, 2.2, 2.3, 3.2, 4.2, 4.4, 5, 7 and 8 shall survive the expiration or termination of this Agreement. No other provisions shall survive expiration or termination of this Agreement.

5. CONFIDENTIALITY.

5.1 Confidentiality. Except as otherwise provided herein, until the date that is five (5) years after the expiration or earlier termination of this Agreement—except with respect to any Confidential Information constituting a trade secret, in which case the receiving party's obligation pursuant to this paragraph continues in perpetuity, provided such receiving party has been informed as to the status of such Confidential Information as a trade secret—each party shall maintain in confidence all Confidential Information disclosed by the other party and the terms of this Agreement, and shall not use, grant the use of, or disclose to any Third Party any Confidential Information of the other party other than as expressly permitted hereby. Each party shall notify the other promptly upon discovery of any unauthorized use or disclosure of the other party's Confidential Information or the terms of this Agreement.

5.2 Permitted Disclosures. Either party may disclose Confidential Information of the disclosing party (a) on a need-to-know basis, to such party's directors, officers and employees to the extent such disclosure is reasonably necessary in connection with such party's activities as expressly authorized by this Agreement, and (b) to those agents and consultants, and contract manufacturers who need to know such information to accomplish the purposes of this Agreement (collectively, "**Permitted Recipients**"); provided such Permitted Recipients are bound to maintain such Confidential Information in confidence at least to the same extent as set forth in Section 5.1.

5.3 Litigation and Governmental Disclosure. Each party may disclose Confidential Information of the other party to the extent such disclosure is reasonably necessary for prosecuting or defending litigation or complying with a court order or applicable law, governmental regulations or investigation, provided that if a party is required by court order, law or regulation (except for disclosure requested or required by the I.R.S., or disclosure required under securities laws as described in Section 5.5) to make any such disclosure of the other party's Confidential Information it will give reasonable advance notice to the other party of such disclosure requirement and will use good faith efforts to assist such other party to secure a protective order or confidential treatment of such Confidential Information required to be disclosed.

5.4 Return of Confidential Information. Upon expiration or termination of this Agreement for any reason, the receiving party, upon receipt of a written request from the Disclosing Party, shall return to the Disclosing Party all copies of the Confidential Information received from the Disclosing Party hereunder, provided, however, that the receiving party's legal counsel may retain one copy of such Confidential Information in a secure location solely for purposes of determining the receiving party's continuing obligations under this Agreement.

5.5 Publicity. Except as expressly authorized hereunder, neither party shall make any publicity releases, interviews or other dissemination of information concerning this Agreement or its terms, or either party's performance hereunder, to communication media, financial analysts or others without the prior written approval of the other party, which approval shall not be unreasonably withheld, delayed or conditioned. Notwithstanding anything to the contrary in this Agreement, the parties understand and agree that either party, may disclose the existence and/or terms of this Agreement or other Confidential Information of the other party (a) to comply with its obligations under the law, including, without limitation, the United States Securities Act of 1933, as amended and the United States Securities Exchange Act of 1934, as amended (the "**Exchange Act**"); (b) in order to comply with the listing standards, rules, regulations or agreements of any national or international securities exchange, The NASDAQ Global Market or New York Stock Exchange or other similar laws, rules or regulations of a governmental or regulatory authority; (c) to respond to an inquiry of a governmental authority or regulatory authority as required by law; or (d) in a judicial, administrative or arbitration proceeding. In any such event the party making such disclosure shall (i) provide the other party with as much advance notice as reasonably practicable of the required disclosure, (ii) cooperate with the other party in any reasonable attempt to prevent or limit the disclosure, and (iii) limit any disclosure to the specific purpose at issue. In furtherance of the foregoing, the parties acknowledge that Vanda will be permitted pursuant to the rules and regulations promulgated under the Exchange Act to file a Current Report on Form 8-K disclosing the entry into this Agreement by Vanda and a description of the terms and conditions hereof and thereof. In connection with any filing of a copy of this Agreement with the Securities and Exchange Commission, the filing party shall endeavor to obtain confidential treatment of economic and trade secret information, and shall keep the other party informed as to the planned filing (including, but not limited to providing the other party with the proposed filing reasonably in advance of making the planned filing) and consider the reasonable requests of the other party regarding such confidential treatment. For avoidance of doubt, any information that has been publicly disclosed in accordance with this Section shall no longer be deemed Confidential Information.

