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

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**Form 10-Q**

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(Mark One)

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

For the quarterly period ended September 30, 2021  
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

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**VANDA PHARMACEUTICALS INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

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

2200 Pennsylvania Avenue NW, Suite 300E  
Washington, DC 20037  
(202) 734-3400

(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

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

As of October 28, 2021, there were 55,712,230 shares of the registrant's common stock issued and outstanding.

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**Vanda Pharmaceuticals Inc.**  
**Quarterly Report on Form 10-Q**  
**For the Quarter Ended September 30, 2021**  
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### **CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

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

- our ability to continue to commercialize HETLIOZ<sup>®</sup> (tasimelteon) capsules for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in the United States (U.S.) and Europe and HETLIOZ<sup>®</sup> capsules and oral suspension (HETLIOZ LQ<sup>™</sup>) for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in the U.S.;
- our ability to increase market awareness of Non-24 and SMS and market acceptance of HETLIOZ<sup>®</sup>;
- our ability to continue to generate U.S. sales of Fanapt<sup>®</sup> (iloperidone) oral tablets for the treatment of schizophrenia;
- the impact of the novel coronavirus (COVID-19) on our business and operations, including our revenue, our supply chain, our commercial activities, our ongoing and planned clinical trial and our regulatory activities;
- our dependence on third-party manufacturers to manufacture HETLIOZ<sup>®</sup>, HETLIOZ LQ<sup>™</sup>, and Fanapt<sup>®</sup> in sufficient quantities and quality;
- our level of success in commercializing HETLIOZ<sup>®</sup> and Fanapt<sup>®</sup> 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 and maintain regulatory approval of our products, and the labeling for any approved products;
- our ability to obtain approval from the FDA for HETLIOZ<sup>®</sup> for the treatment of jet lag disorder;
- our expectations regarding the timing and success of preclinical studies and clinical trials;
- the safety and efficacy of our products;
- regulatory developments in the U.S., Europe and other jurisdictions;
- limitations on our ability to utilize some or all of our prior net operating losses and orphan drug and research and development credits;
- the size and growth of the potential markets for our products and our ability to serve those markets;
- our expectations regarding trends with respect to our revenues, costs, expenses, liabilities and cash, cash equivalents and marketable securities;
- our ability to identify or obtain rights to new products;
- our ability to attract and retain key scientific or management personnel;
- the cost and effects of litigation;
- our ability to obtain the capital necessary to fund our research and development or commercial activities;
- potential losses incurred from product liability claims made against us; and
- the use of our existing cash, cash equivalents and marketable securities.

All written and verbal forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained throughout this report. We caution you not to rely too heavily on the forward-looking statements we make or that are made on our behalf. Each forward-looking statement speaks only as of the date of this Quarterly Report, and we undertake no obligation, and specifically decline any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

We encourage you to read *Management's Discussion and Analysis of Financial Condition and Results of Operations* and our unaudited condensed consolidated financial statements contained in this Quarterly Report. In addition to the risks described in Part I, Item 1A, *Risk Factors*, of our annual report on Form 10-K for the fiscal year ended December 31, 2020, other unknown or unpredictable factors also could affect our results. Therefore, the information in this report should be read together with other reports and documents that we file with the Securities and Exchange Commission from time to time, including on Form 10-Q and Form 8-K, which may supplement, modify, supersede or update those risk factors. As a result of these factors, we cannot assure you that the forward-looking statements in this report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all.

**Part I — FINANCIAL INFORMATION****ITEM 1 Financial Statements (Unaudited)**

**VANDA PHARMACEUTICALS INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)**

<i>(in thousands, except for share and per share amounts)</i>	September 30, 2021	December 31, 2020
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 50,522	\$ 61,031
Marketable securities	355,446	306,709
Accounts receivable, net	41,496	30,036
Inventory	902	1,280
Prepaid expenses and other current assets	13,442	10,089
Total current assets	461,808	409,145
Property and equipment, net	3,318	4,136
Operating lease right-of-use assets	9,580	10,459
Intangible assets, net	20,450	21,559
Deferred tax assets	76,105	81,516
Non-current inventory and other	8,506	6,641
Total assets	\$ 579,767	\$ 533,456
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued liabilities	\$ 31,820	\$ 31,509
Product revenue allowances	40,177	34,427
Total current liabilities	71,997	65,936
Operating lease non-current liabilities	10,457	11,497
Other non-current liabilities	3,992	2,757
Total liabilities	86,446	80,190
<b>Commitments and contingencies (Notes 8 and 13)</b>		
<b>Stockholders' equity:</b>		
Preferred stock, \$0.001 par value; 20,000,000 shares authorized, and no shares issued or outstanding at September 30, 2021 and December 31, 2020	—	—
Common stock, \$0.001 par value; 150,000,000 shares authorized; 55,708,730 and 54,865,092 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	56	55
Additional paid-in capital	664,408	650,300
Accumulated other comprehensive income	111	239
Accumulated deficit	(171,254)	(197,328)
Total stockholders' equity	493,321	453,266
Total liabilities and stockholders' equity	\$ 579,767	\$ 533,456

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

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

<i>(in thousands, except for share and per share amounts)</i>	Three Months Ended		Nine Months Ended	
	September 30, 2021	September 30, 2020	September 30, 2021	September 30, 2020
<b>Revenues:</b>				
Net product sales	\$ 70,095	\$ 60,308	\$ 200,663	\$ 180,515
Total revenues	70,095	60,308	200,663	180,515
<b>Operating expenses:</b>				
Cost of goods sold excluding amortization	6,797	5,898	19,393	16,952
Research and development	19,653	12,298	56,032	40,728
Selling, general and administrative	32,456	34,001	90,600	104,939
Intangible asset amortization	370	369	1,109	1,108
Total operating expenses	59,276	52,566	167,134	163,727
Income from operations	10,819	7,742	33,529	16,788
Other income (expense)	(97)	659	225	3,943
Income before income taxes	10,722	8,401	33,754	20,731
Provision for income taxes	2,951	2,454	7,680	5,584
Net income	\$ 7,771	\$ 5,947	\$ 26,074	\$ 15,147
<b>Net income per share:</b>				
Basic	\$ 0.14	\$ 0.11	\$ 0.47	\$ 0.28
Diluted	\$ 0.14	\$ 0.11	\$ 0.46	\$ 0.28
<b>Weighted average shares outstanding:</b>				
Basic	55,668,156	54,666,128	55,467,528	54,325,832
Diluted	57,040,736	55,209,032	56,818,295	55,054,772

