
**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, 2020
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
(State or other jurisdiction of
incorporation or organization)

03-0491827
(I.R.S. Employer
Identification No.)

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

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

<u>Title of Each Class</u>	<u>Trading Symbol</u>	<u>Name of Exchange on Which Registered</u>
Common Stock, par value \$0.001 per share	VNDA	The Nasdaq Global Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of April 30, 2020, there were 54,550,461 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, 2020

Table of Contents

	<u>Page</u>
<u>PART I – FINANCIAL INFORMATION</u>	
ITEM 1	Financial Statements (Unaudited)
	5
	Condensed Consolidated Balance Sheets as of March 31, 2020 and December 31, 2019
	5
	Condensed Consolidated Statements of Operations for the three months ended March 31, 2020 and 2019
	6
	Condensed Consolidated Statements of Comprehensive Income (Loss) for the three months ended March 31, 2020 and 2019
	7
	Condensed Consolidated Statement of Changes in Stockholders' Equity for the three months ended March 31, 2020 and 2019
	8
	Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2020 and 2019
	9
	Notes to the Condensed Consolidated Financial Statements
	10
ITEM 2	Management's Discussion and Analysis of Financial Condition and Results of Operations
	22
ITEM 3	Quantitative and Qualitative Disclosures about Market Risk
	30
ITEM 4	Controls and Procedures
	31
<u>PART II – OTHER INFORMATION</u>	
ITEM 1	Legal Proceedings
	31
ITEM 1A	Risk Factors
	34
ITEM 2	Unregistered Sales of Equity Securities and Use of Proceeds
	35
ITEM 3	Defaults Upon Senior Securities
	35
ITEM 4	Mine Safety Disclosures
	35
ITEM 5	Other Information
	35
ITEM 6	Exhibits
	37
	Signatures
	38

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q 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 that involve risks, changes in circumstances, assumptions and uncertainties. The forward-looking statements in this quarterly report on Form 10-Q may include, among other things, statements about:

- the ability of Vanda Pharmaceuticals Inc. (we, our, the Company or Vanda) to continue to commercialize HETLIOZ[®] (tasimelteon) for the treatment of Non-24-hour Sleep-Wake Disorder (Non-24) in the United States (U.S.) and Europe;
- our ability to increase market awareness of Non-24 and the market acceptance of HETLIOZ[®];
- our ability to continue to generate U.S. sales of Fanapt[®] (iloperidone) for the treatment of schizophrenia;
- the impact of the novel coronavirus (COVID-19) on our business and operations, including our revenues, our supply chain, our commercial activities, our ongoing and planned clinical trials and our regulatory activities;
- our dependence on third-party manufacturers to manufacture HETLIOZ[®] and Fanapt[®] in sufficient quantities and quality;
- our level of success in commercializing HETLIOZ[®] and Fanapt[®] in new markets;
- our ability to reach agreement with the U.S. Food and Drug Administration (FDA) regarding our regulatory approval strategy, preclinical animal testing requirements or proposed path to approval for tradipitant;
- 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 approval from the FDA for HETLIOZ[®] for the treatment of jet lag disorder;
- the ability to obtain and maintain regulatory approval of our products, and the labeling for any approved products;
- our expectations regarding the timing and success of preclinical studies and clinical trials;
- the ability of our products to be demonstrably safe and effective;
- 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 the ability to serve those markets;
- our expectations regarding trends with respect to our revenues, costs, expenses, liabilities and cash, cash equivalents and marketable securities;
- the scope, progress, expansion and costs of developing and commercializing our products;
- 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;
- regulatory developments in the United States (U.S.), Europe and other jurisdictions;
- 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 investors not to rely too heavily on the forward-looking statements we make or that are made on our behalf. 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 on Form 10-Q. In addition to the risks described below and in Item 1A of Part I of our annual report on Form 10-K for the fiscal year ended December 31, 2019, 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)

<i>(in thousands, except for share and per share amounts)</i>	March 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 64,950	\$ 45,072
Marketable securities	247,376	267,057
Accounts receivable, net	29,272	26,367
Inventory	1,320	1,140
Prepaid expenses and other current assets	17,828	14,500
Total current assets	360,746	354,136
Property and equipment, net	3,877	3,864
Operating lease right-of-use assets	10,875	11,180
Intangible assets, net	22,667	23,037
Deferred tax assets	86,641	87,680
Non-current inventory and other	3,719	3,851
Total assets	\$ 488,525	\$ 483,748
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 26,045	\$ 27,590
Product revenue allowances	33,177	31,915
Total current liabilities	59,222	59,505
Operating lease non-current liabilities	12,139	12,455
Other non-current liabilities	778	843
Total liabilities	72,139	72,803
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, 2020 and December 31, 2019	—	—
Common stock, \$0.001 par value; 150,000,000 shares authorized; 54,132,336 and 53,549,612 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	54	54
Additional paid-in capital	635,730	631,307
Accumulated other comprehensive income	781	249
Accumulated deficit	(220,179)	(220,665)
Total stockholders' equity	416,386	410,945
Total liabilities and stockholders' equity	\$ 488,525	\$ 483,748

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

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

<i>(in thousands, except for share and per share amounts)</i>	Three Months Ended	
	March 31, 2020	March 31, 2019
Revenues:		
Net product sales	\$ 58,000	\$ 47,713
Total revenues	58,000	47,713
Operating expenses:		
Cost of goods sold excluding amortization	5,207	5,113
Research and development	15,527	13,278
Selling, general and administrative	37,021	31,029
Intangible asset amortization	370	380
Total operating expenses	58,125	49,800
Loss from operations	(125)	(2,087)
Other income	1,366	1,485
Income (loss) before income taxes	1,241	(602)
Provision for income taxes	755	10
Net income (loss)	\$ 486	\$ (612)
Net income (loss) per share:		
Basic	\$ 0.01	\$ (0.01)
Diluted	\$ 0.01	\$ (0.01)
Weighted average shares outstanding:		
Basic	53,806,317	52,752,774
Diluted	54,870,146	52,752,774

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)

<i>(in thousands)</i>	Three Months Ended	
	March 31, 2020	March 31, 2019
Net income (loss)	\$ 486	\$ (612)
Other comprehensive income (loss):		
Net foreign currency translation loss	(13)	(4)
Change in net unrealized gain on marketable securities	705	138
Tax provision on other comprehensive income (loss)	(160)	—
Other comprehensive income, net of tax	532	134
Comprehensive income (loss)	\$ 1,018	\$ (478)

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)

<i>(in thousands, except for share amounts)</i>	Common Stock		Additional Paid-in Capital	Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Par Value				
Balances at December 31, 2019	53,549,612	\$ 54	\$ 631,307	\$ 249	\$ (220,665)	\$ 410,945
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	582,724	—	479	—	—	479
Stock-based compensation expense	—	—	3,944	—	—	3,944
Net income	—	—	—	—	486	486
Other comprehensive income, net of tax	—	—	—	532	—	532
Balances at March 31, 2020	54,132,336	54	635,730	781	(220,179)	416,386
<i>(in thousands, except for share amounts)</i>	Common Stock		Additional Paid-in Capital	Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Par Value				
Balances at December 31, 2018	52,477,593	\$ 52	\$ 611,587	\$ 1	\$ (336,218)	\$ 275,422
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	485,083	1	178	—	—	179
Stock-based compensation expense	—	—	3,282	—	—	3,282
Net loss	—	—	—	—	(612)	(612)
Other comprehensive income, net of tax	—	—	—	134	—	134
Balances at March 31, 2019	52,962,676	53	615,047	135	(336,830)	278,405

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

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

<i>(in thousands)</i>	Three Months Ended	
	March 31, 2020	March 31, 2019
Cash flows from operating activities		
Net income (loss)	\$ 486	\$ (612)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation of property and equipment	351	332
Stock-based compensation	3,944	3,282
Amortization of discounts and premiums on marketable securities	(287)	(906)
Intangible asset amortization	370	380
Deferred income taxes	879	—
Other non-cash adjustments, net	314	317
Changes in operating assets and liabilities:		
Accounts receivable	(2,905)	2,434
Prepaid expenses and other assets	(3,524)	247
Inventory	76	(44)
Accounts payable and other liabilities	(1,795)	3,507
Product revenue allowances	1,184	706
Net cash provided by (used in) operating activities	(907)	9,643
Cash flows from investing activities		
Purchases of property and equipment	(373)	(393)
Purchases of marketable securities	(41,400)	(100,803)
Maturities of marketable securities	62,073	64,745
Net cash provided by (used in) investing activities	20,300	(36,451)
Cash flows from financing activities		
Proceeds from the exercise of stock options	479	179
Net cash provided by financing activities	479	179
Effect of exchange rate changes on cash, cash equivalents and restricted cash	5	2
Net change in cash, cash equivalents and restricted cash	19,877	(26,627)
Cash, cash equivalents and restricted cash		
Beginning of period	45,650	61,749
End of period	\$ 65,527	\$ 35,122

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 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. 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 Fanapt[®] for the treatment of schizophrenia. HETLIOZ[®] is the first treatment for Non-24 approved by the U.S. Food and Drug Administration (FDA). In addition, the Company has a number of drugs in development, including:

- HETLIOZ[®] (tasimelteon) for the treatment of jet lag disorder (JLD), Smith-Magenis Syndrome (SMS), pediatric Non-24 and delayed sleep phase disorder (DSPD);
- Fanapt[®] (iloperidone) for the treatment of bipolar disorder and a long acting injectable (LAI) formulation program for the treatment of schizophrenia;
- Tradipitant (VLY-686), a small molecule neurokinin-1 receptor (NK-1R) antagonist, for the treatment of atopic dermatitis, gastroparesis, motion sickness and COVID-19 Acute Respiratory Distress Syndrome (ARDS);
- 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;
- VQW-765, a small molecule nicotinic acetylcholine receptor partial agonist, with potential use for the treatment of psychiatric disorders; and
- Portfolio of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) activators and inhibitors for the treatment of dry eye and ocular inflammation and for the treatment of secretory diarrhea disorders, including cholera.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. 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, 2019. The financial information as of March 31, 2020 and for the three months ended March 31, 2020 and 2019 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, 2019 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:

<i>(in thousands)</i>	March 31, 2020	March 31, 2019
Cash and cash equivalents	\$ 64,950	\$ 34,379
Restricted cash included in:		
Prepaid expenses and other current assets	—	157
Non-current inventory and other	577	586
Total cash, cash equivalents and restricted cash	<u>\$ 65,527</u>	<u>\$ 35,122</u>

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, 2020 and 2019 were as follows:

<i>(in thousands)</i>	Three Months Ended	
	March 31, 2020	March 31, 2019
HETLIOZ [®] product sales, net	\$ 35,336	\$ 28,957
Fanapt [®] product sales, net	22,664	18,756
Total net product sales	<u>\$ 58,000</u>	<u>\$ 47,713</u>

Major Customers

HETLIOZ[®] is available in the U.S. for distribution through a limited number of specialty pharmacies, and is not available in retail pharmacies. Fanapt[®] is available in the U.S. for distribution through a limited number of wholesalers and is available in retail pharmacies. The Company invoices and records revenue when its customers, specialty pharmacies and wholesalers, receive product from the third-party logistics warehouse which is the point at which control is transferred to the customer. There were five major customers that each accounted for more than 10% of total revenues and, as a group, represented 96% of total revenues for the three months ended March 31, 2020. There were five major customers that each accounted for more than 10% of accounts receivable and, as a group, represented 94% of total accounts receivable at March 31, 2020. Receivables are carried at transaction price net of allowance for credit losses. Allowance for credit losses is measured using historical loss rates based on the aging of receivables and incorporating current conditions and forward-looking estimates.