6. REPRESENTATIONS AND WARRANTIES.

6.1 Representations. Each party hereby represents and warrants as of the Effective Date to the other party that (a) the person executing this Agreement is authorized to execute this Agreement; (b) this Agreement is legal and valid and the obligations binding upon such party are enforceable by their terms; and (c) the execution, delivery and performance of this Agreement does not conflict with any agreement, instrument or understanding, oral or written, to which such party may be bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

6.2 Disclaimer of Warranties. Except as explicitly set forth herein, neither party makes any warranty, written, oral, express or implied, with respect to this Agreement. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT HEREBY ARE DISCLAIMED BY BOTH PARTIES.

6.3 Limitation of Liability. WITH THE EXCEPTION OF DAMAGES RESULTING FROM A PARTY'S BREACH OF ITS CONFIDENTIALITY OBLIGATIONS UNDER THIS AGREEMENT OR ITS OBLIGATIONS UNDER SECTION 7 (INDEMNIFICATION), OR A BREACH BY MSN OR IMPAX OF SECTION 2, UNDER NO CIRCUMSTANCES SHALL EITHER PARTY BE LIABLE FOR LOSS OF USE OR PROFITS OR OTHER COLLATERAL, SPECIAL, CONSEQUENTIAL, INCIDENTAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT, WHETHER SUCH CLAIMS ARE FOUNDED IN TORT OR CONTRACT.

6.4 Equitable Relief Against MSN and Impax. MSN and Impax acknowledge and agree that the obligations and undertakings of MSN and Impax pursuant to Section 2 of this Agreement are reasonable and necessary to protect the legitimate interests of Vanda, that Vanda would not have entered into this Agreement in the absence of such provisions, and that MSN or Impax's material breach or threatened breach or failure to comply with Section 2 shall cause Vanda significant and irreparable harm, the amount of which shall be extremely difficult to estimate and ascertain, and for which money damages shall not be adequate. MSN and Impax further acknowledge and agree that Vanda shall have the right to apply to any court of competent jurisdiction for an injunction order restraining any material breach or threatened breach of Section 2 of this Agreement and specifically enforcing the terms and provisions of such Sections of this Agreement. MSN and Impax agree that neither of them shall challenge any of the foregoing acknowledgements and agreements in this Section concerning injunctive relief in any proceeding brought by Vanda.

7. INDEMNIFICATION.

7.1 MSN and Impax shall indemnify, defend and hold harmless Vanda, its directors, managers, members, officers, employees, authorized subcontractors and agents (collectively the "**Vanda Indemnified Parties**") from and against any and all liabilities, losses, damages, costs and expenses (including, without limitation, reasonable attorney's fees and costs) (collectively, **"Losses"**) incurred as a result of any claims, demands, actions or other proceedings by a [***] against a Vanda Indemnified Party, [***]. MSN and Impax's obligation to indemnify Vanda Indemnified Parties shall exclude any claim asserted by any [***].

