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

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 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	**03-0491827**
(State or other jurisdiction of incorporation or organization)	**(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:

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

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

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

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

Large accelerated filer	x	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

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

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

As of July 30, 2020, there were 54,651,399 shares of the registrant's common stock issued and outstanding.

Vanda Pharmaceuticals Inc.

Quarterly Report on Form 10-Q
For the Quarter Ended June 30, 2020

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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 Smith-Magenis Syndrome (SMS) and 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 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)

(in thousands, except for share and per share amounts)	June 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 95,305	$ 45,072
Marketable securities	244,544	267,057
Accounts receivable, net	24,587	26,367
Inventory	1,384	1,140
Prepaid expenses and other current assets	15,041	14,500
Total current assets	380,861	354,136
Property and equipment, net	3,744	3,864
Operating lease right-of-use assets	10,601	11,180
Intangible assets, net	22,298	23,037
Deferred tax assets	85,558	87,680
Non-current inventory and other	3,569	3,851
Total assets	$ 506,631	$ 483,748
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 28,398	$ 27,590
Product revenue allowances	33,194	31,915
Total current liabilities	61,592	59,505
Operating lease non-current liabilities	11,720	12,455
Other non-current liabilities	1,735	843
Total liabilities	75,047	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 June 30, 2020 and December 31, 2019	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized; 54,628,336 and 53,549,612 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	55	54
Additional paid-in capital	642,398	631,307
Accumulated other comprehensive income	596	249
Accumulated deficit	(211,465)	(220,665)
Total stockholders' equity	431,584	410,945
Total liabilities and stockholders' equity	$ 506,631	$ 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)

(in thousands, except for share and per share amounts)	Three Months Ended		Six Months Ended	
	June 30, 2020	June 30, 2019	June 30, 2020	June 30, 2019
Revenues:				
Net product sales	$ 62,207	$ 59,060	$ 120,207	$ 106,773
Total revenues	62,207	59,060	120,207	106,773
Operating expenses:				
Cost of goods sold excluding amortization	5,847	6,368	11,054	11,481
Research and development	12,903	10,950	28,430	24,228
Selling, general and administrative	33,917	31,468	70,938	62,497
Intangible asset amortization	369	379	739	759
Total operating expenses	53,036	49,165	111,161	98,965
Income from operations	9,171	9,895	9,046	7,808
Other income	1,918	1,649	3,284	3,134
Income before income taxes	11,089	11,544	12,330	10,942
Provision for income taxes	2,375	18	3,130	28
Net income	$ 8,714	$ 11,526	$ 9,200	$ 10,914
Net income per share:				
Basic	$ 0.16	$ 0.22	$ 0.17	$ 0.21
Diluted	$ 0.16	$ 0.21	$ 0.17	$ 0.20
Weighted average shares outstanding:				
Basic	54,501,308	53,101,499	54,153,812	52,928,101
Diluted	55,081,397	54,579,982	54,975,771	54,932,932

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

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

(in thousands)	Three Months Ended		Six Months Ended	
	June 30, 2020	June 30, 2019	June 30, 2020	June 30, 2019
Net income	$ 8,714	$ 11,526	$ 9,200	$ 10,914
Other comprehensive income (loss):				
Net foreign currency translation gain (loss)	10	6	(3)	2
Change in net unrealized gain (loss) on marketable securities	(252)	245	453	383
Tax provision on other comprehensive income (loss)	57	—	(103)	—
Other comprehensive income (loss), net of tax	(185)	251	347	385
Comprehensive income	$ 8,529	$ 11,777	$ 9,547	$ 11,299

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

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

(in thousands, except for share amounts)	Common Stock Shares	Common Stock Par Value	Additional Paid-in Capital	Other Comprehensive Income	Accumulated Deficit	Total
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
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	496,000	1	3,599	—	—	3,600
Stock-based compensation expense	—	—	3,069	—	—	3,069
Net income	—	—	—	—	8,714	8,714
Other comprehensive loss, net of tax	—	—	—	(185)	—	(185)
Balances at June 30, 2020	54,628,336	$ 55	$ 642,398	$ 596	$ (211,465)	$ 431,584