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

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

<i>(in thousands)</i>	Three Months Ended		Nine Months Ended	
	September 30, 2021	September 30, 2020	September 30, 2021	September 30, 2020
Net income	\$ 7,771	\$ 5,947	\$ 26,074	\$ 15,147
Other comprehensive income (loss):				
Net foreign currency translation gain (loss)	(17)	32	(48)	29
Change in net unrealized gain (loss) on marketable securities	33	(323)	(102)	130
Tax benefit (provision) on other comprehensive income (loss)	(8)	74	22	(29)
Other comprehensive income (loss), net of tax	8	(217)	(128)	130
Comprehensive income	<u>\$ 7,779</u>	<u>\$ 5,730</u>	<u>\$ 25,946</u>	<u>\$ 15,277</u>

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



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

<i>(in thousands, except for share amounts)</i>	Common Stock		Additional Paid-in Capital	Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Par Value				
<b>Balances at December 31, 2020</b>	54,865,092	\$ 55	\$ 650,300	\$ 239	\$ (197,328)	\$ 453,266
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	695,122	1	1,848	—	—	1,849
Stock-based compensation expense	—	—	3,909	—	—	3,909
Net income	—	—	—	—	8,650	8,650
Other comprehensive loss, net of tax	—	—	—	(47)	—	(47)
<b>Balances at March 31, 2021</b>	55,560,214	\$ 56	\$ 656,057	\$ 192	\$ (188,678)	\$ 467,627
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	67,452	—	289	—	—	289
Stock-based compensation expense	—	—	3,740	—	—	3,740
Net income	—	—	—	—	9,653	9,653
Other comprehensive loss, net of tax	—	—	—	(89)	—	(89)
<b>Balances at June 30, 2021</b>	55,627,666	\$ 56	\$ 660,086	\$ 103	\$ (179,025)	\$ 481,220
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	81,064	—	371	—	—	371
Stock-based compensation expense	—	—	3,951	—	—	3,951
Net income	—	—	—	—	7,771	7,771
Other comprehensive income, net of tax	—	—	—	8	—	8
<b>Balances at September 30, 2021</b>	55,708,730	\$ 56	\$ 664,408	\$ 111	\$ (171,254)	\$ 493,321

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) (Continued)**

<i>(in thousands, except for share amounts)</i>	Common Stock		Additional Paid-in Capital	Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Par Value				
<b>Balances at December 31, 2019</b>	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
<b>Balances at March 31, 2020</b>	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)
<b>Balances at June 30, 2020</b>	54,628,336	\$ 55	\$ 642,398	\$ 596	\$ (211,465)	\$ 431,584
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	61,318	—	123	—	—	123
Stock-based compensation expense	—	—	3,135	—	—	3,135
Net income	—	—	—	—	5,947	5,947
Other comprehensive loss, net of tax	—	—	—	(217)	—	(217)
<b>Balances at September 30, 2020</b>	54,689,654	\$ 55	\$ 645,656	\$ 379	\$ (205,518)	\$ 440,572

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

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

<i>(in thousands)</i>	Nine Months Ended	
	September 30, 2021	September 30, 2020
<b>Cash flows from operating activities</b>		
Net income	\$ 26,074	\$ 15,147
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation of property and equipment	1,026	1,043
Stock-based compensation	11,600	10,148
Amortization of premiums and accretion of discounts on marketable securities	1,451	(175)
Gain on sale of marketable securities	(12)	(229)
Intangible asset amortization	1,109	1,108
Deferred income taxes	5,432	3,793
Other non-cash adjustments, net	1,222	1,361
Changes in operating assets and liabilities:		
Accounts receivable	(11,484)	(1,774)
Prepaid expenses and other assets	(2,932)	2,897
Inventory	(2,156)	(3,128)
Accounts payable and other liabilities	860	1,408
Product revenue allowances	5,417	874
Net cash provided by operating activities	37,607	32,473
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	(418)	(829)
Purchases of marketable securities	(315,187)	(264,112)
Sales and maturities of marketable securities	264,907	240,128
Net cash used in investing activities	(50,698)	(24,813)
<b>Cash flows from financing activities</b>		
Proceeds from the exercise of stock options	2,509	4,202
Net cash provided by financing activities	2,509	4,202
Effect of exchange rate changes on cash, cash equivalents and restricted cash	10	41
Net change in cash, cash equivalents and restricted cash	(10,572)	11,903
<b>Cash, cash equivalents and restricted cash</b>		
Beginning of period	61,613	45,650
End of period	\$ 51,041	\$ 57,553

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

**VANDA PHARMACEUTICALS INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)****1. Business Organization and Presentation*****Business Organization***

Vanda Pharmaceuticals Inc. (the Company) is a global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high unmet medical needs and improve the lives of patients. The Company commenced its operations in 2003 and operates in one reporting segment.

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

- HETLIOZ<sup>®</sup> (tasimelteon) for the treatment of jet lag disorder, delayed sleep phase disorder (DSPD), sleep disturbances in autism spectrum disorder (ASD) and pediatric Non-24;
- Fanapt<sup>®</sup> (iloperidone) for the treatment of bipolar disorder and Parkinson's disease psychosis and a long acting injectable (LAI) formulation for the treatment of schizophrenia;
- Tradipitant (VLY-686), a small molecule neurokinin-1 (NK-1) receptor antagonist, for the treatment of gastroparesis, motion sickness, atopic dermatitis and COVID-19 pneumonia;
- VTR-297, a small molecule histone deacetylase (HDAC) inhibitor for the treatment of hematologic malignancies and with potential use as a treatment for several oncology indications;
- Portfolio of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) activators and inhibitors, including VSJ-110 for the treatment of dry eye and ocular inflammation and BPO-27 for the treatment of secretory diarrhea disorders, including cholera; and
- VQW-765, a small molecule nicotinic acetylcholine receptor partial agonist, with potential use for the treatment of psychiatric disorders.

***Basis of Presentation***

The accompanying unaudited condensed consolidated financial statements includes the accounts of Vanda Pharmaceuticals Inc. and its wholly-owned subsidiaries and have been prepared in accordance with United States generally accepted accounting principles (GAAP) for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the Company's consolidated financial statements and accompanying notes included in the Company's annual report on Form 10-K (Annual Report) for the fiscal year ended December 31, 2020. The financial information as of September 30, 2021 and for the three and nine months ended September 30, 2021 and 2020 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, 2020 was derived from audited financial statements but does not include all disclosures required by GAAP. The results of the Company's operations for any interim period are not necessarily indicative of the results that may be expected for any other interim period or any future year or period.

**2. Summary of Significant Accounting Policies**

There have been no material changes to the significant accounting policies previously disclosed in the Annual Report.