7.2 A Vanda Indemnified Party that intends to claim indemnification under this Section 7 shall promptly notify MSN or Impax, as the case may be, in writing of any claim, demand, action, or other proceeding in respect of which the Vanda Indemnified Party intends to claim such indemnification; provided, however, that failure to provide such notice within a reasonable period of time shall not relieve MSN or Impax of any of its obligations hereunder except to the extent MSN or Impax is prejudiced by such failure. The Vanda Indemnified Party shall permit MSN or Impax, at its discretion, to settle any such action, claim or other matter. Notwithstanding the foregoing, MSN or Impax shall not enter into any settlement that would adversely affect the Vanda Indemnified Party's rights hereunder, or impose any obligations on the Vanda Indemnified Party in addition to those set forth herein, in order for it to exercise such

rights, without the Vanda Indemnified Party's prior written consent, which shall not be unreasonably withheld or delayed. No such action, claim or other matter shall be settled without the prior written consent of MSN or Impax, which shall not be unreasonably withheld or delayed. The Vanda Indemnified Party shall reasonably cooperate with MSN or Impax and its legal representatives in the investigation and defense of any claim, demand, action, or other proceeding covered by the indemnification obligations of this Section 7. The Vanda Indemnified Party shall have the right, but not the obligation, to be represented in such defense by counsel of its own selection at its own expense.

7.3 Vanda shall indemnify, defend and hold harmless MSN, Impax, their Affiliates, directors, managers, members, officers, employees, authorized subcontractors and agents (collectively the "MSN/Impax Indemnified Parties") from and against any and all Losses (as defined above) incurred as a result of any claims, demands, actions or other proceedings by a [***] against an MSN/Impax Indemnified Party, [***]. Vanda's obligation to indemnify MSN/Impax Indemnified Parties shall exclude any claim asserted by any [***].

7.4 An MSN/Impax Indemnified Party that intends to claim indemnification under this Section 7 shall promptly notify Vanda in writing of any claim, demand, action, or other proceeding in respect of which the MSN/Impax Indemnified Party intends to claim such indemnification; provided, however, that failure to provide such notice within a reasonable period of time shall not relieve Vanda of any of its obligations hereunder except to the extent Vanda is prejudiced by such failure. The MSN/Impax Indemnified Party shall permit Vanda, at its discretion, to settle any such action, claim or other matter. Notwithstanding the foregoing, Vanda shall not enter into any settlement that would adversely affect the MSN/Impax Indemnified Party's rights hereunder, or impose any obligations on the MSN/Impax Indemnified Party in addition to those set forth herein, in order for it to exercise such rights, without the MSN/Impax Indemnified Party's prior written consent, which shall not be unreasonably withheld or delayed. No such action, claim or other matter shall be settled without the prior written consent of Vanda, which shall not be unreasonably withheld or delayed. The MSN/Impax Indemnified Party shall reasonably cooperate with Vanda and its legal representatives in the investigation and defense of any claim, demand, action, or other proceeding covered by the indemnification obligations of this Section 7. The MSN/Impax Indemnified Party shall have the right, but not the obligation, to be represented in such defense by counsel of its own selection at its own expense.

8. GENERAL PROVISIONS.

8.1 Notices. All notices hereunder shall be delivered by overnight delivery with a reputable overnight delivery service, to the following address of the respective parties:

If to Vanda: Vanda Pharmaceutical Corporation
2200 Pennsylvania Avenue, N.W.
Washington, DC 20037
Attn: Chief Executive Officer

with a copy to: Vanda Pharmaceutical Corporation
2200 Pennsylvania Avenue, N.W.
Washington, DC 20037
Attn: General Counsel

If to MSN: MSN Pharmaceuticals Inc.
Attn: Kondal Reddy
20 Duke Rd
Piscataway, NJ 08854

If to Impax: Impax Laboratories LLC
Attn: General Counsel
400 Crossing Blvd.
Bridgewater, NJ 08807

Notices shall be effective on the day of receipt. A party may change its address listed above by notice to the other party given in accordance with this Section 8.1.