(in thousands, except for share amounts)	Common Stock Shares	Common Stock Par Value	Additional Paid-in Capital	Other Comprehensive Income	Accumulated Deficit	Total
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
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	302,108	—	3,411	—	—	3,411
Stock-based compensation expense	—	—	3,101	—	—	3,101
Net income	—	—	—	—	11,526	11,526
Other comprehensive income, net of tax	—	—	—	251	—	251
Balances at June 30, 2019	53,264,784	$ 53	$ 621,559	$ 386	$ (325,304)	$ 296,694

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

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

(in thousands)	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Cash flows from operating activities		
Net income	$ 9,200	$ 10,914
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation of property and equipment	694	672
Stock-based compensation	7,013	6,383
Amortization of premiums and accretion of discounts on marketable securities	(420)	(1,848)
Gain on sale of marketable securities	(229)	—
Intangible asset amortization	739	759
Deferred income taxes	2,019	—
Other non-cash adjustments, net	695	740
Changes in operating assets and liabilities:		
Accounts receivable	1,672	4,851
Prepaid expenses and other assets	(591)	681
Inventory	10	(191)
Accounts payable and other liabilities	883	5,159
Product revenue allowances	1,414	2,038
Net cash provided by operating activities	23,099	30,158
Cash flows from investing activities		
Purchases of property and equipment	(583)	(657)
Purchases of marketable securities	(151,124)	(191,293)
Sales and maturities of marketable securities	174,739	143,745
Net cash provided by (used in) investing activities	23,032	(48,205)
Cash flows from financing activities		
Proceeds from the exercise of stock options	4,079	3,590
Net cash provided by financing activities	4,079	3,590
Effect of exchange rate changes on cash, cash equivalents and restricted cash	23	(5)
Net change in cash, cash equivalents and restricted cash	50,233	(14,462)
Cash, cash equivalents and restricted cash		
Beginning of period	45,650	61,749
End of period	$ 95,883	$ 47,287

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 Smith-Magenis Syndrome (SMS), jet lag disorder (JLD), pediatric Non-24 and delayed sleep phase disorder (DSPD);
- Fanapt® (iloperidone) for the treatment of bipolar disorder and a long acting injectable (LAI) formulation 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 June 30, 2020 and for the three and six months ended June 30, 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:

(in thousands)	June 30, 2020	June 30, 2019
Cash and cash equivalents	$ 95,305	$ 46,543
Restricted cash included in:		
Prepaid expenses and other current assets	—	157
Non-current inventory and other	578	587
Total cash, cash equivalents and restricted cash	$ 95,883	$ 47,287

Revenue from Net Product Sales

The Company's net product sales consist of sales of HETLIOZ® and Fanapt®. Net sales by product for the three and six months ended June 30, 2020 and 2019 were as follows:

	Three Months Ended		Six Months Ended	
(in thousands)	June 30, 2020	June 30, 2019	June 30, 2020	June 30, 2019
HETLIOZ® net product sales	$ 41,561	$ 37,835	$ 76,897	$ 66,792
Fanapt® net product sales	20,646	21,225	43,310	39,981
Total net product sales	$ 62,207	$ 59,060	$ 120,207	$ 106,773

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 six months ended June 30, 2020. There were five major customers that each accounted for more than 10% of accounts receivable and, as a group, represented 93% of total accounts receivable at June 30, 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.

Certain Risks and Uncertainties

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 continues to rapidly evolve. The extent to which the outbreak may impact the Company's business, financial condition and results of operations will depend on future developments, which are highly uncertain and the effects of which cannot be reasonably estimated at this time.

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 June 30, 2020, which all have contractual maturities of less than two years:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
U.S. Treasury and government agencies	$ 149,821	$ 309	$ (10)	$ 150,120
Corporate debt	93,963	461	—	94,424
Total marketable securities	$ 243,784	$ 770	$ (10)	$ 244,544

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:

(in thousands)	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	$ 266,750	$ 313	$ (6)	$ 267,057

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 June 30, 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 June 30, 2020, the Company held certain assets that are required to be measured at fair value on a recurring basis, as follows:

		Fair Value Measurement as of June 30, 2020 Using		
(in thousands)	Total Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
U.S. Treasury and government agencies	$ 150,120	$ 150,120	$ —	$ —
Corporate debt	136,942	—	136,942	—
Total assets measured at fair value	$ 287,062	$ 150,120	$ 136,942	$ —

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:

		Fair Value Measurement as of December 31, 2019 Using		
(in thousands)	Total Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
U.S. Treasury and government agencies	$ 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 June 30, 2020 and December 31, 2019 include $42.5 million and $7.0 million of cash equivalents, respectively.