***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates that affect the reported amounts of assets and liabilities at the date of the financial statements, disclosure of contingent assets and liabilities, and the reported amounts of revenue and expenses during the reporting period. Management continually re-evaluates its estimates, judgments and assumptions, and management's evaluation could change. Actual results could differ from those estimates.

### Cash, Cash Equivalents and Restricted Cash

For purposes of the Condensed Consolidated Balance Sheets and Condensed Consolidated Statements of Cash Flows, cash equivalents represent highly-liquid investments with a maturity date of three months or less at the date of purchase. Cash and cash equivalents include investments in money market funds with commercial banks and financial institutions, and commercial paper of high-quality corporate issuers. Restricted cash relates primarily to amounts held as collateral for letters of credit for leases for office space at the Company's Washington, D.C. headquarters.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the Condensed Consolidated Balance Sheets to the total end of period cash, cash equivalents and restricted cash reported within the Condensed Consolidated Statement of Cash Flows:

<i>(in thousands)</i>	September 30, 2021	September 30, 2020
Cash and cash equivalents	\$ 50,522	\$ 56,973
Restricted cash included in:		
Prepaid expenses and other current assets	—	57
Non-current inventory and other	519	523
Total cash, cash equivalents and restricted cash	<u>\$ 51,041</u>	<u>\$ 57,553</u>

### Revenue from Net Product Sales

The Company's net product sales consist of sales of HETLIOZ® and Fanapt®. Net sales by product for the three and nine months ended September 30, 2021 and 2020 were as follows:

<i>(in thousands)</i>	Three Months Ended		Nine Months Ended	
	September 30, 2021	September 30, 2020	September 30, 2021	September 30, 2020
HETLIOZ® net product sales	\$ 45,615	\$ 39,618	\$ 129,467	\$ 116,515
Fanapt® net product sales	24,480	20,690	71,196	64,000
Total net product sales	<u>\$ 70,095</u>	<u>\$ 60,308</u>	<u>\$ 200,663</u>	<u>\$ 180,515</u>

### Major Customers

HETLIOZ® is available in the United States (U.S.) for distribution through a limited number of specialty pharmacies, and is not available in retail pharmacies. Fanapt® is available in the U.S. for distribution through a limited number of wholesalers and is available in retail pharmacies. The Company invoices and records revenue when its customers, specialty pharmacies and wholesalers, receive product from the third-party logistics warehouse, which is the point at which control is transferred to the customer. There were five major customers that each accounted for more than 10% of total revenues and, as a group, represented 92% of total revenues for the nine months ended September 30, 2021. 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 September 30, 2021. Receivables are carried at transaction price net of allowance for credit losses. Allowance for credit losses is measured using historical loss rates based on the aging of receivables and incorporating current conditions and forward-looking estimates.

### Recent Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2019-12, Income Taxes (Topic 740), *Simplifying the Accounting for Income Taxes*, which clarifies and simplifies certain aspects of the accounting for income taxes. The standard is effective for years beginning after December 15, 2020, and interim periods within annual periods beginning after December 15, 2020. The adoption of this standard on January 1, 2021 did not have a material impact on the Company's condensed consolidated financial statements.

### 3. Marketable Securities

The following is a summary of the Company's available-for-sale marketable securities as of September 30, 2021, which all have contractual maturities of less than two years:

<i>(in thousands)</i>	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
U.S. Treasury and government agencies	\$ 177,091	\$ 29	\$ (22)	\$ 177,098
Corporate debt	178,252	106	(10)	178,348
<b>Total marketable securities</b>	<b>\$ 355,343</b>	<b>\$ 135</b>	<b>\$ (32)</b>	<b>\$ 355,446</b>

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

<i>(in thousands)</i>	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
U.S. Treasury and government agencies	\$ 165,966	\$ 129	\$ (3)	\$ 166,092
Corporate debt	140,538	87	(8)	140,617
<b>Total marketable securities</b>	<b>\$ 306,504</b>	<b>\$ 216</b>	<b>\$ (11)</b>	<b>\$ 306,709</b>

### 4. Fair Value Measurements

Authoritative guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include:

- Level 1 — defined as observable inputs such as quoted prices in active markets
- Level 2 — defined as inputs other than quoted prices in active markets that are either directly or indirectly observable
- Level 3 — defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions

The Company's assets classified in Level 1 and Level 2 as of September 30, 2021 and December 31, 2020 consist of cash equivalents and available-for-sale marketable securities. The valuation of Level 1 instruments is determined using a market approach and is based upon unadjusted quoted prices for identical assets in active markets. The valuation of Level 2 instruments is also determined using a market approach based upon quoted prices for similar assets in active markets, or other inputs that are observable for substantially the full term of the financial instrument. Level 2 securities include certificates of deposit, commercial paper, corporate notes and asset-backed securities that use as their basis readily observable market parameters.

The Company held certain assets that are required to be measured at fair value on a recurring basis as of September 30, 2021, as follows:

<i>(in thousands)</i>	Fair Value Measurement as of September 30, 2021 Using			
	Total Fair Value	Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs
			(Level 1)	(Level 2)
U.S. Treasury and government agencies	\$ 177,098	\$ 177,098	\$ —	\$ —
Corporate debt	178,348	—	178,348	—
<b>Total assets measured at fair value</b>	<b>\$ 355,446</b>	<b>\$ 177,098</b>	<b>\$ 178,348</b>	<b>\$ —</b>

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

<i>(in thousands)</i>	Total Fair Value	Fair Value Measurement as of December 31, 2020 Using		
		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	\$ 166,092	\$ 166,092	\$ —	\$ —
Corporate debt	140,617	—	140,617	—
<b>Total assets measured at fair value</b>	<b>\$ 306,709</b>	<b>\$ 166,092</b>	<b>\$ 140,617</b>	<b>\$ —</b>

Total assets measured at fair value as of September 30, 2021 and December 31, 2020 include no cash equivalents.

The Company also has financial assets and liabilities, not required to be measured at fair value on a recurring basis, which primarily consist of cash, accounts receivable, restricted cash, accounts payable and accrued liabilities, product revenue allowances, and milestone obligations under license agreements, the carrying values of which materially approximate their fair values.

## 5. Inventory

Inventory consisted of the following as of September 30, 2021 and December 31, 2020:

<i>(in thousands)</i>	September 30, 2021	December 31, 2020
<b>Current assets</b>		
Work-in-process	\$ —	\$ 66
Finished goods	902	1,214
Total inventory, current	<u>\$ 902</u>	<u>\$ 1,280</u>
<b>Non-Current assets</b>		
Raw materials	\$ 2,016	\$ 744
Work-in-process	4,233	4,045
Finished goods	1,032	302
Total inventory, non-current	<u>7,281</u>	<u>5,091</u>
Total inventory	<u>\$ 8,183</u>	<u>\$ 6,371</u>

## 6. Intangible Assets

**HETLIOZ®**. In January 2014, the Company announced that the FDA had approved the New Drug Application (NDA) for HETLIOZ®. As a result of this approval, the Company met a milestone under its license agreement with Bristol-Myers Squibb (BMS) that required the Company to make a license payment of \$8.0 million to BMS. The \$8.0 million is being amortized on a straight-line basis over the estimated economic useful life of the related product patents.