8.2 Entire Agreement. The parties hereto acknowledge that this Agreement sets forth the entire agreement and understanding of the parties and supersede all prior written or oral agreements or understandings with respect to the subject matter hereof. No modification of any of the terms of this Agreement, or any amendments thereto, shall be deemed to be valid unless in writing and signed by an authorized agent or representative of both parties hereto. No course of dealing or usage of trade shall be used to modify the terms and conditions herein. This Agreement shall be binding on each of MSN, Impax and Vanda and their respective permitted successors and assigns.

8.3 Waiver. None of the provisions of this Agreement shall be considered waived by any party hereto unless such waiver is agreed to, in writing, by authorized agents of such party. The failure of a party to insist upon strict conformance to any of the terms and conditions hereof, or failure or delay to exercise any rights provided herein or by law shall not be deemed a waiver of any rights of any party hereto.

8.4 Obligations to Third Parties. Each party warrants and represents that this Agreement does not conflict with any contractual obligations, expressed or implied, undertaken with any Third Party.

8.5 Assignment. Neither party shall assign this Agreement or any part hereof or any interest herein (whether by operation of law or otherwise) to any Third Party (or use any subcontractor) without the written approval of the other party, which shall not be unreasonably withheld, conditioned, or delayed; provided, however, that either party may assign this Agreement without such consent (i) to any Affiliate; and (ii) in the case of a merger, consolidation, change in control or sale of all or substantially all of the assets related to this Agreement, provided further that with respect to MSN or Impax, any such Affiliate or Third Party agrees to be bound by the terms and conditions of this Agreement. No assignment shall be valid unless the permitted assignee(s) assumes all obligations of its assignor under this Agreement. No assignment shall relieve any party of responsibility for the performance of its obligations hereunder. Any purported assignment in violation of this Section 8.5 shall be void.

8.6 Governing Law. Any action brought regarding the validity, construction or enforcement of this Agreement shall be governed in all respects by the laws of the State of Delaware, without regard to the principles of conflicts of laws. The federal and state courts in the State of Delaware shall have exclusive jurisdiction over the parties hereto in all such actions, and each party irrevocably consents to the personal jurisdiction of those courts and agrees not to challenge the venue of such courts or to seek to transfer any such action to any other forum.

8.7 Severability. If any term or provision of this Agreement shall for any reason be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other term or provision hereof, and this Agreement shall be interpreted and construed as if such term or provision, to the extent the same shall have been held to be invalid, illegal or unenforceable, had never been contained herein.

8.8 Headings, Interpretation. The headings used in this Agreement are for convenience only and are not part of this Agreement.

8.9 Counterparts. The Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[Remainder of this page intentionally blank]

IN WITNESS WHEREOF, the parties hereto have each caused this Agreement to be executed by their duly-authorized representatives effective as of the Effective Date.

VANDA PHARMACEUTICALS INC.

By: /s/ Mihael H. Polymeropoulos
Name: Mihael H. Polymeropoulos, M.D.
Title: President and Chief Executive Officer

MSN PHARMACEUTICALS INC.

By: /s/ Kondal Reddy Bairy
Name: Kondal Reddy Bairy
Title: Senior Director

MSN LABORATORIES PRIVATE LIMITED

By: [/s/ Srinivasan Thirumalai Rajan]
Name: Srinivasan Thirumalai Rajan
Title: Head IPM & Technical

IMPAX LABORATORIES LLC

By: /s/ Andrew S. Boyer
Name: Andrew S. Boyer
Title: EVP, CCO – Generics

EXHIBIT A

Hetlioz Products

PRODUCT
[***]

EXHIBIT B

Patent Rights

U.S. Patent No. RE46,604
U.S. Patent No. 9,060,995
U.S. Patent No. 9,539,234
U.S. Patent No. 9,549,913
U.S. Patent No. 9,730,910
U.S. Patent No. 9,855,241
U.S. Patent No. 10,071,977
U.S. Patent No. 10,149,829
U.S. Patent No. 10,376,487
U.S. Patent No. 10,449,176
U.S. Patent No. 10,610,510
U.S. Patent No. 10,610,511
U.S. Patent No. 10,829,465
U.S. Patent No. 10,611,744

Any patents issuing to or assigned to Vanda that claim priority to any of the applications for the patents listed above.