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 June 30, 2020 and December 31, 2019:

(in thousands)	June 30, 2020	December 31, 2019
Current assets		
Finished goods	$ 1,384	$ 1,140
Total inventory, current	$ 1,384	$ 1,140
Non-Current assets		
Raw materials	$ 745	$ 659
Work-in-process	1,247	1,109
Finished goods	552	1,056
Total inventory, non-current	2,544	2,824
Total inventory	$ 3,928	$ 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 with BMS when cumulative worldwide sales of HETLIOZ® reached $250.0 million. As a result of the achievement of this milestone, the Company made a payment to BMS of $25.0 million in 2018. The $25.0 million, which was capitalized as an intangible asset in the first quarter of 2015, was determined to be additional consideration for the acquisition of the HETLIOZ® intangible asset and is being amortized on a straight-line basis over the estimated economic useful life of the related product patents, the 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 June 30, 2020:

		June 30, 2020		
(in thousands)	Estimated Useful Life	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	July 2035	$ 33,000	$ 10,702	$ 22,298

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

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

As of June 30, 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 June 30, 2020 and 2019. Amortization expense was $0.7 million and $0.8 million for the six months ended June 30, 2020 and 2019, respectively. The following is a summary of the future intangible asset amortization schedule as of June 30, 2020:

(in thousands)	Total	2020	2021	2022	2023	2024	Thereafter
HETLIOZ®	$ 22,298	$ 739	$ 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 June 30, 2020 and December 31, 2019:

(in thousands)	June 30, 2020	December 31, 2019
Research and development expenses	$ 6,459	$ 5,893
Consulting and other professional fees	6,286	5,376
Compensation and employee benefits	5,536	6,597
Royalties payable	5,418	5,904
Operating lease liabilities	2,181	2,147
Other	2,518	1,673
Total accounts payable and accrued liabilities	$ 28,398	$ 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 June 30, 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 is obligated 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 June 30, 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 June 30, 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 June 30, 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 June 30, 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 data services, of which $0.5 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 June 30, 2020 and December 31, 2019:

(in thousands)	June 30, 2020	December 31, 2019
Foreign currency translation	$ 10	$ 13
Unrealized gain on marketable securities	586	236
Accumulated other comprehensive income	$ 596	$ 249

10. Stock-Based Compensation

As of June 30, 2020, there were 5,445,343 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 three times to increase the number of shares reserved for issuance, among other administrative changes. Each of the amendments and restatements of the 2016 Plan was approved by the Company's stockholders. There are a total of 8,790,000 shares of common stock reserved for issuance under the 2016 Plan, 4,041,406 shares of which remained available for future grant as of June 30, 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 June 30, 2020, $8.4 million of unrecognized compensation costs related to unvested service option awards are expected to be recognized over a weighted average period of 1.4 years. No option awards are classified as a liability as of June 30, 2020.

A summary of option activity under the Plans for the six months ended June 30, 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	$ 22,148
Granted	537,500	11.34		
Forfeited	(225,000)	18.83		
Expired	(545,104)	14.29		
Exercised	(554,844)	7.35		2,113
Outstanding at June 30, 2020	3,707,697	12.10	5.90	5,415
Exercisable at June 30, 2020	2,562,003	10.95	4.51	5,317
Vested and expected to vest at June 30, 2020	3,518,867	12.03	5.71	5,395

The weighted average grant-date fair value of options granted was $5.65 and $11.16 per share for the six months ended June 30, 2020 and 2019, respectively. Proceeds from the exercise of stock options amounted to $4.1 million and $3.6 million for the six months ended June 30, 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 June 30, 2020, $23.5 million of unrecognized compensation costs related to unvested service RSUs are expected to be recognized over a weighted average period of 1.8 years. No RSUs are classified as a liability as of June 30, 2020.