Recent Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2019-12, Income Taxes (Topic 740), *Simplifying the Accounting for Income Taxes*, which clarifies and simplifies certain aspects of the accounting for income taxes. The standard is effective for years beginning after December 15, 2020, and interim periods within annual periods beginning after December 15, 2020. The Company is evaluating this standard to determine if adoption will have a material impact on the Company's condensed consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses*, which changes the impairment model for most financial assets and certain other financial instruments. The standard requires the use of a forward-looking "expected loss" model for instruments measured at amortized cost that generally will result in the earlier recognition of allowances for losses. The standard is effective for years beginning after December 15, 2019, and interim periods within annual periods beginning after December 15, 2019. The adoption of this standard on January 1, 2020 did not have a material impact on the Company's condensed consolidated financial results.

3. Marketable Securities

The following is a summary of the Company's available-for-sale marketable securities as of March 31, 2020, which all have contractual maturities of less than two years:

<i>(in thousands)</i>	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
U.S. Treasury and government agencies	\$ 87,014	\$ 558	\$ —	\$ 87,572
Corporate debt	122,964	572	(110)	123,426
Asset-backed securities	36,386	56	(64)	36,378
Total marketable securities	<u>\$ 246,364</u>	<u>\$ 1,186</u>	<u>\$ (174)</u>	<u>\$ 247,376</u>

The following is a summary of the Company's available-for-sale marketable securities as of December 31, 2019, which all have contractual maturities of less than two years:

<i>(in thousands)</i>	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
U.S. Treasury and government agencies	\$ 88,535	\$ 68	\$ (2)	\$ 88,601
Corporate debt	129,860	196	(1)	130,055
Asset-backed securities	48,355	49	(3)	48,401
Total marketable securities	<u>\$ 266,750</u>	<u>\$ 313</u>	<u>\$ (6)</u>	<u>\$ 267,057</u>

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

Marketable securities classified in Level 1 and Level 2 as of March 31, 2020 and December 31, 2019 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 investments classified in Level 2 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.

As of March 31, 2020, the Company held certain assets that are required to be measured at fair value on a recurring basis, as follows:

<i>(in thousands)</i>	Total Fair Value	Fair Value Measurement as of March 31, 2020 Using		
		Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs
		(Level 1)	(Level 2)	(Level 3)
U.S. Treasury and government agencies	\$ 87,572	\$ 87,572	\$ —	\$ —
Corporate debt	123,426	—	123,426	—
Asset-backed securities	36,378	—	36,378	—
Total assets measured at fair value	<u>\$ 247,376</u>	<u>\$ 87,572</u>	<u>\$ 159,804</u>	<u>\$ —</u>

As of December 31, 2019, the Company held certain assets that are required to be measured at fair value on a recurring basis, as follows:

<i>(in thousands)</i>	Total Fair Value	Fair Value Measurement as of December 31, 2019 Using		
		Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs
		(Level 1)	(Level 2)	(Level 3)
U.S. Treasury and government agencies	\$ 88,601	\$ 88,601	\$ —	\$ —
Corporate debt	137,025	—	137,025	—
Asset-backed securities	48,401	—	48,401	—
Total assets measured at fair value	\$ 274,027	\$ 88,601	\$ 185,426	\$ —

Total assets measured at fair value as of December 31, 2019 include \$7.0 million of 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, product revenue allowances and milestone obligations under license agreements, the carrying values of which materially approximate their fair values.

5. Inventory

The Company evaluates expiry risk by evaluating current and future product demand relative to product shelf life. The Company builds demand forecasts by considering factors such as, but not limited to, overall market potential, market share, market acceptance and patient usage. Inventory levels are evaluated for the amount of inventory that would be sold within one year. At certain times, the level of inventory can exceed the forecasted level of cost of goods sold for the next twelve months. The Company classifies the estimate of such inventory as non-current.

Inventory consisted of the following as of March 31, 2020 and December 31, 2019:

<i>(in thousands)</i>	March 31, 2020	December 31, 2019
Current assets		
Finished goods	\$ 1,320	\$ 1,140
Total inventory, current	\$ 1,320	\$ 1,140
Non-Current assets		
Raw materials	\$ 659	\$ 659
Work-in-process	949	1,109
Finished goods	934	1,056
Total inventory, non-current	2,542	2,824
Total inventory	\$ 3,862	\$ 3,964

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, the latest of which expires in July 2035.

In April 2018, the Company met its final milestone under its license agreement 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 latest of which expires in July 2035.

The estimated economic useful life of both the \$8.0 million and the \$25.0 million intangible assets were changed from February 2035 to July 2035 based on the July 2035 expiration date of U.S. patent number 10,376,487 ('487 Patent) issued by the U.S. Patent and Trademark Office in August 2019.

The following is a summary of the Company's intangible assets as of March 31, 2020:

<i>(in thousands)</i>	Estimated Useful Life (Years)	March 31, 2020		
		Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	July 2035	\$ 33,000	\$ 10,333	\$ 22,667

The following is a summary of the Company's intangible assets as of December 31, 2019:

<i>(in thousands)</i>	Estimated Useful Life (Years)	December 31, 2019		
		Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	July 2035	\$ 33,000	\$ 9,963	\$ 23,037

As of March 31, 2020 and December 31, 2019, 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, 2020 and 2019. The following is a summary of the future intangible asset amortization schedule as of March 31, 2020:

<i>(in thousands)</i>	Total	2020	2021	2022	2023	2024	Thereafter
HETLIOZ®	\$ 22,667	\$ 1,108	\$ 1,478	\$ 1,478	\$ 1,478	\$ 1,478	\$ 15,647

7. Accounts Payable and Accrued Liabilities

The following is a summary of the Company's accounts payable and accrued liabilities as of March 31, 2020 and December 31, 2019:

<i>(in thousands)</i>	March 31, 2020	December 31, 2019
Consulting and other professional fees	\$ 7,636	\$ 5,376
Research and development expenses	5,839	5,893
Royalties payable	4,912	5,904
Compensation and employee benefits	3,762	6,597
Operating lease liabilities	2,101	2,147
Other	1,795	1,673
Total accounts payable and accrued liabilities	\$ 26,045	\$ 27,590

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, 2020, 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). The Company has no remaining milestone obligations to BMS. Additionally, the Company is obligated to make royalty payments on HETLIOZ® net sales to BMS in any territory where the Company commercializes HETLIOZ® for a period equal to the greater of 10 years following the first commercial sale in the territory or the expiry of the new chemical entity (NCE) patent in that territory. During the period prior to the expiry of the NCE patent in a territory, the Company is obligated to pay a 10% royalty on net sales in that territory. The royalty rate is decreased by half for countries in which no NCE patent existed or for the remainder of the 10 years after the expiry of the NCE patent. 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 has agreed with BMS in the license agreement for HETLIOZ® to use its commercially reasonable efforts to develop and commercialize HETLIOZ®.

Fanapt®. Pursuant to the terms of a settlement agreement with 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-1R 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, 2020, the Company has paid Lilly \$3.0 million in upfront fees and development milestones, including a \$2.0 million milestone payment in July 2018 as a result of enrolling the first subject into a Phase III study for tradipitant. As of March 31, 2020, 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.

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.

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, 2020, the Company has paid UCSF \$1.2 million in upfront fees and development milestones, including an upfront license fee payment of \$1.0 million in 2017 and a \$0.2 million development milestone payment in March 2019. As of

March 31, 2020, remaining milestone obligations include \$12.2 million for development milestones and \$33.0 million for future regulatory approval and sales milestones. Included in the \$12.2 million in development milestones is a \$350,000 milestone due upon the conclusion of a Phase I study for each licensed product but not to exceed \$1.1 million in total for the CFTR portfolio.

Purchase Commitments

In the course of its business, the Company regularly enters into agreements with clinical organizations to provide services relating to clinical development and clinical manufacturing activities under fee service arrangements. The Company's current agreements for clinical, marketing, and other services may be terminated on generally 90 days' notice without incurring additional charges, other than charges for work completed 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. Noncancellable long-term contractual cash obligations include noncancellable purchase commitments longer than one year and primarily relate to commitments for media and data services, of which \$3.2 million, \$1.0 million, and \$0.5 million are expected to be paid in 2020, 2021 and 2022, respectively.

9. Accumulated Other Comprehensive Income

The accumulated balances related to each component of other comprehensive income (loss), net of taxes, were as follows as of March 31, 2020 and December 31, 2019:

<i>(in thousands)</i>	March 31, 2020	December 31, 2019
Foreign currency translation	\$ —	\$ 13
Unrealized gain on marketable securities	781	236
Accumulated other comprehensive income	<u>\$ 781</u>	<u>\$ 249</u>

There were no reclassifications out of accumulated other comprehensive income for either of the three months ended March 31, 2020 or 2019.

10. Stock-Based Compensation

As of March 31, 2020, there were 6,335,548 shares that were 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 and RSUs 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 and restated twice to increase the number of shares reserved for issuance, among other administrative changes. Both amendments and restatements of the 2016 Plan were approved by the Company's stockholders. There are a total of 7,100,000 shares of common stock reserved for issuance under the 2016 Plan, 2,153,920 shares of which remained available for future grant as of March 31, 2020.

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 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 to executives and directors provide for accelerated vesting if there is a change in control of the Company. Certain service option awards to employees and executives provide for accelerated vesting if the respective employee's or executive's service is terminated by the Company for any reason other than cause or permanent disability.

As of March 31, 2020, \$9.1 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, 2020.