EXHIBIT C

Consent Judgement

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS INC., Plaintiff, v. MSN PHARMACEUTICALS INC. ET AL., Defendants.	)))))))))	C.A. No. 18-690 (CFC) CONSOLIDATED

STIPULATION FOR ENTRY OF CONSENT JUDGMENT AND PERMANENT INJUNCTION AS TO MSN PHARMACEUTICALS INC. AND MSN LABORATORIES PRIVATE LIMITED.

Plaintiff Vanda Pharmaceuticals Inc. and Defendants MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited. having met, conferred, and agreed to resolve their dispute upon execution of a separate License Agreement, hereby stipulate to entry of the executed Consent Judgment and Permanent Injunction submitted herewith, subject to the Court's approval.

Morris, Nichols, Arsht &
Tunnell LLP

_____

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MSN Laboratories Private Limited.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS INC., Plaintiff, v. MSN PHARMACEUTICALS INC. ET AL., Defendants.	)	C.A. No. 18-690 (CFC) CONSOLIDATED

CONSENT JUDGMENT AND PERMANENT INJUNCTION
AS TO MSN PHARMACEUTICALS INC. AND MSN LABORATORIES PRIVATE LIMITED.

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This matter is before the Court on the unopposed motion of Plaintiff Vanda Pharmaceuticals Inc. ("Vanda") and Defendants MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited. (together, "MSN").

WHEREAS, Vanda owns U.S. Patent Nos. RE46,604, 9,060,995, 9,539,234, 9,549,913, 9,730,910, 9,855,241, 10,149,829, 10,071,977, 10,376,487, 10,449,176, 10,610,510, 10,610,511, 10,829,465, and 10,611,744 ("the asserted patents").

WHEREAS, MSN submitted Abbreviated New Drug Application No. 211654 ("MSN's ANDA") to the FDA under 21 U.S.C. § 355(j) seeking to obtain approval to commercially manufacture and sell generic tasimelteon for the treatment of Non-24-Hour Sleep-Wake Disorder.

WHEREAS, in this Action, Vanda alleges that MSN infringed one or more of claims 1-3 and 6-8 of U.S. Patent No. RE46,604, claim 1 of U.S. Patent No. 9,060,995, claims 1-5 of U.S. Patent No. 9,539,234, claims 1-6 and 11-14 of U.S. Patent No. 9,549,913, claims 1-5

of U.S. Patent No. 9,730,910, claims 1-6 and 9 of U.S. Patent No. 9,855,241, claims 1-14 of U.S. Patent No. 10,149,829, claims 1-4 and 13-22 and 24 of U.S. Patent No. 10,071,977, claims 1-2 and 4-7 and 9-20 of U.S. Patent No. 10,376,487, claims 1-9 of U.S. Patent No. 10,449,176, claims 1-13 of U.S. Patent No. 10,610,510, claims 1-2 and 4-19 of U.S. Patent No. 10,610,511, claims 1 and 3-20 of U.S. Patent No. 10,829,465, and claims 1-2 and 4-9 of U.S. Patent No. 10,611,744 under 35 U.S.C. § 271(e)(2) by virtue of MSN's submission of MSN's ANDA to the FDA.