In April 2018, the Company met its final milestone under its license agreement with BMS when cumulative worldwide sales of HETLIOZ® reached \$250.0 million. As a result of the achievement of this milestone, the Company made a payment to BMS of \$25.0 million in 2018. The \$25.0 million, which was capitalized as an intangible asset in the first quarter of 2015, was determined to be additional consideration for the acquisition of the HETLIOZ® intangible asset and is being amortized on a straight-line basis over the estimated economic useful life of the related product patents.

The following is a summary of the Company's intangible assets as of September 30, 2021:

<i>(in thousands)</i>	Estimated Useful Life	September 30, 2021		
		Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	July 2035	\$ 33,000	\$ 12,550	\$ 20,450

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

(in thousands)	Estimated Useful Life	December 31, 2020		
		Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	July 2035	\$ 33,000	\$ 11,441	\$ 21,559

As of September 30, 2021 and December 31, 2020, 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 September 30, 2021 and 2020. Amortization expense was \$1.1 million for each of the nine months ended September 30, 2021 and 2020. The following is a summary of the future intangible asset amortization schedule as of September 30, 2021:

(in thousands)	Total	2021	2022	2023	2024	2025	Thereafter
HETLIOZ®	\$ 20,450	\$ 370	\$ 1,478	\$ 1,478	\$ 1,478	\$ 1,478	\$ 14,168

## 7. Accounts Payable and Accrued Liabilities

The following is a summary of the Company's accounts payable and accrued liabilities as of September 30, 2021 and December 31, 2020:

(in thousands)	September 30, 2021	December 31, 2020
Research and development expenses	\$ 9,010	\$ 6,173
Consulting and other professional fees	7,371	5,052
Royalties payable	6,061	5,817
Compensation and employee benefits	5,434	10,951
Operating lease liabilities	2,295	2,117
Milestone obligations under license agreements	350	350
Accounts payable and other accrued liabilities	1,299	1,049
Total accounts payable and accrued liabilities	\$ 31,820	\$ 31,509

## 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 September 30, 2021, the Company has paid BMS \$37.5 million in upfront fees and milestone obligations, including \$33.0 million of regulatory approval and commercial milestones capitalized as intangible



assets (see Note 6, *Intangible Assets*). The Company has no remaining milestone obligations to BMS. Additionally, the Company is obligated to make royalty payments on HETLIOZ<sup>®</sup> net sales to BMS in any territory where the Company commercializes HETLIOZ<sup>®</sup> 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<sup>®</sup>.

*Fanapt<sup>®</sup>*. Pursuant to the terms of a settlement agreement with Novartis Pharma AG (Novartis), Novartis transferred all U.S. and Canadian rights in the Fanapt<sup>®</sup> 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<sup>®</sup> net sales equal to 6% on Sanofi know-how not related to manufacturing under certain conditions for a period of up to 10 years in markets where the NCE patent has expired or was not issued. The Company is obligated to pay this 6% royalty on net sales in the U.S. through November 2026.

*Tradipitant*. In April 2012, the Company entered into a license agreement with Eli Lilly and Company (Lilly) pursuant to which the Company acquired an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize an NK-1 receptor antagonist, tradipitant, for all human indications. Lilly is eligible to receive future payments based upon achievement of specified development, regulatory approval and commercialization milestones as well as tiered-royalties on net sales at percentage rates up to the low double digits. As of September 30, 2021, the Company has paid Lilly \$3.0 million in upfront fees and development milestones. As of September 30, 2021, remaining milestone obligations include a \$2.0 million development milestone due upon the filing of the first marketing authorization for tradipitant in either the U.S. or European Union (E.U.), \$10.0 million and \$5.0 million for the first approval of a marketing authorization for tradipitant in the U.S. and E.U., respectively, and up to \$80.0 million for sales milestones. The Company is obligated to use its commercially reasonable efforts to develop and commercialize tradipitant.

*Portfolio of CFTR activators and inhibitors*. In March 2017, the Company entered into a license agreement with the University of California San Francisco (UCSF), under which the Company acquired an exclusive worldwide license to develop and commercialize a portfolio of CFTR activators and inhibitors. Pursuant to the license agreement, the Company will develop and commercialize the CFTR activators and inhibitors and is responsible for all development costs under the license agreement, including current pre-investigational new drug development work. UCSF is eligible to receive future payments based upon achievement of specified development and commercialization milestones as well as single-digit royalties on net sales. As of September 30, 2021, the Company has paid UCSF \$1.2 million in upfront fees and development milestones. As of September 30, 2021, 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 of development milestones are \$1.1 million of milestone obligations due upon the conclusion of clinical studies for each licensed product but not to exceed \$3.2 million in total for the CFTR portfolio. In the fourth quarter of 2020, the Company determined a \$350,000 development milestone to be probable based upon the first clinical study initiated by the Company in the fourth quarter of 2020 and recorded it as research and development expense in the Condensed Consolidated Statements of Operations. The milestone obligation was accrued as a current liability in the Condensed Consolidated Balance Sheets as of September 30, 2021 and December 31, 2020.

*VQW-765*. In connection with a settlement agreement with Novartis relating to Fanapt<sup>®</sup>, the Company received an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize VQW-765, a Phase II alpha-7 nicotinic acetylcholine receptor partial agonist. Pursuant to the license agreement, the Company is obligated to use its commercially reasonable efforts to develop and commercialize VQW-765 and is responsible for all development costs. The Company has no milestone obligations; however, Novartis is eligible to receive tiered-royalties on net sales at percentage rates up to the mid-teens.

#### **Purchase Commitments**

In the course of its business, the Company regularly enters into agreements with 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.