A summary of option activity under the Plans for the three months ended March 31, 2020 follows:

2006 and 2016 Plans (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, 2019	4,495,145	\$ 12.21	5.58	\$ 21,148
Granted	487,500	11.42		
Forfeited	(225,000)	18.83		
Expired	(10,104)	11.78		
Exercised	(172,500)	4.96		890
Outstanding at March 31, 2020	<u>4,575,041</u>	12.07	5.81	4,818
Exercisable at March 31, 2020	<u>3,379,139</u>	11.02	4.63	4,818
Vested and expected to vest at March 31, 2020	<u>4,340,916</u>	11.99	5.60	4,818

The weighted average grant-date fair value of options granted was \$5.73 and \$11.50 per share for the three months ended March 31, 2020 and 2019, respectively. Proceeds from the exercise of stock options amounted to \$0.5 million and \$0.2 million for the three months ended March 31, 2020 and 2019, respectively.

Restricted Stock Units

An RSU is a stock award that entitles the holder to receive shares of the Company's common stock as the award vests. The fair value of each RSU is based on the closing price of the Company's stock on the date of grant. The Company has granted RSUs under the Plans with service conditions (service RSUs) that vest in four equal annual installments provided that the employee remains employed with the Company. Annual service RSUs granted to directors vest on the first anniversary of the grant date.

As of March 31, 2020, \$25.9 million of unrecognized compensation costs related to unvested service RSUs are expected to be recognized over a weighted average period of 2.0 years. No RSUs are classified as a liability as of March 31, 2020.

A summary of RSU activity under the Plans for the three months ended March 31, 2020 follows:

2006 and 2016 Plans	Number of Shares Underlying RSUs	Weighted Average Grant Date Fair Value
Unvested at December 31, 2019	1,649,285	\$ 18.04
Granted	745,818	11.32
Forfeited	(136,091)	18.65
Vested	(498,505)	16.73
Unvested at March 31, 2020	<u>1,760,507</u>	15.52

The grant date fair value for the 498,505 shares underlying RSUs that vested during the three months ended March 31, 2020 was \$8.3 million.

Stock-Based Compensation Expense

Stock-based compensation expense recognized for the three months ended March 31, 2020 and 2019 was comprised of the following:

(in thousands)	Three Months Ended	
	March 31, 2020	March 31, 2019
Research and development	\$ 1,111	\$ 728
Selling, general and administrative	2,833	2,554
Total stock-based compensation expense	<u>\$ 3,944</u>	<u>\$ 3,282</u>

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 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, 2020 and 2019 were as follows:

	Three Months Ended	
	March 31, 2020	March 31, 2019
Expected dividend yield	0%	0%
Weighted average expected volatility	52%	58%
Weighted average expected term (years)	6.09	5.92
Weighted average risk-free rate	1.37%	2.51%

11. Income Taxes

For the three months ended March 31, 2020 and 2019, the Company recorded income tax expense of \$0.8 million and less than \$0.1 million, respectively. The income tax expense for the three months ended March 31, 2020 was primarily driven by the estimated effective tax rate for the year and the discrete impact of \$0.4 million of net shortfall tax expense related to stock-based compensation activity during the quarter. As a result of the tax valuation allowance against deferred tax assets in the U.S., there was no benefit for federal income taxes associated with the loss before taxes for the three months ended March 31, 2019. Income taxes were recorded related to certain U.S. state and foreign jurisdictions for the three months ended March 31, 2019.

The Company assesses the need for a valuation allowance against its deferred tax asset each quarter through the review of all available positive and negative evidence. Deferred tax assets are reduced by a tax valuation allowance when, in the opinion of management, it is more likely than not that some portion of the deferred tax assets will not be realized. The analysis depends on historical and projected taxable income. Projected taxable income includes significant assumptions related to revenue, commercial expenses and research and development activities. During the third quarter of 2019, after considering all available positive and negative evidence, including but not limited to cumulative income in recent periods, historical, current and future projected results and significant risks and uncertainties related to forecasts, the Company concluded that it was more likely than not that substantially all of its deferred tax assets in the U.S. are realizable in future periods. A valuation allowance was retained against certain U.S. federal tax attributes with short carryforward periods and District of Columbia state deferred tax assets as of March 31, 2020 and December 31, 2019.

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, 2020 and 2019:

<i>(in thousands, except for share and per share amounts)</i>	Three Months Ended	
	March 31, 2020	March 31, 2019
Numerator:		
Net income (loss)	\$ 486	\$ (612)
Denominator:		
Weighted average shares outstanding, basic	53,806,317	52,752,774
Effect of dilutive securities	1,063,829	—
Weighted average shares outstanding, diluted	54,870,146	52,752,774
Net income (loss) per share, basic and diluted:		
Basic	\$ 0.01	\$ (0.01)
Diluted	\$ 0.01	\$ (0.01)
Antidilutive securities excluded from calculations of diluted net income (loss) per share	3,095,224	3,068,806

The Company incurred a net loss for the three months ended March 31, 2019 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®. The Company has been involved in litigation with Roxane Laboratories, Inc. (Roxane) and its affiliates, West-Ward Pharmaceuticals International Limited and West-Ward Pharmaceuticals Corp (West-Ward), since the Company filed a lawsuit against Roxane in the U.S. District Court for the District of Delaware (Delaware District Court) for patent infringement in June 2014. The lawsuit was filed in response to Roxane's submission to the U.S. Food and Drug Administration (FDA) of an Abbreviated New Drug Application (ANDA) for a generic version 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). 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. In April 2018, following an appeal by Roxane of the Delaware District Court's decision to the Federal Circuit Court of Appeals (Federal Circuit), the Federal Circuit affirmed the Delaware District Court's ruling. In June 2018, West-Ward, having replaced Roxane as defendants following the acquisition of Roxane by West-Ward's parent company, Hikma Pharmaceuticals PLC, petitioned the Federal Circuit for a rehearing en banc. In August 2018, the Federal Circuit denied West-Ward's petition. In January 2019, West-Ward filed a petition in the U.S. Supreme Court for a writ of certiorari seeking reversal of the Federal Circuit's decision. In March 2019, the U.S. Supreme Court invited the Solicitor General of the U.S. to file a brief in the matter expressing the views of the U.S. In January 2020, the U.S. Supreme Court denied West-Ward's petition for writ of certiorari.

In 2015, the Company filed six separate patent infringement lawsuits in the Delaware District Court against Roxane, 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, and collectively with Roxane, Inventia, Lupin and Taro, the Fanapt® Defendants). These lawsuits were filed in response to the submission to the FDA by each of the Fanapt® Defendants of ANDAs for generic versions of Fanapt® prior to the expiration of the '610 Patent in November 2027 or the U.S. Patent No. 9,138,432 in September 2025. The Company entered into separate confidential stipulations with each of Inventia and Lupin regarding any potential launch of their generic versions of Fanapt®. The parties are scheduled to provide the court with a status report on May 28, 2020 with respect to the remaining lawsuits against the other Fanapt® Defendants.

HETLIOZ®. In April and May 2018, the Company filed three separate patent infringement lawsuits in the Delaware District Court against Teva Pharmaceuticals USA, Inc. (Teva), MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited (MSN) and Apotex (collectively with Teva and MSN, the HETLIOZ® Defendants) after having received Paragraph IV certification notice letters (Paragraph IV Letters) from each of the HETLIOZ® Defendants alleging that certain of the Company's patents covering HETLIOZ® (collectively, the HETLIOZ® Patents) were invalid, unenforceable and/or would not be infringed by the manufacture, use or sale of their generic versions of HETLIOZ®, as described in the ANDAs submitted to

the FDA by each of the HETLIOZ[®] Defendants, prior to the expiration of the latest to expire of the HETLIOZ[®] Patents in 2034. Each of the HETLIOZ[®] Patents are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book). In December 2018, the Company filed amended complaints against each of the HETLIOZ[®] Defendants following the receipt of additional Paragraph IV Letters from Teva and Apotex concerning its Orange Book listed '977 Patent, which expires in 2035. These lawsuits are scheduled for trial in July 2021.

In March 2019, April 2019, and May 2019, the Company filed three additional patent infringement lawsuits in the Delaware District Court against the HETLIOZ[®] Defendants following the receipt of additional Paragraph IV Letters from each concerning its Orange Book listed U.S. Patent No. 10,149,829, which expires in 2033. These lawsuits have been consolidated with the other lawsuits against the HETLIOZ[®] Defendants and are also scheduled for trial in July 2021.

In November and December 2019, the Company filed additional patent infringement lawsuits in the Delaware District Court against Apotex and Teva, respectively, for infringement of its Orange Book listed U.S. Patent No. 10,376,487 ('487 Patent) following the receipt of additional Paragraph IV Letters from Apotex and Teva regarding the '487 Patent, which expires in July 2035. Teva asserted a counterclaim for a declaratory judgment that the '487 Patent is invalid. The Company answered Teva's counterclaim by denying their allegation that the '487 Patent is invalid. In January 2020, the Company filed two additional patent infringement lawsuits in the Delaware District Court against Teva and Apotex for infringement of its Orange Book-listed U.S. Patent No. 10,449,176 ('176 Patent) following the receipt of additional Paragraph IV Letters from Teva and Apotex regarding the '176 Patent, which expires in January 2033. These lawsuits have been consolidated with the other lawsuits against the HETLIOZ[®] Defendants and are also scheduled for trial in July 2021.

In January 2020 and February 2020, the Company received additional Paragraph IV Letters from MSN concerning the '487 patent and the '176 Patent, respectively, in which MSN alleges that the '487 and the '176 Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation of MSN's generic version of HETLIOZ[®] as described in MSN's ANDA. In February and March 2020 the Company filed two additional lawsuits in the Delaware District Court against MSN for infringement of its '487 Patent and '176 Patent. These lawsuits have been consolidated with the other lawsuits against the HETLIOZ[®] Defendants and are also scheduled for trial in July 2021.

Other Matters. In April 2018, the Company submitted a protocol amendment to the FDA, proposing a 52-week open-label extension (OLE) period for patients who had completed the tradipitant Phase II clinical study (2301) in gastroparesis. In May 2018, based on feedback from the FDA, the Company amended the protocol limiting the duration of treatment in the 2301 study to a total of three months, while continuing to seek further dialogue with the FDA on extending the study duration to 52-weeks. As a part of this negotiation process, in September 2018, the Company submitted a new follow-on 52-week OLE protocol to the FDA (2302) for patients who had completed the 2301 study. While waiting for further feedback, the Company did not enroll any patients in any study beyond 12 weeks. In December 2018, the FDA imposed a partial clinical hold (PCH) on the two proposed studies, stating that the Company is required first to conduct additional chronic toxicity studies in canines, monkeys or minipigs before allowing patients access in any clinical protocol beyond 12 weeks. At that time, the FDA informed the Company that the original PCH was not based on any safety or efficacy data related to tradipitant, but, rather that these additional toxicity studies were required by a guidance document. Subsequently, the FDA has taken the position that an additional study was required in order for the FDA to have adequate toxicology data to undertake a risk analysis of tradipitant.