WHEREAS, in this Action, Vanda alleges that it would be irreparably harmed if MSN were not enjoined from infringing or actively inducing or contributing to infringement of one or more of claims 1-3 and 6-8 of U.S. Patent No. RE46,604, claim 1 of U.S. Patent No. 9,060,995, claims 1-5 of U.S. Patent No. 9,539,234, claims 1-6 and 11-14 of U.S. Patent No. 9,549,913, claims 1-5 of U.S. Patent No. 9,730,910, claims 1-6 and 9 of U.S. Patent No. 9,855,241, claims 1-14 of U.S. Patent No. 10,149,829, claims 1-4 and 13-22 and 24 of U.S. Patent No. 10,071,977, claims 1-2 and 4-7 and 9-20 of U.S. Patent No. 10,376,487, claims 1-9 of U.S. Patent No. 10,449,176, claims 1-13 of U.S. Patent No. 10,610,510, claims 1-2 and 4-19 of U.S. Patent No. 10,610,511, claims 1 and 3-20 of U.S. Patent No. 10,829,465, and claims 1-2 and 4-9 of U.S. Patent No. 10,611,744.

WHEREAS, in this Action, Vanda requested that this Court enter a permanent injunction enjoining MSN from infringing the asserted patents.

WHEREAS, in this Action, MSN has denied that the asserted patents are valid, enforceable, and infringed by the product described in MSN's ANDA.

WHEREAS, Vanda and MSN have reached an agreement to finally settle the Litigation as set forth in this Consent Judgment and Permanent Injunction as to MSN and a

separate License Agreement ("License Agreement") which is contemporaneously and separately being executed.

WHEREAS, final settlement of this Action will help Vanda and MSN avoid the substantial uncertainty and risks involved with prolonged litigation.

WHEREAS, final settlement of this Action will permit Vanda and MSN to save litigation costs, as well as adhere to the judicially recognized mandate that encourages the settlement of litigation whenever possible.

WHEREAS, final settlement of the Action serves the public interest by saving judicial resources and avoiding the risks to each of Vanda and MSN associated with infringement.

WHEREAS, Vanda and MSN each consent to personal jurisdiction in Delaware for purposes of enforcing the License Agreement.

IT IS HEREBY ORDERED, DECREED, and ADJUDGED as follows:

1. The Court has jurisdiction over Vanda and MSN and the subject matter of this litigation.

2. MSN acknowledges Vanda's ownership and standing to sue for infringement of the asserted patents.

3. MSN acknowledges that the asserted patents are valid and enforceable, as described more fully and subject to the restrictions contained in the License Agreement.

4. MSN acknowledges that it has infringed the asserted patents under 35 U.S.C. § 271(e)(2) and that Vanda did not authorize the manufacture, use, sale, offer for sale, importation and distribution of the product described in MSN's ANDA.

5. MSN and its successors, assigns, and affiliates, and partners or joint-venturers with are permanently enjoined as of the date hereof from infringing the asserted patents by the commercial manufacture, use, offer to sell, sale, importation, or distribution of any generic tasimelteon products that are the subject of MSN's ANDA that is not pursuant to a license granted by Vanda or otherwise exempt from infringement under 35 U.S.C. § 271(e)(1), and from inducing others to infringe or contributing to the infringement of the asserted patents by inducing others to manufacture, use, offer to sell, sale, import, or distribute or contributing to others' manufacture, use, offer for sale, sale, importation, or distribution of any generic tasimelteon products that are the subject of MSN's ANDA that is not pursuant to a license granted by Vanda or otherwise exempt from infringement under 35 U.S.C. § 271(e)(1).

6. All claims in this Action are hereby dismissed without prejudice.

7. Each party shall bear its own costs and attorneys' fees.

8. This Court shall retain jurisdiction over MSN and Vanda for the purpose of enforcing the terms of this Consent Judgment and Permanent Injunction and over any matters related to or arising from the interpretation or enforcement of the License Agreement or any legal or equitable claim concerning the License Agreement by any third party.

IT IS SO ORDERED, DECREED AND ADJUDGED this _____ day of ____, 2022 by:

_____
The Honorable Colm F. Connolly
United States District Judge

Agreed to:

Morris, Nichols, Arsht & Tunnell LLP

_____

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Attorneys for Defendants MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited.

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.

May 6, 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.

May 6, 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 March 31, 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.

May 6, 2022

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

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

May 6, 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.