## 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 September 30, 2021 and December 31, 2020:

<i>(in thousands)</i>	September 30, 2021	December 31, 2020
Foreign currency translation	\$ 33	\$ 81
Unrealized gain on marketable securities	78	158
Accumulated other comprehensive income	<u>\$ 111</u>	<u>\$ 239</u>

## 10. Stock-Based Compensation

As of September 30, 2021, there were 5,875,098 shares subject to outstanding options and restricted stock units (RSUs) under the 2006 Equity Incentive Plan (2006 Plan) and the Amended and Restated 2016 Equity Incentive Plan (2016 Plan, and together with the 2006 Plan, Plans). The 2006 Plan expired by its terms in April 2016, and the Company adopted the 2016 Plan. Outstanding options under the 2006 Plan remain in effect and the terms of the 2006 Plan continue to apply, but no additional awards can be granted under the 2006 Plan. In June 2016, the Company's stockholders approved the 2016 Plan. The 2016 Plan has been amended a number of times since to increase the number of shares reserved for issuance, among other administrative changes. Each of the amendments to the 2016 Plan was approved by the Company's stockholders. There is a total of 10,790,000 shares of common stock authorized for issuance under the 2016 Plan, 4,517,717 shares of which remained available for future grant as of September 30, 2021.

### Stock Options

The Company has granted option awards under the Plans with service conditions (service option awards) that are subject to terms and conditions established by the compensation committee of the board of directors. Service option awards have 10-year contractual terms. Service option awards granted to employees and new directors upon their election vest and become exercisable over four years, with the first 25% of the shares subject to service option awards vesting on the first anniversary of the grant date and the remaining 75% of the shares subject to the service option awards in 36 equal monthly installments thereafter. Subsequent annual service option awards granted to directors vest and become exercisable in full on the first anniversary of the grant date. Certain service option awards granted to employees and executive officers provide for partial acceleration of vesting if the employee or executive officer is subject to an involuntary termination, and full acceleration of vesting if the employee or executive officer is subject to an involuntary termination within 24 months after a change in control of the Company. Service option awards granted to directors provide for accelerated vesting if there is a change in control of the Company or if the director's service terminates as a result of the director's death or total and permanent disability.

As of September 30, 2021, \$9.9 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 September 30, 2021.

A summary of option activity under the Plans for the nine months ended September 30, 2021 follows:

<i>(in thousands, except for share and per share amounts)</i>	Number of Shares	Weighted Average Exercise Price at Grant Date	Weighted Average Remaining Term (Years)	Aggregate Intrinsic Value
<b>Outstanding at December 31, 2020</b>	3,606,818	\$ 12.24	5.76	\$ 8,511
Granted	708,500	20.20		
Expired	(10,000)	18.30		
Exercised	(272,760)	9.20		2,075
<b>Outstanding at September 30, 2021</b>	<u>4,032,558</u>	13.83	5.88	17,304
Exercisable at September 30, 2021	<u>2,717,949</u>	12.12	4.47	14,951
Vested and expected to vest at September 30, 2021	<u>3,856,582</u>	13.64	5.73	17,061

The weighted average grant-date fair value of options granted was \$8.91 and \$5.53 per share for the nine months ended September 30, 2021 and 2020, respectively. Proceeds from the exercise of stock options amounted to \$2.5 million and \$4.2 million for the nine months ended September 30, 2021 and 2020, respectively.

### Restricted Stock Units

An RSU is a stock award that entitles the holder to receive shares of the Company's common stock as the award vests. The fair value of each RSU is based on the closing price of the Company's stock on the date of grant. The Company has granted RSUs under the Plans with service conditions (service RSUs) that are subject to terms and conditions established by the compensation committee of the board of directors. Service RSUs granted to employees vest in four equal annual installments provided that the employee remains employed with the Company. Certain service RSUs granted to employees and executive officers provide for accelerated vesting if the employee or executive officer is subject to an involuntary termination within 24 months after a change in control. Annual service RSUs granted to directors vest on the first anniversary of the grant date and provide for accelerated vesting if there is a change in control of the Company.

As of September 30, 2021, \$25.7 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 September 30, 2021.

A summary of RSU activity under the Plans for the nine months ended September 30, 2021 follows:

	Number of Shares	Weighted Average Grant Date Fair Value
<b>Unvested at December 31, 2020</b>	1,639,563	\$ 15.26
Granted	891,305	19.59
Forfeited	(115,950)	16.15
Vested	(572,378)	15.72
<b>Unvested at September 30, 2021</b>	<u>1,842,540</u>	<u>17.15</u>

The grant date fair value for the 572,378 shares underlying RSUs that vested during the nine months ended September 30, 2021 was \$9.0 million.

### Stock-Based Compensation Expense

Stock-based compensation expense recognized for the three and nine months ended September 30, 2021 and 2020 was comprised of the following:

	Three Months Ended		Nine Months Ended	
	September 30, 2021	September 30, 2020	September 30, 2021	September 30, 2020
<i>(in thousands)</i>				
Research and development	\$ 893	\$ 853	\$ 2,970	\$ 2,864
Selling, general and administrative	3,058	2,282	8,630	7,284
Total stock-based compensation expense	<u>\$ 3,951</u>	<u>\$ 3,135</u>	<u>\$ 11,600</u>	<u>\$ 10,148</u>

The fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton option pricing model that uses the assumptions noted in the following table. Expected volatility rates are based on the historical volatility of the Company's publicly traded common stock and other factors. The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The Company has never paid cash dividends to its stockholders and does not plan to pay dividends in the foreseeable future. Assumptions used in the Black-Scholes-Merton option pricing model for employee and director stock options granted during the nine months ended September 30, 2021 and 2020 were as follows:

	Nine Months Ended	
	September 30, 2021	September 30, 2020
Expected dividend yield	0 %	0 %
Weighted average expected volatility	46 %	51 %
Weighted average expected term (years)	5.98	6.07
Weighted average risk-free rate	0.75 %	1.14 %

## 11. Income Taxes

For the three months ended September 30, 2021 and 2020, the Company recorded income tax expense of \$3.0 million and \$2.5 million, respectively. For the nine months ended September 30, 2021 and 2020, the Company recorded income tax expense of \$7.7 million and \$5.6 million, respectively. The income tax expense for the three months ended September 30, 2021 and 2020 was primarily driven by the estimated effective tax rate for the year, as well as discrete income tax expense of \$0.1 million and \$0.5 million, respectively. The income tax expense for the nine months ended September 30, 2021 and 2020 was primarily driven by the estimated effective tax rate for the year, as well as discrete income tax expense of \$0.2 million and \$1.6 million, respectively.