On February 5, 2019, the Company filed a lawsuit against the FDA in the U.S. District Court for the District of Columbia (DC District Court), challenging the FDA's legal authority to issue the PCH, and seeking an order to set it aside. In February 2019, the FDA filed a Motion for Voluntary Remand to the Agency and for a Stay of the Case. In March 2019, the DC District Court granted the FDA's request for voluntary remand and returned the matter to the FDA for further consideration. In April 2019, the FDA provided its remand response, in which it indicated that, upon review of scientific literature and tradipitant data, it believes that a PCH continues to be appropriate until the Company has adequate safety data from a nine-month non-rodent toxicity study. In May 2019, the Company filed an amended complaint, and in July 2019, the Company filed a Motion for Summary Judgment based on its continuing belief after review of the FDA's remand response that additional chronic toxicity studies are unjustified, and that it has provided the FDA with sufficient information regarding the safety of tradipitant to justify the continued study of tradipitant in patients beyond 12 weeks, in accordance with applicable law and FDA regulations. The FDA filed a reply and cross-motion for summary judgment in October 2019 and an oral hearing was held in December 2019. In January 2020, the Court granted the FDA's cross-motion for summary judgment and granted judgment in favor of the FDA on the Company's claims. The Company has elected not to appeal the Court's ruling.

In February 2019, a qui tam action filed against the Company was unsealed by order of the DC District Court. The qui tam action, which was filed under seal in March 2017, 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. By virtue of the DC District Court having unsealed the original complaint, the Company learned that in January 2019, the U.S. Department of Justice (the DOJ), as well as the Plaintiff States, elected not to intervene in the qui tam action at that time. In May 2019, the plaintiff filed an amended complaint under seal repeating the same allegations and seeking the same relief. According to a filing unsealed in June 2019, the DOJ reaffirmed its decision not to intervene and incorporated its prior filing, indicating that neither the DOJ nor the Plaintiff States were intervening regarding the original complaint. Although the DOJ and the Plaintiff States have elected not to intervene, the plaintiff may litigate this action and the DOJ and the Plaintiff States may later seek to intervene in the action. In August 2019, the Company filed a motion to dismiss, and in October 2019 the plaintiff filed a reply. In March 2020, the DC District Court vacated the scheduled hearing on the Company's motion to dismiss and will notify the parties of a new hearing date if one is deemed necessary by the DC District Court. The Company intends to vigorously defend itself in the case.

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. On March 23, 2020, the Company filed a motion to dismiss the complaint. The plaintiff is expected to file its reply by May 7, 2020. The Company believes that it has meritorious defenses and intends to vigorously defend this lawsuit. The Company does not anticipate that this litigation will have a material adverse effect on its business, results of operations or financial condition. However, this lawsuit is subject to inherent uncertainties, the actual cost may be significant, and the Company may not prevail. The Company believes it is entitled to coverage under its relevant insurance policies, subject to a retention, but coverage could be denied or prove to be insufficient.

In July 2019, a shareholder derivative complaint, *Samuel Williams vs. Mihael Polymeropoulos, et al.*, was filed in the U.S. District Court for the Eastern District of New York naming certain current and former Company directors and officers as defendants. In September 2019, a shareholder derivative complaint, *Michael Bavaro v. Mihael Polymeropoulos, et al.*, was filed in the Delaware District Court naming certain current and former Company directors and officers as defendants. In October 2019, the Company filed a motion to transfer the *Bavaro* case to the Eastern District of New York, where the *Gordon* and *Williams* cases are pending. In March 2020, the Delaware District Court transferred the *Bavaro* case to the Eastern District of New York, consolidating the *Williams* and *Bavaro* cases, and the plaintiffs filed a consolidated complaint on April 24, 2020. These complaints, filed on behalf of purported stockholders, derivatively on behalf of the Company, assert claims for alleged breach of fiduciary duties by certain of the Company's current and former directors and officers. The Company believes that it has meritorious defenses and intends to vigorously defend these lawsuits. The Company does not anticipate that this litigation will have a material adverse effect on its business, results of operations or financial condition. However, these lawsuits are subject to inherent uncertainties, the actual cost may be significant, and the Company may not prevail. The Company believes it is entitled to coverage under its relevant insurance policies, subject to a retention, but coverage could be denied or prove to be insufficient.

In July 2017, the CHMP issued a negative opinion recommending against approval of Fanaptum® (oral iloperidone tablets) for the treatment of schizophrenia in adult patients in the E.U. The CHMP was of the opinion that the benefits of Fanaptum® did not outweigh its risks and recommended against marketing authorization. In March 2018, the Company filed an application seeking annulment of the EMA's negative opinion and the subsequent European Commission decision refusing marketing authorization of Fanaptum in the European General Court. In December 2019, the General Court issued its judgment dismissing the action, leaving the EMA opinion and Commission decision intact. In February 2020, the Company filed an appeal of this judgment with the Court of Justice of the E.U.

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 Fanapt[®] for the treatment of schizophrenia. HETLIOZ[®] is the first treatment for Non-24 approved by the U.S. Food and Drug Administration (FDA). In addition, we have a number of drugs in development, including:

- HETLIOZ[®] (tasimelteon) for the treatment of jet lag disorder (JLD), Smith-Magenis Syndrome (SMS), pediatric Non-24 and delayed sleep phase disorder (DSPD);
- Fanapt[®] (iloperidone) for the treatment of bipolar disorder and a long acting injectable (LAI) formulation program for the treatment of schizophrenia;
- Tradipitant (VLY-686), a small molecule neurokinin-1 receptor (NK-1R) antagonist, for the treatment of atopic dermatitis, gastroparesis, motion sickness and COVID-19 Acute Respiratory Distress Syndrome (ARDS);
- 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;
- VQW-765, a small molecule nicotinic acetylcholine receptor partial agonist, with potential use for the treatment of psychiatric disorders; and
- Portfolio of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) activators and inhibitors for the treatment of dry eye and ocular inflammation and for the treatment of secretory diarrhea disorders, including cholera.

Operational Highlights

We are working proactively across our business and research units to protect employees and customers, and to maintain business continuity as a result of the COVID-19 pandemic.

Products

We are encouraged by the strong performance of our commercial products during the first quarter of 2020, driving 22% year-over-year growth. We are implementing marketing and sales strategies aimed at overcoming the disruptions caused by the pandemic. We remain committed to continue innovating and bringing value to patients and prescribers, while advancing and strengthening the awareness and use of our products.

Pipeline

The COVID-19 pandemic has impacted clinical research globally, including our previously reported clinical trials. New recruitment for the tradipitant atopic dermatitis, gastroparesis and motion sickness programs, as well as the HETLIOZ[®] DSPD and Fanapt[®] bipolar disorder and LAI studies, is currently on hold.

Tradipitant

- The ongoing atopic dermatitis and gastroparesis studies, have been adapted in accordance with FDA guidance to protect the health and safety of currently enrolled patients and healthcare providers.
- The results of the recent atopic dermatitis (EPIONE), gastroparesis (VLY686-2301) and motion sickness (Motion Sifnos) studies have all been submitted to peer-review publications.
- See below for details on our clinical study, ODYSSEY VLY-686-3501, for the treatment of patients with COVID-19 ARDS.

HETLIOZ®

- Discussions with the FDA are ongoing regarding the supplemental New Drug Applications for HETLIOZ® in the treatments of JLD and SMS.

COVID-19 Therapeutic Program

We initiated the following activities aimed at combating COVID-19:

- We announced the initiation of ODYSSEY VLY-686-3501, a Phase III double-blind placebo-controlled trial investigating the efficacy and safety of tradipitant for the treatment of patients with COVID-19 ARDS. Results of this study are expected in the third quarter of 2020.
- We also announced the initiation of the CALYPSO genetics study to evaluate the role of human and viral genetic variations in COVID-19 infection and disease severity.
- We and the University of Illinois at Chicago announced a research partnership to identify small molecule inhibitors of cathepsin-L, a host enzyme required for viral processing.

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 which are detailed in *Risk Factors* reported in Item 1A of Part I of our annual report on Form 10-K (Annual Report) for the year ended December 31, 2019 and Item 1A of Part II of this quarterly report on Form 10-Q.

Critical Accounting Policies

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 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. We believe that the following accounting policies are important to understanding and evaluating our reported financial results, and we have accordingly included them in this discussion.

Net Product Sales. Our net product sales consist of sales of HETLIOZ® and sales of Fanapt®. In accordance with Accounting Standards Codification (ASC) 606, *Revenue from Contracts with Customers*, 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 commercially launched HETLIOZ® in Germany in August 2016. We have also entered into 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. We estimate the amount of variable consideration that should be included in the transaction price utilizing the most likely amount method and update our estimate at each reporting date.

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. 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. Reserves for variable consideration are classified as product revenue allowances on our 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 on our 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 which 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, non-profit clinics, 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: Medicare Part D prescription drug benefit mandates 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. 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, 2020 or December 31, 2019.

The following table summarizes sales discounts and allowance activity for the three months ended March 31, 2020:

<i>(in thousands)</i>	Rebates & Chargebacks	Discounts, Returns and Other	Total
Balances at December 31, 2019	\$ 22,392	\$ 10,151	\$ 32,543
Provision related to current period sales	17,245	6,872	24,117
Adjustments for prior period sales	(531)	(231)	(762)
Credits/payments made	(14,701)	(7,286)	(21,987)
Balances at March 31, 2020	\$ 24,405	\$ 9,506	\$ 33,911

The provision of \$17.2 million for rebates and chargebacks for the three months ended March 31, 2020 primarily represents Medicaid rebates applicable to sales of Fanapt® and HETLIOZ®. The provision of \$6.9 million for discounts, returns and other for the three months ended March 31, 2020 primarily 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 since our inception 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 which 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. During the third quarter of 2019, after considering all available positive and negative evidence, including but not limited to cumulative income in recent periods, historical, current and future projected results and significant risks and uncertainties related to forecasts, we concluded that it was more likely than not that substantially all of our deferred tax assets in the U.S. are realizable in future periods. A valuation allowance has been retained against certain U.S. federal tax attributes with short carryforward periods and District of Columbia state deferred tax assets as of March 31, 2020 and December 31, 2019. 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 *Summary of Significant Accounting Policies* footnote to the condensed consolidated financial statements included in Part I of this quarterly report on Form 10-Q 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 successfully commercialize our products, any possible payments made or received pursuant to license or collaboration agreements, progress of our research and development efforts, the timing and outcome of clinical trials and related possible regulatory approvals. Since our inception, we have incurred significant losses resulting in an accumulated deficit of \$220.2 million as of March 31, 2020. Our total stockholders' equity was \$416.4 million as of March 31, 2020.