A summary of RSU activity under the Plans for the six months ended June 30, 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	786,818	11.28
Forfeited	(174,577)	18.19
Vested	(523,880)	16.65
Unvested at June 30, 2020	1,737,646	15.39

The grant date fair value for the 523,880 shares underlying RSUs that vested during the six months ended June 30, 2020 was $8.7 million.

Stock-Based Compensation Expense

Stock-based compensation expense recognized for the three and six months ended June 30, 2020 and 2019 was comprised of the following:

	Three Months Ended		Six Months Ended	
(in thousands)	June 30, 2020	June 30, 2019	June 30, 2020	June 30, 2019
Research and development	$ 900	$ 756	$ 2,011	$ 1,484
Selling, general and administrative	2,169	2,345	5,002	4,899
Total stock-based compensation expense	$ 3,069	$ 3,101	$ 7,013	$ 6,383

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 six months ended June 30, 2020 and 2019 were as follows:

	Six Months Ended	
	June 30, 2020	June 30, 2019
Expected dividend yield	0 %	0 %
Weighted average expected volatility	52 %	59 %
Weighted average expected term (years)	6.09	5.93
Weighted average risk-free rate	1.28 %	2.48 %

11. Income Taxes

For the three months ended June 30, 2020 and 2019, the Company recorded income tax expense of $2.4 million and less than $0.1 million, respectively. For the six months ended June 30, 2020 and 2019, the Company recorded income tax expense of $3.1 million and less than $0.1 million, respectively. The income tax expense for the three and six months ended June 30, 2020 was primarily driven by the estimated effective tax rate for the year and the discrete impact of net shortfall tax expense related to stock-based compensation activity. 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 income before taxes for the three and six months ended June 30, 2019. Income taxes were recorded related to certain U.S. state and foreign jurisdictions for the three and six months ended June 30, 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 District of Columbia state deferred tax assets as of June 30, 2020 and December 31, 2019.

12. Earnings per Share

Basic earnings per share (EPS) is calculated by dividing the net income by the weighted average number of shares of common stock outstanding. Diluted EPS is computed by dividing the net income 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 per share of common stock for the three and six months ended June 30, 2020 and 2019:

(in thousands, except for share and per share amounts)	Three Months Ended		Six Months Ended	
	June 30, 2020	June 30, 2019	June 30, 2020	June 30, 2019
Numerator:				
Net income	$ 8,714	$ 11,526	$ 9,200	$ 10,914
Denominator:				
Weighted average shares outstanding, basic	54,501,308	53,101,499	54,153,812	52,928,101
Effect of dilutive securities	580,089	1,478,483	821,959	2,004,831
Weighted average shares outstanding, diluted	55,081,397	54,579,982	54,975,771	54,932,932
Net income per share, basic and diluted:				
Basic	$ 0.16	$ 0.22	$ 0.17	$ 0.21
Diluted	$ 0.16	$ 0.21	$ 0.17	$ 0.20
Antidilutive securities excluded from calculations of diluted net income per share	3,813,824	2,294,277	3,454,524	1,415,953

13. Legal Matters

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

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

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

HETLIOZ®. 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 10,071,977 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 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 May 2020, the DC District Court dismissed the plaintiff’s complaint in its entirety, without prejudice. In June 2020, the plaintiff filed a second amended complaint with similar allegations and seeking the same relief. On July 30, 2020, the Company filed another motion to dismiss. The Company intends to continue 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. In March 2020, the Company filed a motion to dismiss the complaint. 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 v. 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 in April 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 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 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 E.U. 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 Smith-Magenis Syndrome (SMS), jet lag disorder (JLD), pediatric Non-24 and delayed sleep phase disorder (DSPD);
- Fanapt® (iloperidone) for the treatment of bipolar disorder and a long acting injectable (LAI) formulation 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

Products

We are encouraged by our record commercial performance during the second quarter of 2020. We continue to implement marketing and sales strategies aimed at supporting continued growth and minimizing the impact of disruptions caused by the COVID-19 pandemic, including the launch of a Fanapt® for schizophrenia direct-to-consumer campaign at the end of the second quarter of 2020.