## 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 nine months ended September 30, 2021 and 2020:

<i>(in thousands, except for share and per share amounts)</i>	Three Months Ended		Nine Months Ended	
	September 30, 2021	September 30, 2020	September 30, 2021	September 30, 2020
<b>Numerator:</b>				
Net income	\$ 7,771	\$ 5,947	\$ 26,074	\$ 15,147
<b>Denominator:</b>				
Weighted average shares outstanding, basic	55,668,156	54,666,128	55,467,528	54,325,832
Effect of dilutive securities	1,372,580	542,904	1,350,767	728,940
Weighted average shares outstanding, diluted	57,040,736	55,209,032	56,818,295	55,054,772
<b>Net income per share, basic and diluted:</b>				
Basic	\$ 0.14	\$ 0.11	\$ 0.47	\$ 0.28
Diluted	\$ 0.14	\$ 0.11	\$ 0.46	\$ 0.28
Antidilutive securities excluded from calculations of diluted net income per share	2,233,806	3,898,896	2,194,547	3,602,648

## 13. Legal Matters

*Fanapt*<sup>®</sup>. 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*<sup>®</sup> Defendants) each submitted an Abbreviated New Drug Applications (ANDA) to the FDA seeking approval to market generic versions of *Fanapt*<sup>®</sup> prior to the expiration of certain of the Company's patents covering *Fanapt*<sup>®</sup>, 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*<sup>®</sup> Defendants in the U.S. District Court for the District of Delaware (Delaware District Court) for patent infringement.

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

The Company entered into separate license agreements with each of Taro, Apotex and Lupin resolving these lawsuits in October 2016, December 2016 and July 2020, respectively. The license agreements grant Taro, Apotex and Lupin non-

exclusive licenses to manufacture and commercialize a version of Fanapt® in the U.S. effective as of the expiration of the '610 Patent or earlier under certain limited circumstances. The Company entered into a confidential stipulation with Inventia regarding any potential launch of its generic versions of Fanapt®, but the Company's lawsuit against Inventia regarding the '610 and '432 Patents remains pending.

**HETLIOZ®.** Between April 2018 and March 2021, the Company filed numerous Hatch-Waxman lawsuits in the Delaware District Court against Teva Pharmaceuticals USA, Inc. (Teva), MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited (MSN) and Apotex (collectively, the HETLIOZ® Defendants) asserting that U.S. Patent Nos. RE46,604, 9,060,995, 9,539,234, 9,549,913, 9,730,910, 9,844,241, 10,071,977, 10,149,829, 10,376,487, 10,449,176, 10,610,510, 10,610,511, 10,829,465, and 10,611,744 will be infringed by the HETLIOZ® Defendants' generic versions of HETLIOZ® for which they are seeking FDA approval. These consolidated lawsuits are scheduled for trial in March 2022.

**Other Matters.** In February 2019, a qui tam action filed against the Company was unsealed by order of the U.S. District Court for the District of Columbia (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 has continued to litigate this action and the DOJ and the Plaintiff States may later seek to intervene. In August 2019, the Company filed a motion to dismiss, and 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. In July 2020, the Company filed another motion to dismiss, which was denied by the DC District Court in March 2021. The Company filed its answer to the plaintiff's second amended complaint in April 2021 and 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. In March 2021, the motion to dismiss was granted in part and denied in part. In April 2021, the Company filed its answer to the amended 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. In April 2021, the parties to the consolidated case reached a settlement to resolve all of the claims asserted in the consolidated complaint for the *Williams* and *Bavaro* cases, with no admission of wrongdoing by any defendant. In September 2021, the Court issued an order approving the settlement, which does not have a material impact to the Company's business, results of operation or financial condition.

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

- HETLIOZ<sup>®</sup> (tasimelteon) for the treatment of jet lag disorder, delayed sleep phase disorder (DSPD), sleep disturbances in autism spectrum disorder (ASD) and pediatric Non-24;
- Fanapt<sup>®</sup> (iloperidone) for the treatment of bipolar disorder and Parkinson's disease psychosis and a long acting injectable (LAI) formulation for the treatment of schizophrenia;
- Tradipitant (VLY-686), a small molecule neurokinin-1 (NK-1) receptor antagonist, for the treatment of gastroparesis, motion sickness, atopic dermatitis and COVID-19 pneumonia;
- VTR-297, a small molecule histone deacetylase (HDAC) inhibitor for the treatment of hematologic malignancies and with potential use as a treatment for several oncology indications;
- Portfolio of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) activators and inhibitors, including VSJ-110 for the treatment of dry eye and ocular inflammation and BPO-27 for the treatment of secretory diarrhea disorders, including cholera; and
- VQW-765, a small molecule nicotinic acetylcholine receptor partial agonist, with potential use for the treatment of psychiatric disorders.

### Operational Highlights

#### Tradipitant

- Enrollment of the randomized portion of the Phase III clinical study of tradipitant in gastroparesis is complete. The randomized portion of the study is a 12-week study of approximately 200 patients with idiopathic or diabetic gastroparesis. Results are expected by the end of 2021. Enrollment of the open label portion of the study is ongoing with more than 250 patients enrolled.

#### HETLIOZ<sup>®</sup>

- In December 2020, the FDA approved HETLIOZ<sup>®</sup> capsule and liquid formulations for the treatment of adults and children, respectively, with nighttime sleep disturbances in SMS. To date, more than 90 patients with SMS have been prescribed HETLIOZ<sup>®</sup> or HETLIOZ LQ<sup>™</sup> and a broad awareness campaign is expected to begin during the fourth quarter of 2021.
- A Phase III clinical study of HETLIOZ<sup>®</sup> in DSPD is currently enrolling patients. The study has a 28-day randomized evaluation period and plans to enroll approximately 300 patients. DSPD is likely the most prevalent circadian-rhythm sleep disorder, affecting approximately 1% of the population, and there is no FDA approved treatment at this time.

#### Fanapt<sup>®</sup>

- A Phase III clinical study of Fanapt<sup>®</sup> in acute bipolar mania disorder is currently enrolling. The study is a placebo controlled four-week evaluation of approximately 400 patients at sites in the U.S. and Europe.
- A repeat-dose clinical pharmacology study of the LAI formulation of Fanapt<sup>®</sup> is ongoing. A Phase III study of the LAI formulation for the treatment of acute schizophrenia is planned to follow the pharmacology study.

- Evaluation of P88, the active metabolite of iloperidone, has been initiated. P88 has the potential to improve the clinical profile of Fanapt® and create sustained, long-term value in the treatment of psychiatric disorders.

Since we began operations, we have devoted substantially all of our resources to the in-licensing, clinical development and commercialization of our products. Our ability to generate meaningful product sales and achieve profitability largely depends on our level of success in commercializing HETLIOZ® and Fanapt® in the U.S. and Europe, on our ability, alone or with others, to complete the development of our products, and to obtain the regulatory approvals for and to manufacture, market and sell our products. The results of our operations will vary significantly from year-to-year and quarter-to-quarter and depend on a number of factors, including risks related to our business, risks related to our industry, and other risks that are detailed in Part I, Item 1A, *Risk Factors*, of our annual report on Form 10-K (Annual Report) for the year ended December 31, 2020.

### **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 Part II, Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations*, included in the Annual Report. A summary of our significant accounting policies appears in the notes to our audited consolidated financial statements included in the Annual Report. 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.