Three months ended March 31, 2020 compared to three months ended March 31, 2019

Revenues. Total revenues increased by \$10.3 million, or 22%, to \$58.0 million for the three months ended March 31, 2020 compared to \$47.7 million for the three months ended March 31, 2019. Revenues were as follows:

<i>(in thousands)</i>	Three Months Ended			
	March 31, 2020	March 31, 2019	Net Change	Percent
HETLIOZ [®] product sales, net	\$ 35,336	\$ 28,957	\$ 6,379	22%
Fanapt [®] product sales, net	22,664	18,756	3,908	21%
Total net product sales	\$ 58,000	\$ 47,713	\$ 10,287	22%

HETLIOZ[®] product sales, net increased by \$6.4 million, or 22%, to \$35.3 million for the three months ended March 31, 2020 compared to \$29.0 million for the three months ended March 31, 2019. The increase to net product sales was attributable to an increase in volume and an increase in price net of deductions.

Fanapt[®] product sales, net increased by \$3.9 million, or 21%, to \$22.7 million for the three months ended March 31, 2020 compared to \$18.8 million for the three months ended March 31, 2019. The increase to net product sales was attributable to an increase in volume and an increase in price net of deductions.

Cost of goods sold. Cost of goods sold increased by \$0.1 million, or 2%, to \$5.2 million for the three months ended March 31, 2020 compared to \$5.1 million for the three months ended March 31, 2019. 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 net product sales of HETLIOZ[®] in the U.S. and Germany, respectively. Third-party royalty costs on net product sales of Fanapt[®] decreased from 9% to 6% beginning January 2020.

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 our net product sales of HETLIOZ®. We expect that, in the future, total Fanapt® manufacturing costs included in cost of goods sold will continue to be less than 3% of our net product sales of Fanapt®.

Research and development expenses. Research and development expenses were \$15.5 million and \$13.3 million for the three months ended March 31, 2020 and 2019, respectively. The increase in clinical trial expenses was primarily associated with our Fanapt® development programs. The following table summarizes the costs of our product development initiatives for the three months ended March 31, 2020 and 2019:

<i>(in thousands)</i>	Three Months Ended	
	March 31, 2020	March 31, 2019
Direct project costs (1)		
HETLIOZ®	\$ 1,898	\$ 2,097
Fanapt®	2,685	1,081
Tradipitant	7,193	6,652
VTR-297	368	390
CFTR	780	1,367
Other	471	105
	13,395	11,692
Indirect project costs (1)		
Stock-based compensation	1,111	728
Other indirect overhead	1,021	858
	2,132	1,586
Total research and development expense	\$ 15,527	\$ 13,278

- (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 \$6.0 million, or 19%, to \$37.0 million for the three months ended March 31, 2020 compared to \$31.0 million for the three months ended March 31, 2019. The increase was primarily the result of increased spending on 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, 2020 and 2019.

Other income. Other income was \$1.4 million for the three months ended March 31, 2020 compared to \$1.5 million for the three months ended March 31, 2019. Other income primarily relates to investment income on our marketable securities.

Provision for income taxes. For the three months ended March 31, 2020 and 2019, we recorded income tax expense of \$0.8 million and less than \$0.1 million, respectively. The income tax expense for the three months ended March 31, 2020 was primarily driven by the estimated effective tax rate for the year and the discrete impact of \$0.4 million of net shortfall tax expense related to stock-based compensation activity during the quarter. As a result of the tax valuation allowance against deferred tax assets in the U.S., there was no benefit for federal income taxes associated with the loss before taxes for the three months ended March 31, 2019. Income taxes were recorded related to certain U.S. state and foreign jurisdictions for the three months ended March 31, 2019.

Liquidity and Capital Resources

As of March 31, 2020, our total cash and cash equivalents and marketable securities were \$312.3 million compared to \$312.1 million at December 31, 2019. 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, commercial paper and asset-backed securities.

Our liquidity resources as of March 31, 2020 and December 31, 2019 are summarized as follows:

<i>(in thousands)</i>	March 31, 2020	December 31, 2019
Cash and cash equivalents	\$ 64,950	\$ 45,072
Marketable securities:		
U.S. Treasury and government agencies	87,572	88,601
Corporate debt	123,426	130,055
Asset-backed securities	36,378	48,401
Total marketable securities	247,376	267,057
Total cash, cash equivalents and marketable securities	<u>\$ 312,326</u>	<u>\$ 312,129</u>

As of March 31, 2020, we maintained all of our Cash 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.

We expect to incur substantial costs and expenses throughout the remainder of 2020 and beyond in connection with our continued clinical development of tradipitant and our other products, U.S. commercial activities for HETLIOZ[®] and Fanapt[®], the European commercial launch activities for HETLIOZ[®] and payments due upon achievement of milestones under our license agreements. Additionally, we continue to pursue market approval of HETLIOZ[®] and Fanapt[®] in other regions. The actual costs to advance tradipitant and our research and development projects and commercial activities for HETLIOZ[®] and Fanapt[®] are difficult to estimate and may vary significantly. We believe that our existing funds will be sufficient to meet our operating plans for at least the next twelve months. Our future capital requirements and the adequacy of our available funds will depend on many factors, primarily including our ability to generate revenue, the scope and costs of our commercial, manufacturing and process development activities, the magnitude of our discovery, preclinical and clinical development programs, and potential costs to acquire or license the rights to additional products.

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

Cash Flow

The following table summarizes our net cash flows from operating, investing and financing activities for the three months ended March 31, 2020 and 2019:

<i>(in thousands)</i>	Three Months Ended		Net Change
	March 31, 2020	March 31, 2019	
Net cash provided by (used in):			
Operating activities:			
Net income (loss)	\$ 486	\$ (612)	\$ 1,098
Non-cash charges	5,571	3,405	2,166
Net change in operating assets and liabilities	(6,964)	6,850	(13,814)
Operating activities	(907)	9,643	(10,550)
Investing activities:			
Purchases of property and equipment	(373)	(393)	20
Net maturities (purchases) of marketable securities	20,673	(36,058)	56,731
Investing activities	20,300	(36,451)	56,751
Financing activities:			
Proceeds from the exercise of stock options	479	179	300
Financing activities	479	179	300
Effect of exchange rate changes on cash, cash equivalents and restricted cash	5	2	3
Net change in cash, cash equivalents and restricted cash	\$ 19,877	\$ (26,627)	\$ 46,504

Operating Activities: Cash flows used in operating activities during the three months ended March 31, 2020 were \$0.9 million, a decrease of \$10.6 million compared to cash flows provided by operating activities of \$9.6 million for the three months ended March 31, 2019. The decrease reflects a decrease of \$13.8 million from the net change in operating assets and liabilities, partially offset by an increase of \$1.1 million in net income and an increase of \$2.2 million in non-cash charges. The decrease of \$13.8 million from the net change in operating assets and liabilities primarily relates to an increase in accounts receivable attributable to the timing of shipments and payments, an increase in prepaid expenses and other assets attributable to the timing of activities and payments, partially offset by a decrease in accounts payable and other liabilities attributable to the timing of activities and payments.

Investing Activities: Cash flows provided by investing activities during the three months ended March 31, 2020 were \$20.3 million, an increase of \$56.8 million compared to cash flows used in investing activities of \$36.5 million for the three months ended March 31, 2019. Investing activities primarily include purchases and maturities of marketable securities.

Financing Activities: Cash flows provided by financing activities during the three months ended March 31, 2020 were \$0.5 million, an increase of \$0.3 million compared to \$0.2 million for the three months ended March 31, 2019. Financing activities include proceeds from exercises of stock options.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements, as defined in Item 303(a)(4) of the Securities and Exchange Commission's Regulation S-K.

Contractual Obligations and Commitments

The following is a summary of our noncancellable long-term contractual cash obligations as of March 31, 2020:

(in thousands)	Cash Payments Due by Year (3)(4)						
	Total	2020	2021	2022	2023	2024	Thereafter
Operating leases(1)	\$ 19,445	\$ 1,671	\$ 2,329	\$ 2,355	\$ 2,420	\$ 2,488	\$ 8,182
Purchase commitments(2)	4,665	3,218	966	481	—	—	—
Total noncancellable long-term contractual cash obligations	\$ 24,110	\$ 4,889	\$ 3,295	\$ 2,836	\$ 2,420	\$ 2,488	\$ 8,182

- (1) Operating leases include the minimum lease payments for our operating lease liabilities. This table does not include obligations under short-term lease agreements, variable payments for building maintenance and other services and executory costs associated with our operating lease agreements.
- (2) Purchase commitments include noncancellable purchase commitments for agreements longer than one year and primarily relate to commitments for media and data services. This table does not include various other long-term agreements entered into for services with other third-party vendors, such as inventory purchase commitments, due to the cancelable nature of the services or variable terms within the agreement. Additionally, this table does not include rebates, chargebacks or discounts recorded as liabilities at the time that product sales are recognized as revenue.
- (3) This table does not include potential future milestone obligations under our license agreements for which we have not deemed it probable that the milestone event will occur as of March 31, 2020. See *Commitments and Contingencies* footnote to the condensed consolidated financial statements included in Part I of this quarterly report on Form 10-Q for a description of our licensing arrangements and remaining milestone obligations.
- (4) This table does not include liabilities related to uncertain tax positions taken as of March 31, 2020. Due to the uncertainties in the timing of potential tax audits, the timing associated with the resolution of these positions is also uncertain.

ITEM 3 Quantitative and Qualitative Disclosures about Market Risk

Interest rate risks

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. Because of the short-term maturities of our cash and cash equivalents and marketable securities, we do not believe that an increase in market rates would have any significant impact on the realized value of our investments.

Concentrations of credit risk

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

Revenues and accounts receivable are concentrated with specialty pharmacies and wholesalers. There were five major customers that each accounted for more than 10% of total revenues and, as a group, represented 96% of total revenues for the three months ended March 31, 2020. There were five major customers that each accounted for more than 10% of accounts receivable and, as a group, represented 94% of total accounts receivable at March 31, 2020. We mitigate our credit risk relating to accounts receivable from customers by performing ongoing credit evaluations.

Foreign currency risk

We are 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.