Pipeline

The COVID-19 pandemic has impacted clinical research globally, including our previously reported clinical trials. The tradipitant gastroparesis and motion sickness programs have resumed, while recruitment for the tradipitant atopic dermatitis program, as well as the HETLIOZ® delayed sleep phase disorder study and Fanapt® bipolar disorder and long acting injectable studies, is currently on hold.

Tradipitant

- An Individual Patient Expanded Access protocol (VP-VLY-686-3303) for tradipitant in gastroparesis was approved by the FDA and the patient was enrolled in July 2020. Under this protocol, this patient will receive tradipitant treatment for a period of up to six months, which may be extended upon review by the FDA.
- The gastroparesis Phase III clinical study (VP-VLY-686-3301) resumed recruitment. Enrollment in this 200-person study is expected to be completed in the first half of 2021 with a New Drug Application (NDA) filing projected for later that year.
- The protocol for the pivotal Phase III motion sickness study was discussed with the FDA at the end of Phase II meeting, and the FDA agrees with the adequacy of the program design to support an application. Preparations for this study have begun with the boat trip portion of the study expected to commence as soon as local restrictions are lifted.
- Patient enrollment in the Phase III clinical study (ODYSSEY VLY-686-3501) of tradipitant in COVID-19 ARDS is ongoing and an interim analysis will be conducted to determine next steps.

HETLIOZ®

- The SMS marketing authorization applications were accepted by the FDA for priority review with a Prescription Drug User Fee Act (PDUFA-VI) target action date of December 1, 2020.
- The FDA appeals process related to the supplemental New Drug Application (sNDA) for HETLIOZ® for the treatment of jet lag disorder is ongoing.

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 June 30, 2020 or December 31, 2019.

The following table summarizes sales discounts and allowance activity for the six months ended June 30, 2020:

(in thousands)	Rebates & Chargebacks	Discounts, Returns and Other	Total
Balances at December 31, 2019	$ 22,392	$ 10,151	$ 32,543
Provision related to current period sales	34,157	13,526	47,683
Adjustments for prior period sales	(572)	435	(137)
Credits/payments made	(31,646)	(14,552)	(46,198)
Balances at June 30, 2020	$ 24,331	$ 9,560	$ 33,891

The provision of $34.2 million for rebates and chargebacks for the six months ended June 30, 2020 primarily represents Medicaid rebates applicable to sales of Fanapt® and HETLIOZ®. The provision of $13.5 million for discounts, returns and other for the six months ended June 30, 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 District of Columbia state deferred tax assets as of June 30, 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, and the impact of the COVID-19 pandemic.

Three months ended June 30, 2020 compared to three months ended June 30, 2019

Revenues. Total revenues increased by $3.1 million, or 5%, to $62.2 million for the three months ended June 30, 2020 compared to $59.1 million for the three months ended June 30, 2019. Revenues were as follows:

	Three Months Ended			
(in thousands)	**June 30, 2020**	**June 30, 2019**	**Net Change**	**Percent**
HETLIOZ® net product sales	$ 41,561	$ 37,835	$ 3,726	10 %
Fanapt® net product sales	20,646	21,225	(579)	(3)%
Total net product sales	$ 62,207	$ 59,060	$ 3,147	5 %

HETLIOZ® net product sales increased by $3.7 million, or 10%, to $41.6 million for the three months ended June 30, 2020 compared to $37.8 million for the three months ended June 30, 2019. The increase to net product sales was attributable to an increase in volume and an increase in price net of deductions.

Fanapt® net product sales decreased by $0.6 million, or 3%, to $20.6 million for the three months ended June 30, 2020 compared to $21.2 million for the three months ended June 30, 2019. The decrease to net product sales was attributable to a decrease in volume, partially offset by an increase in price net of deductions.