*Revenue from 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 sell HETLIOZ® in Germany and have a distribution agreement with Megapharm Ltd. for the commercialization of Fanapt® in Israel. Receivables are carried at transaction price net of allowance for credit losses. Allowance for credit losses is measured using historical loss rates based on the aging of receivables and incorporating current conditions and forward-looking estimates.

The transaction price is determined based upon the consideration to which we will be entitled in exchange for transferring product to the customer. Our product sales are recorded net of applicable product revenue allowances for which reserves are established and include discounts, rebates, chargebacks, service fees, co-pay assistance and product returns that are applicable for various government and commercial payors. Where appropriate, our estimates of variable consideration included in the transaction price consider a range of possible outcomes. Allowances for rebates, chargebacks and co-pay assistance are based upon the insurance benefits of the end customer, which are estimated using historical activity and, where available, actual and pending prescriptions for which we have validated the insurance benefits. Variable consideration is included in the transaction price if, in our judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which we are entitled based on the terms of the respective underlying contracts. If actual results in the future vary from our estimates, we adjust our estimate in the period identified, which would affect net product sales in the period such variances become known.

Reserves for variable consideration are classified as product revenue allowances on the Condensed Consolidated Balance Sheets, with the exception of prompt-pay discounts which are classified as reductions of accounts receivable. The reserve for product returns for which the product may not be returned for a period of greater than one year from the balance sheet date is included as a component of other non-current liabilities in the Condensed Consolidated Balance Sheets. Uncertainties related to

variable consideration are generally resolved in the quarter subsequent to period end, with the exception of Medicaid rebates, which are dependent upon the timing of when states submit reimbursement claims, and product returns that are resolved during the product expiry period specified in the customer contract. We currently record sales allowances for the following:

*Prompt-pay:* Specialty pharmacies and wholesalers are offered discounts for prompt payment. We expect that the specialty pharmacies and wholesalers will earn prompt payment discounts and, therefore, deduct the full amount of these discounts from total product sales when revenues are recognized.

*Rebates:* Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program as well as contracted rebate programs with other payors. Rebate amounts owed after the final dispensing of the product to a benefit plan participant are based upon contractual agreements or legal requirements with public sector benefit providers, such as Medicaid. The allowance for rebates is based on statutory or contracted discount rates and estimated patient utilization.

*Chargebacks:* Chargebacks are discounts that occur when contracted indirect customers purchase directly from specialty pharmacies and wholesalers. Contracted indirect customers, which currently consist primarily of Public Health Service institutions and federal government entities purchasing via the Federal Supply Schedule, generally purchase the product at a discounted price. The specialty pharmacy or wholesaler, in turn, charges back the difference between the price initially paid by the specialty pharmacy or wholesaler and the discounted price paid to the specialty pharmacy or wholesaler by the contracted customer.

*Medicare Part D coverage gap:* The Medicare Part D prescription drug benefit requires manufacturers to fund approximately 70% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients for applicable drugs. We account for the Medicare Part D coverage gap using a point of sale model. Estimates for expected Medicare Part D coverage gap are based in part on historical activity and, where available, actual and pending prescriptions when we have validated the insurance benefits.

*Service fees:* We receive sales order management, data and distribution services from certain customers for which we are assessed fees. These fees are based on contracted terms and are known amounts. We accrue service fees at the time of revenue recognition, resulting in a reduction of product sales and the recognition of an accrued liability, unless it is a payment for a distinct good or service from the customer in which case the fair value of those distinct goods or services are recorded as selling, general and administrative expense.

*Co-payment assistance:* Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. Co-pay assistance utilization is based on information provided by our third-party administrator.

*Product returns:* We generally offer direct customers a limited right to return as contractually defined with our customers. We consider several factors in the estimation process, including expiration dates of product shipped to customers, inventory levels within the distribution channel, product shelf life, historical return activity, including activity for product sold for which the return period has past, prescription trends and other relevant factors. We do not expect returned goods to be resalable. There was no right of return asset as of September 30, 2021 or December 31, 2020.

The following table summarizes sales discounts and allowance activity as of and for the nine months ended September 30, 2021:

<i>(in thousands)</i>	Rebates & Chargebacks	Discounts, Returns and Other	Total
<b>Balances at December 31, 2020</b>	\$ 26,870	\$ 8,873	\$ 35,743
Provision related to current period sales	62,616	23,163	85,779
Adjustments for prior period sales	(778)	(132)	(910)
Credits/payments made	(56,268)	(22,937)	(79,205)
<b>Balances at September 30, 2021</b>	<b>\$ 32,440</b>	<b>\$ 8,967</b>	<b>\$ 41,407</b>

The provision of \$62.6 million for rebates and chargebacks for the nine months ended September 30, 2021 primarily represents Medicaid rebates applicable to sales of Fanapt® and HETLIOZ®. The provision of \$23.2 million for discounts, returns and other for the nine months ended September 30, 2021 represents wholesaler distribution fees applicable to sales of Fanapt® and, to a lesser extent, estimated product returns of Fanapt®, and co-pay assistance costs and prompt pay discounts applicable to the sales of both HETLIOZ® and Fanapt®.

*Stock-based compensation.* Compensation costs for all stock-based awards to employees and directors are measured based on the grant date fair value of those awards and recognized over the period during which the employee or director is required to perform service in exchange for the award. We use the Black-Scholes-Merton option pricing model to determine the fair value



of stock options. The determination of the fair value of stock options on the date of grant using an option pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include the expected stock price volatility over the expected term of the awards, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends. Expected volatility rates are based on the historical volatility of our publicly traded common stock and other factors. The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. We have never paid cash dividends to our stockholders and do not plan to pay dividends in the foreseeable future. As stock-based compensation expense recognized in the Condensed Consolidated Statements of Operations is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

*Research and development expenses.* Research and development expenses consist primarily of fees for services provided by third parties in connection with the clinical trials, costs of contract manufacturing services for clinical trial use, milestone payments made under licensing agreements prior to regulatory approval, costs of materials used in clinical trials and research and development, costs for regulatory consultants and filings, depreciation of capital resources used to develop products, related facilities costs, and salaries, other employee-related costs and stock-based compensation for research and development personnel. We expense research and development costs as they are incurred for products in the development stage, including manufacturing costs and milestone payments made under license agreements prior to FDA approval. Upon and subsequent to FDA approval, manufacturing and milestone payments made under license agreements are capitalized. Milestone payments are accrued when it is deemed probable that the milestone event will be achieved. Costs related to the acquisition of intellectual property are expensed as incurred if the underlying technology is developed in connection with our research and development efforts and has no alternative future use.