Effects of inflation

Inflation 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, 2020. Based upon that evaluation, our Chief Executive Officer and Acting Chief Financial Officer concluded that our disclosure controls and procedures are effective as of March 31, 2020, 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 Acting 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 2020 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

Fanapt[®]. We have been involved in litigation with Roxane Laboratories, Inc. (Roxane) and its affiliates, West-Ward Pharmaceuticals International Limited and West-Ward Pharmaceuticals Corp (West-Ward), since we filed a lawsuit against Roxane in the U.S. District Court for the District of Delaware (Delaware District Court) for patent infringement in June 2014. The lawsuit was filed in response to Roxane's submission to the U.S. Food and Drug Administration (FDA) of an Abbreviated New Drug Application (ANDA) for a generic version of *Fanapt*[®] prior to the expiration of certain of our patents covering *Fanapt*[®], including U.S. Patent No. 8,586,610 ('610 Patent). In August 2016, the Delaware District Court ruled in our 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 we obtain pediatric exclusivity. In April 2018, following an appeal by Roxane of the Delaware District Court's decision to the Federal Circuit Court of Appeals (Federal Circuit), the Federal Circuit affirmed the Delaware District Court's ruling. In June 2018, West-Ward, having replaced Roxane as defendants following the acquisition of Roxane by West-Ward's parent company, Hikma Pharmaceuticals PLC, petitioned the Federal Circuit for a rehearing en banc. In August 2018, the Federal Circuit denied West-Ward's petition. In January 2019, West-Ward filed a petition in the U.S. Supreme Court for a writ of certiorari seeking reversal of the Federal Circuit's decision. In March 2019, the U.S. Supreme Court invited the Solicitor General of the U.S. to file a brief in the matter expressing the views of the U.S. In January 2020, the U.S. Supreme Court denied West-Ward's petition for writ of certiorari.

In 2015, we filed six separate patent infringement lawsuits in the Delaware District Court against Roxane, 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, and collectively with Roxane, Inventia, Lupin and Taro, the *Fanapt*[®] Defendants). These lawsuits were filed in response to the submission to the FDA by each of the *Fanapt*[®] Defendants of ANDAs for generic versions of *Fanapt*[®] prior to the expiration of the '610 Patent in November 2027 or the U.S. Patent No. 9,138,432 in September 2025. We entered into separate confidential stipulations with each of Inventia and Lupin regarding any potential launch of their generic versions of *Fanapt*[®]. The parties are scheduled to provide the court with a status report on May 28, 2020 with respect to the remaining lawsuits against the other *Fanapt*[®] Defendants.

HETLIOZ[®]. In April and May 2018, we filed three separate patent infringement lawsuits in the Delaware District Court against Teva Pharmaceuticals USA, Inc. (Teva), MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited (MSN) and Apotex (collectively with Teva and MSN, the *HETLIOZ*[®] Defendants) after having received Paragraph IV certification notice letters (Paragraph IV Letters) from each of the *HETLIOZ*[®] Defendants alleging that certain of our patents covering *HETLIOZ*[®] (collectively, the *HETLIOZ*[®] Patents) were invalid, unenforceable and/or would not be infringed by the manufacture, use or sale of their generic versions of *HETLIOZ*[®], as described in the ANDAs submitted to the FDA by each of the *HETLIOZ*[®] Defendants, prior to the expiration of the latest to expire of the *HETLIOZ*[®] Patents in 2034. Each of the *HETLIOZ*[®] Patents are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book). In December 2018, we filed amended complaints against each of the *HETLIOZ*[®] Defendants following the receipt of additional Paragraph IV Letters from Teva and Apotex concerning our Orange Book listed '977 Patent, which expires in 2035. These lawsuits are scheduled for trial in July 2021.

In March 2019, April 2019, and May 2019, we filed three additional patent infringement lawsuits in the Delaware District Court against the *HETLIOZ*[®] Defendants following the receipt of additional Paragraph IV Letters from each concerning our Orange Book listed U.S. Patent No. 10,149,829, which expires in 2033. These lawsuits have been consolidated with the other lawsuits against the *HETLIOZ*[®] Defendants and are also scheduled for trial in July 2021.

In November and December 2019, we filed additional patent infringement lawsuits in the Delaware District Court against Apotex and Teva, respectively, for infringement of our Orange Book listed U.S. Patent No. 10,376,487 ('487 Patent) following the receipt of additional Paragraph IV Letters from Apotex and Teva regarding the '487 Patent, which expires in July 2035. Teva asserted a counterclaim for a declaratory judgment that the '487 Patent is invalid. We answered Teva's counterclaim by denying their allegation that the '487 Patent is invalid. In January 2020, we filed two additional patent infringement lawsuits in the Delaware District Court against Teva and Apotex for infringement of our Orange Book-listed U.S. Patent No. 10,449,176 ('176 Patent) following the receipt of additional Paragraph IV Letters from Teva and Apotex regarding the '176 Patent, which expires in January 2033. These lawsuits have been consolidated with the other lawsuits against the *HETLIOZ*[®] Defendants and are also scheduled for trial in July 2021.

In January 2020 and February 2020, we received additional Paragraph IV Letters from MSN concerning the '487 patent and the '176 Patent, respectively, in which MSN alleges that the '487 and the '176 Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation of MSN's generic version of *HETLIOZ*[®] as described in MSN's ANDA. In February and March 2020 we filed two additional lawsuits in the Delaware District Court against MSN for infringement of our '487 Patent and '176 Patent. These lawsuits have been consolidated with the other lawsuits against the *HETLIOZ*[®] Defendants and are also scheduled for trial in July 2021.

Other Matters. In April 2018, we submitted a protocol amendment to the FDA, proposing a 52-week open-label extension (OLE) period for patients who had completed the tradipitant Phase II clinical study (2301) in gastroparesis. In May 2018, based on feedback from the FDA, we amended the protocol limiting the duration of treatment in the 2301 study to a total of three months, while continuing to seek further dialogue with the FDA on extending the study duration to 52-weeks. As a part of this negotiation process, in September 2018, we submitted a new follow-on 52-week OLE protocol to the FDA (2302) for patients who had completed the 2301 study. While waiting for further feedback, we did not enroll any patients in any study beyond 12 weeks. In December 2018, the FDA imposed a partial clinical hold (PCH) on the two proposed studies, stating that we are required first to conduct additional chronic toxicity studies in canines, monkeys or minipigs before allowing patients access in any clinical protocol beyond 12 weeks. At that time, the FDA informed us that the original PCH was not based on any safety or efficacy data related to tradipitant, but, rather that these additional toxicity studies were required by a guidance document. Subsequently, the FDA has taken the position that an additional study was required in order for the FDA to have adequate toxicology data to undertake a risk analysis of tradipitant.

On February 5, 2019, we filed a lawsuit against the FDA in the U.S. District Court for the District of Columbia (DC District Court), challenging the FDA's legal authority to issue the PCH, and seeking an order to set it aside. In February 2019, the FDA filed a Motion for Voluntary Remand to the Agency and for a Stay of the Case. In March 2019, the DC District Court granted the FDA's request for voluntary remand and returned the matter to the FDA for further consideration. In April 2019, the FDA provided its remand response, in which it indicated that, upon review of scientific literature and tradipitant data, it believes that a PCH continues to be appropriate until we have adequate safety data from a nine-month non-rodent toxicity study. In May 2019, we filed an amended complaint, and in July 2019, we filed a Motion for Summary Judgment based on our continuing belief after review of the FDA's remand response that additional chronic toxicity studies are unjustified, and that we have provided the FDA with sufficient information regarding the safety of tradipitant to justify the continued study of tradipitant in patients beyond 12 weeks, in accordance with applicable law and FDA regulations. The FDA filed a reply and cross-motion for summary judgment in October 2019 and an oral hearing was held in December 2019. In January 2020, the Court granted the

FDA's cross-motion for summary judgment and granted judgment in favor of the FDA on our claims. We have elected not to appeal the Court's ruling.

In February 2019, a qui tam action filed against us was unsealed by order of the DC District Court. The qui tam action, which was filed under seal in March 2017, was brought by one of our former employees 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 we violated these laws through the promotion and marketing of our products Fanapt® and HETLIOZ® and sought, among other things, treble damages, civil penalties for each alleged false claim, and attorneys' fees and costs. By virtue of the DC District Court having unsealed the original complaint, we learned that in January 2019, the U.S. Department of Justice (the DOJ), as well as the Plaintiff States, elected not to intervene in the qui tam action at that time. In May 2019, the plaintiff filed an amended complaint under seal repeating the same allegations and seeking the same relief. According to a filing unsealed in June 2019, the DOJ reaffirmed its decision not to intervene and incorporated its prior filing, indicating that neither the DOJ nor the Plaintiff States were intervening regarding the original complaint. Although the DOJ and the Plaintiff States have elected not to intervene, the plaintiff may litigate this action and the DOJ and the Plaintiff States may later seek to intervene in the action. In August 2019, we filed a motion to dismiss, and in October 2019 the plaintiff filed a reply. In March 2020, the DC District Court vacated the scheduled hearing on our motion to dismiss and will notify the parties of a new hearing date if one is deemed necessary by the DC District Court. We intend to vigorously defend itself in the case.

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 us and certain of our 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 our 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 our interactions with the FDA regarding tradipitant between November 3, 2015 and February 11, 2019. On March 23, 2020, we filed a motion to dismiss the complaint. The plaintiff is expected to file its reply by May 7, 2020. We believe that it has meritorious defenses and intends to vigorously defend this lawsuit. We do not anticipate that this litigation will have a material adverse effect on our business, results of operations or financial condition. However, this lawsuit is subject to inherent uncertainties, the actual cost may be significant, and we may not prevail. We believe we are entitled to coverage under our relevant insurance policies, subject to a retention, but coverage could be denied or prove to be insufficient.

In July 2019, a shareholder derivative complaint, *Samuel Williams vs. Mihael Polymeropoulos, et al.*, was filed in the U.S. District Court for the Eastern District of New York naming certain current and former of our directors and officers as defendants. In September 2019, a shareholder derivative complaint, *Michael Bavaro v. Mihael Polymeropoulos, et al.*, was filed in the Delaware District Court naming certain current and former of our directors and officers as defendants. In October 2019, we filed a motion to transfer the *Bavaro* case to the Eastern District of New York, where the *Gordon* and *Williams* cases are pending. In March 2020, the Delaware District Court transferred the *Bavaro* case to the Eastern District of New York, consolidating the *Williams* and *Bavaro* cases, and the plaintiffs filed a consolidated complaint on April 24, 2020. These complaints, filed on behalf of purported stockholders, derivatively on behalf of us, assert claims for alleged breach of fiduciary duties by certain of our current and former directors and officers. We believe that it has meritorious defenses and intends to vigorously defend these lawsuits. We do not anticipate that this litigation will have a material adverse effect on our business, results of operations or financial condition. However, these lawsuits are subject to inherent uncertainties, the actual cost may be significant, and we may not prevail. We believe we are entitled to coverage under our relevant insurance policies, subject to a retention, but coverage could be denied or prove to be insufficient.

In July 2017, the CHMP issued a negative opinion recommending against approval of Fanaptum® (oral iloperidone tablets) for the treatment of schizophrenia in adult patients in the E.U. The CHMP was of the opinion that the benefits of Fanaptum® did not outweigh its risks and recommended against marketing authorization. In March 2018, we filed an application seeking annulment of the EMA's negative opinion and the subsequent European Commission decision refusing marketing authorization of Fanaptum in the European General Court. In December 2019, the General Court issued its judgment dismissing the action, leaving the EMA opinion and Commission decision intact. In February 2020, we filed an appeal of this judgment with the Court of Justice of the E.U.