Cost of goods sold. Cost of goods sold decreased by $0.5 million, or 8%, to $5.8 million for the three months ended June 30, 2020 compared to $6.4 million for the three months ended June 30, 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 increased by $2.0 million, or 18%, to $12.9 million for the three months ended June 30, 2020 compared to $11.0 million for the three months ended June 30, 2019. The increase in clinical trial expenses was primarily associated with our Fanapt® and COVID-19 therapeutic development programs. As a result of government-imposed restrictions and other public health safety measures due to the COVID-19 pandemic, new recruitment for certain of our ongoing research and development programs, as well as new studies, was placed on hold during the second quarter of 2020. The following table summarizes the costs of our product development initiatives for the three months ended June 30, 2020 and 2019:

(in thousands)	Three Months Ended June 30, 2020	June 30, 2019
Direct project costs (1)		
HETLIOZ®	$ 2,000	$ 2,067
Fanapt®	1,923	1,044
Tradipitant	5,392	4,706
VTR-297	339	319
CFTR	961	1,099
Other	626	97
	11,241	9,332
Indirect project costs (1)		
Stock-based compensation	900	756
Other indirect overhead	762	862
	1,662	1,618
Total research and development expense	$ 12,903	$ 10,950

(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 $2.4 million, or 8%, to $33.9 million for the three months ended June 30, 2020 compared to $31.5 million for the three months ended June 30, 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 June 30, 2020 and 2019.

Other income. Other income was $1.9 million for the three months ended June 30, 2020 compared to $1.6 million for the three months ended June 30, 2019.

Provision for income taxes. For the three months ended June 30, 2020 and 2019, we recorded income tax expense of $2.4 million and less than $0.1 million, respectively. The income tax expense for the three months ended June 30, 2020 was primarily driven by the estimated effective tax rate for the year and the discrete impact 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 income before taxes for the three months ended June 30, 2019. Income taxes were recorded related to certain U.S. state and foreign jurisdictions for the three months ended June 30, 2019.

Six months ended June 30, 2020 compared to six months ended June 30, 2019

Revenues. Total revenues increased by $13.4 million, or 13%, to $120.2 million for the six months ended June 30, 2020 compared to $106.8 million for the six months ended June 30, 2019. Revenues were as follows:

(in thousands)	Six Months Ended June 30, 2020	June 30, 2019	Net Change	Percent
HETLIOZ® net product sales	$ 76,897	$ 66,792	$ 10,105	15 %
Fanapt® net product sales	43,310	39,981	3,329	8 %
Total net product sales	$ 120,207	$ 106,773	$ 13,434	13 %

HETLIOZ® net product sales increased by $10.1 million, or 15%, to $76.9 million for the six months ended June 30, 2020 compared to $66.8 million for the six months ended June 30, 2019. The increase to net product sales was attributable to an increase in volume and an increase in price net of deductions.

Fanapt® net product sales increased by $3.3 million, or 8%, to $43.3 million for the six months ended June 30, 2020 compared to $40.0 million for the six months ended June 30, 2019. The increase to net product sales was attributable to an increase in price net of deductions.

Cost of goods sold. Cost of goods sold decreased by $0.4 million, or 4%, to $11.1 million for the six months ended June 30, 2020 compared to $11.5 million for the six months ended June 30, 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 increased by $4.2 million, or 17%, to $28.4 million for the six months ended June 30, 2020 compared to $24.2 million for the six months ended June 30, 2019. The increase was primarily due to an increase in clinical trial expenses associated with our Fanapt® and COVID-19 therapeutic development programs. As a result of government-imposed restrictions and other public health safety measures due to the COVID-19 pandemic, new recruitment for certain of our ongoing research and development programs, as well as new studies, was placed on hold during the second quarter of 2020. The following table summarizes the costs of our product development initiatives for the six months ended June 30, 2020 and 2019:

	Six Months Ended	
(in thousands)	**June 30, 2020**	**June 30, 2019**
Direct project costs (1)		
HETLIOZ®	$ 3,898	$ 4,164
Fanapt®	4,608	2,125
Tradipitant	12,585	11,358
VTR-297	707	709
CFTR	1,741	2,466
Other	1,097	202
	24,636	21,024
Indirect project costs (1)		
Stock-based compensation	2,011	1,484
Other indirect overhead	1,783	1,720
	3,794	3,204
Total research and development expense	$ 28,430	$ 24,228

(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 $8.4 million, or 14%, to $70.9 million for the six months ended June 30, 2020 compared to $62.5 million for the six months ended June 30, 2019. The increase was primarily the result of increased spending on marketing activities for our commercial products.