ITEM 1A Risk Factors

We previously disclosed in Part I, Item 1A of our annual report on Form 10-K for the year ended December 31, 2019, filed with the Securities and Exchange Commission on February 26, 2020, 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 current 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. Except as set forth below, there have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2019.

Global health crises and pandemics, such as the global outbreak of the novel coronavirus (COVID-19), may adversely impact our business.

In December 2019, a novel strain of coronavirus (COVID-19) surfaced in Wuhan, China. Since then, COVID-19 has spread to nearly every country in the world, including the U.S. The COVID-19 pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. The effects of shelter-in-place orders and our work-from-home policies may negatively impact productivity and disrupt our business, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course.

Our sales force has had physical access to healthcare providers curtailed, which may have an impact on our future revenues. While we are implementing marketing and sales strategies aimed at overcoming the disruptions caused by the pandemic, we cannot ensure that these methods will be effective. Additionally, patients who might be currently using our products, or might otherwise be eligible to use our products, may be unable to meet with their healthcare providers, which may reduce the number of prescription refills or new patient starts, thereby adversely affecting our revenues.

The COVID-19 pandemic has impacted clinical research globally, including our previously reported clinical trials. New recruitment for the tradipitant atopic dermatitis, gastroparesis, and motion sickness programs, as well as the HETLIOZ[®] delayed sleep phase disorder and Fanapt[®] bipolar disorder and long acting injectable studies, is currently on hold. We may further experience disruptions that could adversely impact our supply chain, our ongoing and planned clinical trials, and other regulatory activities, including:

- interruption of, or delays in receiving, supplies of the active pharmaceutical ingredients that our contract manufacturing organizations use to manufacture our products and any related interruption of, or delays in receiving, supplies of our products from these organizations, due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- delays or difficulties in enrolling patients in our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (such as procedures that are deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- limitations on our employee resources or those of third-party clinical research organizations towards the development of our products, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- interruption or delays in the operations of regulatory agencies, which may impact review and approval timelines.

In addition, the trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the outbreak may impact our business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, travel restrictions and social distancing practices, business closures or business disruptions and the effectiveness of actions taken in the U.S. and other countries to contain and treat the disease.

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 Amended and Restated 2016 Equity Incentive Plan

On April 20, 2020 our Board of Directors approved, subject to stockholder approval, an amendment and restatement of our Amended and Restated 2016 Equity Incentive Plan (the 2016 Plan). The amendment and restatement of 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 1,690,000 shares.

Amended and Restated Employment Agreement with Kevin Moran

On May 5, 2020, we entered into an amended and restated employment agreement (the Employment Agreement) with Kevin Moran, our Vice President, Acting Chief Financial Officer and Treasurer, which amends and restates his prior employment agreement. The Employment Agreement provides for an annual base salary of not less than \$270,113 and the possibility of an annual target cash incentive bonus amount equal to 30% of his annual base salary upon achievement of certain performance criteria, in accordance with his previously approved base salary and target cash bonus. The Employment Agreement provides that if we terminate Mr. Moran's employment for any reason other than cause or permanent disability, or, if he terminates his employment within six months after the occurrence of any event constituting good reason (as defined below), Mr. Moran will receive the following severance benefits following termination: (1) base salary for a period of 12 months; (2) his annual target bonus, payable in a lump sum; and (3) an additional three months of service credit under all options held by him and all such options shall be exercisable for six months following his termination.

Pursuant to the Employment Agreement, the following terms are defined as follows:

"Good reason" means: (i) a change in Mr. Moran's position with us that materially reduces his level of authority or responsibility from what it was prior to his elevation to the position of Acting Chief Financial Officer and Treasurer; (ii) a material reduction in his base compensation; or (iii) receipt of notice that his principal workplace will be relocated by more than 30 miles. A condition shall not be considered "good reason" unless Mr. Moran gives us written notice of such condition within 90 days after such condition comes into existence and we fail to remedy such condition within 30 days after receiving such written notice.

"Cause" means: (i) an unauthorized use or disclosure of our confidential information or trade secrets, which use or disclosure causes material harm to us; (ii) a material breach of any agreement between Mr. Moran and us; (iii) a material failure to comply with our written policies or rules; (iv) conviction of, or plea of "guilty" or "no contest" to, a felony under the laws of the U.S. or any state thereof; (v) Mr. Moran's gross negligence or willful misconduct; (vi) a continuing failure to perform assigned duties after receiving written notification of such failure from the Board; or (vii) a failure by Mr. Moran to cooperate in good faith with a governmental or internal investigation of us or our directors, officers or employees, if we have requested Mr. Moran's cooperation.

The foregoing summary of the Employment Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the Employment Agreement, a copy of which is attached hereto as Exhibit 10.42, and the terms of which are incorporated herein by reference.

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).
10.42	Amended and Restated Employment Agreement, dated May 5, 2020, by and between Kevin Moran 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 Acting 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 Acting 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, 2020 formatted in Inline Extensible Business Reporting Language (iXBRL) and filed electronically herewith: (i) Condensed Consolidated Balance Sheets as of March 31, 2020 and December 31, 2019; (ii) Condensed Consolidated Statements of Operations for the three months ended March 31, 2020 and 2019; (iii) Condensed Consolidated Statements of Comprehensive Income (Loss) for the three months ended March 31, 2020 and 2019; (iv) Condensed Consolidated Statements of Changes in Stockholders' Equity for the three months ended March 31, 2020 and 2019; (v) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2020 and 2019; and (vi) Notes to Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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

Vanda Pharmaceuticals Inc.

May 7, 2020

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

Mihael H. Polymeropoulos, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

May 7, 2020

/s/ Kevin Moran

Kevin Moran
Acting Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

VANDA PHARMACEUTICALS INC.
AMENDED AND RESTATED EMPLOYMENT AGREEMENT

This Employment Agreement (this “Agreement”) by and between **KEVIN MORAN** (the “Executive”) and **VANDA PHARMACEUTICALS INC.**, a Delaware corporation (the “Company”) was originally entered into as of August 6, 2010. This Agreement is hereby amended and restated as of May 5, 2020.

1. Duties and Scope of Employment.

(a) **Position.** During his employment under this Agreement (“Employment”), the Company agrees to employ the Executive in the position of VP, Acting Chief Financial Officer and Treasurer. The Executive shall be subject to the supervision of, and shall have such authority as is delegated to him by, the Company’s Chief Executive Officer. The Executive hereby accepts such employment and agrees to undertake the duties and responsibilities normally inherent in such position and such other duties and responsibilities as the Company’s Chief Executive Officer shall from time to time reasonably assign to him.

(b) **Obligations to the Company.** During his Employment, the Executive shall devote his full business efforts and time to the Company. In addition, during his Employment, without the prior written approval of the Company’s Board of Directors (the “Board”), the Executive shall not render services in any capacity to any other person or entity and shall not act as a sole proprietor or partner of any other person or entity or as a shareholder owning more than five percent of the voting power of any other entity. The Executive shall comply with the Company’s policies and rules, as they may be in effect from time to time during his Employment.

(c) **No Conflicting Obligations.** The Executive represents and warrants to the Company that he is under no obligations or commitments, whether contractual or otherwise, that are inconsistent with his obligations under this Agreement. The Executive represents and warrants that he will not use or disclose, in connection with his Employment, any trade secrets or other proprietary information or intellectual property in which the Executive or any other person has any right, title or interest and that his Employment as contemplated by this Agreement will not infringe or violate the rights of any other person or entity. The Executive represents and warrants to the Company that he has returned all property and confidential information belonging to any prior employers.

2. Cash and Incentive Compensation.

(a) **Salary.** The Company shall pay the Executive as compensation for his services a base salary at a gross annual rate of not less than \$270,113. Such salary shall be payable in accordance with the Company’s standard payroll procedures. The annual compensation specified in this Subsection (a), together with any increases in such compensation that the Company may grant from time to time, is referred to in this Agreement as “Base Compensation.”

(b) **Incentive Bonuses.** The Executive shall be eligible for an annual incentive bonus with a target amount equal to 30% of his Base Compensation (the “Annual Target Bonus”). Such Annual Target Bonus (if any) shall be awarded based on objective or subjective criteria established in advance by the Board or the Compensation Committee of the Board (the “Compensation Committee”). Any Annual Target Bonus for a fiscal year shall in no event be paid later than 2½ months after the close of such fiscal year. Except as provided in Section 6, such Annual Target Bonus shall be paid only if the Executive is employed by the Company at the time of payment. The determinations of the Board or the Compensation Committee with respect to such Annual Target Bonus shall be final and binding.

(c) **Equity Awards.** The Executive has previously been granted options to purchase shares of the Company’s common stock and restricted stock units. In addition, the Executive will be eligible to receive annual equity awards, if any, subject to the approval of the Board or the Compensation Committee in their sole discretion. The timing and size of the annual equity awards, if any, shall be determined in the sole discretion of the Board or the Compensation Committee based on the Executive’s and/or the Company’s performance.

3. Vacation and Employee Benefits.

(a) The Company has adopted an unlimited paid time off policy, as such, during his Employment, the Executive shall be eligible for an unlimited number of paid vacation days each year, subject to the unlimited paid time off policy as in effect from time to time. In accordance with such policy, the Executive shall not be entitled to any accrued vacation upon termination of employment for any reason.

(b) During his Employment, the Executive shall be eligible to participate in any employee benefit plans maintained by the Company for similarly situated employees, subject in each case to the generally applicable terms and conditions of the plan in question and to the determinations of any person or committee administering such plan.

4. Business Expenses. During his Employment, the Executive shall be authorized to incur necessary and reasonable travel, entertainment and other business expenses in connection with his duties hereunder. The Company shall reimburse the Executive for such expenses upon presentation of an itemized account and appropriate supporting documentation, all in accordance with the Company’s generally applicable policies. Any reimbursement shall (a) be paid promptly but not later than the last day of the calendar year following the year in which the expense was incurred, (b) not be affected by any other expenses that are eligible for reimbursement in any calendar year and (c) not be subject to liquidation or exchange for another benefit.

5. Term of Employment.

(a) **Employment at Will.** The Executive’s Employment with the Company shall be “at will,” meaning that either the Executive or the Company may terminate the Executive’s Employment at any time and for any reason, with or without Cause. Any contrary representations which may have been made to the Executive shall be superseded by this Agreement. This Agreement shall constitute the full and complete agreement between the Executive and the

Company on the “at will” nature of the Executive’s Employment, which may only be changed in an express written agreement signed by the Executive and a duly authorized officer of the Company (other than the Executive). The termination of Executive’s Employment shall not limit or otherwise affect his obligations under Section 7 below.

(b) **Termination.** The Company may terminate the Executive’s Employment at any time and for any reason (or no reason), and with or without Cause, by giving the Executive notice in writing. The Executive may terminate his Employment by giving the Company 14 days’ advance notice in writing. The Executive’s Employment shall terminate automatically in the event of his death.

(c) **Rights Upon Termination.** Except as expressly provided in Section 6, upon the termination of the Executive’s Employment pursuant to this Section 5, the Executive shall only be entitled to accrued and unpaid compensation, benefits and expense reimbursements described in Sections 2, 3 and 4 for the period preceding the effective date of the termination. The payments under this Agreement shall fully discharge all responsibilities of the Company to the Executive.

6. Termination Benefits.

(a) **Preconditions.** Any other provision of this Agreement notwithstanding, the remaining Subsections of this Section 6 shall not apply unless each of the following requirements is satisfied:

(i) The Executive has executed a general release of all known and unknown claims that the Executive may then have against the Company or persons affiliated with the Company in a form prescribed by the Company, without alterations. The Executive shall execute and return the release on or before the date specified by the Company in the prescribed form (the “Release Deadline”). The Release Deadline shall in no event be later than 50 days after the Executive’s Separation. If the Executive fails to return the release on or before the Release Deadline, or if the Executive revokes the release, then the Executive shall not be entitled to the benefits described in this Section 6.

(ii) The Executive has returned all property of the Company in the Executive’s possession.

(b) **Severance Pay.** If, during the term of this Agreement, the Executive is subject to an Involuntary Termination, then the Company shall pay the Executive both of the following:

(i) **Base Compensation.** The Company shall continue to pay Executive his Base Compensation for a period of 12 months following the Separation (the “Continuation Period”). Such severance payments shall be paid at the Base Compensation rate in effect at the time of the Separation and in accordance with the Company’s standard payroll procedures. The severance payments shall

commence within 60 days after the Executive's Separation and, once they commence (the "Payment Commencement"), shall include any unpaid amounts accrued from the date of the Employee's Separation. However, if the 60-day period described in the preceding sentence spans two calendar years, then the Payment Commencement shall in any event begin on the first payroll period following expiration of any applicable revocation period in the second calendar year.

(ii) **Target Bonus.** An amount equal to his Annual Target Bonus at the rate in effect at the time of the Separation. Such amount shall be payable in a lump sum on the Company's next regularly scheduled payroll that occurs following the Payment Commencement.

(c) **Options.** If, during the term of this Agreement, Executive is subject to an Involuntary Termination, then (i) the vested portion of the shares of the Company's Common Stock subject to all options held by the Executive at the time of his Separation shall be determined by adding three months to the actual period of service that he has completed with the Company and (ii) such options shall be exercisable for up to six months after the Executive's Separation (provided, however, that the Option shall remain subject to the terms of the Plan in the event the Company is subject to a Change in Control, and further provided that the Option in any event shall expire no later than the Expiration Date set forth in the Notice of Stock Option Grant evidencing the Option).

7. Non-Solicitation, Non-Disclosure and Non-Competition. The Executive has entered into a Proprietary Information and Inventions Agreement with the Company, which agreement is incorporated herein by reference.

8. Successors.

(a) **Company's Successors.** This Agreement shall be binding upon any successor (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets. For all purposes under this Agreement, the term "Company" shall include any successor to the Company's business and/or assets which becomes bound by this Agreement.

(b) **Executive's Successors.** This Agreement and all rights of the Executive hereunder shall inure to the benefit of, and be enforceable by, the Executive's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.

9. Definitions. For all purposes under this Agreement:

"Cause" shall mean:

(a) An unauthorized use or disclosure by the Executive of the Company's confidential information or trade secrets, which use or disclosure causes material harm to the Company;

- (b) A material breach by the Executive of any agreement between the Executive and the Company;
- (c) A material failure by the Executive to comply with the Company's written policies or rules;
- (d) The Executive's conviction of, or plea of "guilty" or "no contest" to, a felony under the laws of the United States or any State thereof;
- (e) The Executive's gross negligence or willful misconduct;
- (f) A continuing failure by the Executive to perform assigned duties after receiving written notification of such failure from the Board; or
- (g) A failure by the Executive to cooperate in good faith with a governmental or internal investigation of the Company or its directors, officers or employees, if the Company has requested the Executive's cooperation.

"Change in Control" shall mean:

(a) The consummation of a merger or consolidation of the Company with or into another entity or any other corporate reorganization, if persons who were not stockholders of the Company immediately prior to such merger, consolidation or other reorganization own immediately after such merger, consolidation or other reorganization 50% or more of the voting power of the outstanding securities of each of (i) the continuing or surviving entity and (ii) any direct or indirect parent corporation of such continuing or surviving entity;

(b) The sale, transfer or other disposition of all or substantially all of the Company's assets;

(c) A change in the composition of the Board, as a result of which fewer than 50% of the incumbent directors are directors who either:

(i) Had been directors of the Company on the date 24 months prior to the date of such change in the composition of the Board (the "Original Directors"); or

(ii) Were appointed to the Board, or nominated for election to the Board, with the affirmative votes of at least a majority of the aggregate of (A) the Original Directors who were in office at the time of their appointment or nomination and (B) the directors whose appointment or nomination was previously approved in a manner consistent with this Subsection (c)(ii); or

(d) Any transaction as a result of which any person is the "beneficial owner" (as defined in Rule 13d-3 under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), directly or indirectly, of securities of the Company representing at least 50% of the total voting power represented by the Company's then outstanding voting securities. For

purposes of this Subsection (d), the term “person” shall have the same meaning as when used in Sections 13(d) and 14(d) of the Exchange Act but shall exclude (i) a trustee or other fiduciary holding securities under an employee benefit plan of the Company or of a parent or subsidiary of the Company and (ii) a corporation owned directly or indirectly by the stockholders of the Company in substantially the same proportions as their ownership of the Common Stock of the Company.

A transaction shall not constitute a Change in Control if its sole purpose is to change the State of the Company’s incorporation or to create a holding company that will be owned in substantially the same proportions by the persons who held the Company’s securities immediately before such transaction.

“**Code**” shall mean the Internal Revenue Code of 1986, as amended.

“**Good Reason**” shall mean Executive’s resignation within 6 months after one of the following conditions has come into existence without Executive’s consent: (i) a change in the Executive’s position with the Company that materially reduces his level of authority or responsibility from what it was prior to his elevation to the position of Acting Chief Financial Officer and Treasurer, (ii) a material reduction in his Base Compensation or (iii) receipt of notice that his principal workplace will be relocated by more than 30 miles. A condition shall not be considered “Good Reason” unless the Executive gives the Company written notice of such condition within 90 days after the initial existence of such condition and the Company fails to remedy such condition within 30 days after receiving the Executive’s written notice.

“**Involuntary Termination**” shall mean a Separation resulting from either (i) the Executive’s involuntary discharge by the Company for reasons other than Cause, Executive’s death or Permanent Disability or (ii) the Executive’s voluntary resignation for Good Reason.

“**Permanent Disability**” shall mean the Executive’s inability to perform the essential functions of the Executive’s position, with or without reasonable accommodation, for a period of at least 120 consecutive days because of a physical or mental impairment.

“**Separation**” shall mean a “separation from service,” as defined in the regulations under Section 409A of the Code.

10. Miscellaneous Provisions.

(a) **Notice.** Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or when mailed by overnight courier, U.S. registered or certified mail, return receipt requested and postage prepaid. In the case of the Executive, mailed notices shall be addressed to him at the home address that he most recently communicated to the Company in writing. In the case of the Company, mailed notices shall be addressed to its corporate headquarters, and all notices shall be directed to the attention of its Secretary.

(b) **Modifications and Waivers.** No provision of this Agreement shall be modified, waived or discharged unless the modification, waiver or discharge is agreed to in

writing and signed by the Executive and by an authorized officer of the Company (other than the Executive). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) **Whole Agreement.** No other agreements, representations or understandings (whether oral or written and whether express or implied) which are not expressly set forth in this Agreement have been made or entered into by either party with respect to the subject matter hereof. This Agreement and the Proprietary Information and Inventions Agreement contain the entire understanding of the parties with respect to the subject matter hereof.

(d) **Tax Matters.** All payments made under this Agreement shall be subject to reduction to reflect taxes or other charges required to be withheld by law. For purposes of Section 409A of the Code, each payment under Section 6(b) is hereby designated as a separate payment. If the Company determines that the Executive is a “specified employee” within the meaning of Section 409A(a)(2)(B)(i) of the Code and the regulations thereunder at the time of his Separation, then:

(i) Any salary continuation payments under Section 6(b)(i), to the extent not exempt from Section 409A of the Code, shall commence with the Company’s first regularly scheduled payroll that occurs following the earlier of (x) expiration of the six-month period measured from Executive’s Separation or (y) the date of Executive’s death and, once such payments commence, any amounts accrued from the Separation date shall be paid in a lump sum on the first payment date; and

(ii) Any lump-sum payment under Section 6(b)(ii), to the extent not exempt from Section 409A of the Code, shall be made with the Company’s first regularly scheduled payroll that occurs following the earlier of (x) expiration of the six-month period measured from Executive’s Separation or (y) the date of Executive’s death.

The Company shall not have a duty to design its compensation policies in a manner that minimizes the Executive’s tax liabilities, and the Executive shall not make any claim against the Company or the Board related to tax liabilities arising from the Executive’s compensation.

(e) **Choice of Law.** The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the District of Columbia (except its provisions governing the choice of law).

(f) **Severability.** The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect.

(g) **No Assignment.** This Agreement and all rights and obligations of the Executive hereunder are personal to the Executive and may not be transferred or assigned by

the Executive at any time. The Company may assign its rights under this Agreement to any entity that assumes the Company's obligations hereunder in connection with any sale or transfer of all or a substantial portion of the Company's assets to such entity.

(h) **Counterparts.** This 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 PAGE LEFT BLANK INTENTIONALLY]

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by its duly authorized officer, as of the date first written above.

/s/ Kevin Moran
Kevin Moran

VANDA PHARMACEUTICALS INC.

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

Title: President and Chief Executive Officer

**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 7, 2020

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

Mihael H. Polymeropoulos, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION OF ACTING 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 7, 2020

/s/ Kevin Moran

Kevin Moran

**Vice President, Acting Chief Financial Officer and Treasurer
(Principal Financial Officer and Principal Accounting Officer)**

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND ACTING 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, 2020 (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 7, 2020

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

Mihael H. Polymeropoulos, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

May 7, 2020

/s/ Kevin Moran

Kevin Moran
Vice President, Acting 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.