Intangible asset amortization. Intangible asset amortization was $0.7 million and $0.8 million for the six months ended June 30, 2020 and June 30, 2019, respectively.

Other income. Other income was $3.3 million for the six months ended June 30, 2020 compared to $3.1 million for the six months ended June 30, 2019. Other income primarily relates to investment income on our marketable securities.

Provision for income taxes. For the six months ended June 30, 2020 and 2019, we recorded income tax expense of $3.1 million and less than $0.1 million, respectively. The income tax expense for the six months ended June 30, 2020 was primarily driven by the estimated effective tax rate for the year and the discrete impact of net shortfall tax expense related to stock-based compensation activity. 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 income before taxes for the six months ended June 30, 2019. Income taxes were recorded related to certain U.S. state and foreign jurisdictions for the six months ended June 30, 2019.

Liquidity and Capital Resources

As of June 30, 2020, our total cash and cash equivalents and marketable securities were $339.8 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 June 30, 2020 and December 31, 2019 are summarized as follows:

(in thousands)	June 30, 2020	December 31, 2019
Cash and cash equivalents	$ 95,305	$ 45,072
Marketable securities:		
U.S. Treasury and government agencies	150,120	88,601
Corporate debt	94,424	130,055
Asset-backed securities	—	48,401
Total marketable securities	244,544	267,057
Total cash, cash equivalents and marketable securities	$ 339,849	$ 312,129

As of June 30, 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 six months ended June 30, 2020 and 2019:

(in thousands)	Six Months Ended June 30, 2020	June 30, 2019	Net Change
Net cash provided by (used in):			
Operating activities:			
Net income	$ 9,200	$ 10,914	$ (1,714)
Non-cash charges	10,511	6,706	3,805
Net change in operating assets and liabilities	3,388	12,538	(9,150)
Operating activities	23,099	30,158	(7,059)
Investing activities:			
Purchases of property and equipment	(583)	(657)	74
Net proceeds from purchases, sales and maturities of marketable securities	23,615	(47,548)	71,163
Investing activities	23,032	(48,205)	71,237
Financing activities:			
Proceeds from the exercise of stock options	4,079	3,590	489
Financing activities	4,079	3,590	489
Effect of exchange rate changes on cash, cash equivalents and restricted cash	23	(5)	28
Net change in cash, cash equivalents and restricted cash	$ 50,233	$ (14,462)	$ 64,695

Operating Activities: Cash flows provided by operating activities during the six months ended June 30, 2020 were $23.1 million, a decrease of $7.1 million compared to cash flows provided by operating activities of $30.2 million for the six months ended June 30, 2019. The decrease reflects a decrease of $1.7 million in net income and a decrease of $9.2 million from the net change in operating assets and liabilities, partially offset by an increase of $3.8 million in non-cash charges. The decrease of $9.2 million from the net change in operating assets and liabilities primarily relates to a decrease in accounts receivable attributable to the timing of shipments and payments, and an increase in accounts payable and other liabilities attributable to the timing of activities and payments during the six months ended June 30, 2019.

Investing Activities: Cash flows provided by investing activities during the six months ended June 30, 2020 were $23.0 million, an increase of $71.2 million compared to cash flows used in investing activities of $48.2 million for the six months ended June 30, 2019. Investing activities primarily include purchases, sales and maturities of marketable securities.

Financing Activities: Cash flows provided by financing activities during the six months ended June 30, 2020 were $4.1 million, an increase of $0.5 million compared to $3.6 million for the six months ended June 30, 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 June 30, 2020:

	Cash Payments Due by Year (3)(4)						
(in thousands)	Total	2020	2021	2022	2023	2024	Thereafter
Operating leases(1)	$ 18,801	$ 1,289	$ 2,067	$ 2,355	$ 2,420	$ 2,488	$ 8,182
Purchase commitments(2)	1,919	472	966	481	—	—	—
Total noncancellable long-term contractual cash obligations	$ 20,720	$ 1,761	$ 3,033	$ 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 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 June 30, 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 June 30, 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 six months ended June 30, 2020. There were five major customers that each accounted for more than 10% of accounts receivable and, as a group, represented 93% of total accounts receivable at June 30, 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 June 30, 2020. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of June 30, 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 Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the second quarter of 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®. In 2014 and 2015 Roxane Laboratories, Inc. (Roxane) and its affiliates, West-Ward Pharmaceuticals International Limited and West-Ward Pharmaceuticals Corp (West-Ward), Inventia Healthcare Pvt. Ltd. (Inventia), Lupin Ltd. and Lupin Pharmaceuticals, Inc. (Lupin), Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd. (Taro), and Apotex Inc. and Apotex Corp. (Apotex) (collectively, the Fanapt® Defendants) each submitted an Abbreviated New Drug Applications (ANDA) to the U.S. Food and Drug Administration (FDA) seeking approval to market generic versions of Fanapt® prior to the expiration of certain of our patents covering Fanapt®, including U.S. Patent No. 8,586,610 ('610 Patent) and U.S. Patent No. 9,138,432 ('432 Patent). In response, we filed separate lawsuits in 2014 and 2015 against each of the Fanapt® Defendants in the U.S. District Court for the District of Delaware (Delaware District Court) for patent infringement.

In August 2016, the Delaware District Court ruled in 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. This ruling was affirmed on appeal by the Federal Circuit Court of Appeals in April 2018. West-Ward, having replaced Roxane as defendant following the acquisition of Roxane by West-Ward's parent company, Hikma Pharmaceuticals PLC (Hikma), petitioned the U.S. Supreme Court for a writ of certiorari, which was denied in January 2020. Our lawsuit against Hikma regarding the '432 Patent remains pending.

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

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 10,071,977 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 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 May 2020, the DC District Court dismissed the plaintiff’s complaint in its entirety, without prejudice. In June 2020, the plaintiff filed a second amended complaint with similar allegations and seeking the same relief. On July 30, 2020, we filed another motion to dismiss. We intend to continue to vigorously defend ourselves 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. We believe that we have meritorious defenses and intend 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 v. 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 in April 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 we have meritorious defenses and intend 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 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 E.U. 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. The tradipitant gastroparesis and motion sickness programs have resumed, while recruitment for the tradipitant atopic dermatitis program, as well as the HETLIOZ® delayed sleep phase disorder study and Fanapt® bipolar disorder and long acting injectable studies, is currently on hold. We may experience further 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

None

ITEM 6 Exhibits

Exhibit Number	Description
3.1	Form of Amended and Restated Certificate of Incorporation of the registrant (filed as Exhibit 3.8 to Amendment No. 2 to the registrant's registration statement on Form S-1 (File No. 333-130759) on March 17, 2006 and incorporated herein by reference).
3.2	Fourth Amended and Restated Bylaws of the registrant, as amended and restated on December 17, 2015 (filed as Exhibit 3.1 to the registrant's current report on Form 8-K (File No. 001-34186) on December 21, 2015 and incorporated herein by reference).
31.1	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer), as required by Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from this quarterly report on Form 10-Q for the fiscal quarter ended June 30, 2020 formatted in Inline Extensible Business Reporting Language (iXBRL) and filed electronically herewith: (i) Condensed Consolidated Balance Sheets as of June 30, 2020 and December 31, 2019; (ii) Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2020 and 2019; (iii) Condensed Consolidated Statements of Comprehensive Income for the three and six months ended June 30, 2020 and 2019; (iv) Condensed Consolidated Statements of Changes in Stockholders' Equity for the three and six months ended June 30, 2020 and 2019; (v) Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 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.

August 6, 2020 /s/ Mihael H. Polymeropoulos, M.D.

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

August 6, 2020 /s/ Kevin Moran

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

EXHIBIT 31.1

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

I, Mihael H. Polymeropoulos, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Vanda Pharmaceuticals Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

August 6, 2020

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

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

EXHIBIT 31.2

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

I, Kevin Moran, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Vanda Pharmaceuticals Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

August 6, 2020

/s/ Kevin Moran

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

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER

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

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

The Quarterly Report on Form 10-Q for the quarter ended June 30, 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.

August 6, 2020

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

Mihael H. Polymeropoulos, M.D.

President and Chief Executive Officer
(Principal Executive Officer)

August 6, 2020

/s/ Kevin Moran

Kevin Moran

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

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission (SEC) or its staff upon request. This certification "accompanies" the Form 10-Q to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.