Clinical trials are inherently complex, often involve multiple service providers, and can include payments made to investigator physicians at study sites. Because billing for services often lags delivery of service by a substantial amount of time, we often are required to estimate a significant portion of our accrued clinical expenses. Our assessments include, but are not limited to: (i) an evaluation by the project manager of the work that has been completed during the period, (ii) measurement of progress prepared internally and/or provided by the third-party service provider, (iii) analyses of data that justify the progress, and (iv) management's judgment. In the event that we do not identify certain costs that have begun to be incurred or we under- or over-estimate the level of services performed or the costs of such services, our reported expenses for such period would be too low or too high.

*Intangible assets.* Our intangible assets consist of capitalized license costs for products approved by the FDA. We amortize our intangible assets on a straight-line basis over the estimated useful economic life of the related product patents. We assess the impairment of intangible assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors we consider important that could trigger an impairment review include significant underperformance relative to expected historical or projected future operating results, a significant adverse change in legal or regulatory factors that could affect the value or patent life including our ability to defend and enforce patent claims and other intellectual property rights and significant negative industry or economic trends. When we determine that the carrying value of our intangible assets may not be recoverable based upon the existence of one or more of the indicators of impairment, we measure any impairment based on the amount that carrying value exceeds fair value. No impairments have been recognized on our intangible assets.

*Income taxes.* We assess the need for a valuation allowance against our deferred tax asset each quarter through the review of all available positive and negative evidence. Deferred tax assets are reduced by a tax valuation allowance when, in the opinion of management, it is more likely than not that some portion of the deferred tax assets will not be realized. The analysis is highly dependent upon historical and projected taxable income. Projected taxable income includes significant assumptions related to revenue, commercial expenses and research and development activities. Tax benefits are recognized from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax benefit recognized in the financial statements for a particular tax position is based on the largest benefit that is more likely than not to be realized upon settlement.

### **Recent Accounting Pronouncements**

See Note 2, *Summary of Significant Accounting Policies*, to the condensed consolidated financial statements included in Part I of this quarterly report on Form 10-Q (Quarterly Report) for information on recent accounting pronouncements.

## Results of Operations

We anticipate that our results of operations will fluctuate for the foreseeable future due to several factors, including our and our partners' ability to continue to successfully commercialize our products, any possible payments made or received pursuant to license agreements, progress of our research and development efforts, the timing and outcome of clinical trials and related possible regulatory approvals, and the impact of the COVID-19 pandemic.

### Three months ended September 30, 2021 compared to three months ended September 30, 2020

*Revenues.* Total revenues increased by \$9.8 million, or 16%, to \$70.1 million for the three months ended September 30, 2021 compared to \$60.3 million for the three months ended September 30, 2020. Revenues were as follows:

<i>(in thousands)</i>	Three Months Ended			
	September 30, 2021	September 30, 2020	Net Change	Percent
HETLIOZ <sup>®</sup> net product sales	\$ 45,615	\$ 39,618	\$ 5,997	15 %
Fanapt <sup>®</sup> net product sales	24,480	20,690	3,790	18 %
Total net product sales	\$ 70,095	\$ 60,308	\$ 9,787	16 %

HETLIOZ<sup>®</sup> net product sales increased by \$6.0 million, or 15%, to \$45.6 million for the three months ended September 30, 2021 compared to \$39.6 million for the three months ended September 30, 2020. The increase to net product sales was attributable to an increase in price net of deductions partially offset by a decrease in volume.

Fanapt<sup>®</sup> net product sales increased by \$3.8 million, or 18%, to \$24.5 million for the three months ended September 30, 2021 compared to \$20.7 million for the three months ended September 30, 2020. The increase to net product sales was attributable to an increase in price net of deductions partially offset by a decrease in volume.

*Cost of goods sold.* Cost of goods sold increased by \$0.9 million, or 15%, to \$6.8 million for the three months ended September 30, 2021 compared to \$5.9 million for the three months ended September 30, 2020. Cost of goods sold includes third-party manufacturing costs of product sold, third-party royalty costs and distribution and other costs. Third-party royalty costs were 10% and 5% of HETLIOZ<sup>®</sup> net product sales in the U.S. and Germany, respectively. Third-party royalty costs on Fanapt<sup>®</sup> net product sales decreased from 9% to 6% beginning January 2020.

In addition to third-party royalty costs, HETLIOZ<sup>®</sup> and Fanapt<sup>®</sup> 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<sup>®</sup> manufacturing costs included in cost of goods sold will continue to be less than 2% of HETLIOZ<sup>®</sup> net product sales. We expect that, in the future, total Fanapt<sup>®</sup> manufacturing costs included in cost of goods sold will continue to be less than 3% of Fanapt<sup>®</sup> net product sales.

*Research and development expenses.* Research and development expenses increased by \$7.4 million, or 60%, to \$19.7 million for the three months ended September 30, 2021 compared to \$12.3 million for the three months ended September 30, 2020. The increase in research and development expenses was associated with our Fanapt<sup>®</sup> and tradipitant development programs, as well as our other development programs, including VQW-765 and P88.

The following table summarizes the costs of our product development initiatives for the three months ended September 30, 2021 and 2020:

<i>(in thousands)</i>	Three Months Ended	
	September 30, 2021	September 30, 2020
Direct project costs (1)		
HETLIOZ®	\$ 3,038	\$ 2,664
Fanapt®	5,713	1,778
Tradipitant	5,389	4,782
VTR-297	526	272
CFTR	586	698
Other	2,612	391
Total direct project costs	17,864	10,585
Indirect project costs (1)		
Stock-based compensation	893	853
Other indirect overhead	896	860
Total indirect project costs	1,789	1,713
Total research and development expense	<u>\$ 19,653</u>	<u>\$ 12,298</u>

(1) We record direct costs, including personnel costs and related benefits, on a project-by-project basis. Many of our research and development costs are not attributable to any individual project because we share resources across several development projects. We record indirect costs that support a number of our research and development activities in the aggregate, including stock-based compensation.

We expect to incur significant research and development expenses as we continue to develop our products. In addition, we expect to incur licensing costs in the future that could be substantial, as we continue our efforts to expand our product pipeline.

*Selling, general and administrative expenses.* Selling, general and administrative expenses decreased by \$1.5 million, or 5%, to \$32.5 million for the three months ended September 30, 2021 compared to \$34.0 million for the three months ended September 30, 2020. The decrease in selling, general and administrative expenses was primarily the result of a decrease in 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 September 30, 2021 and 2020.

*Other income (expense).* Other income (expense) was \$0.1 million expense for the three months ended September 30, 2021 compared to \$0.7 million income for the three months ended September 30, 2020. Other income primarily consists of investment income on our marketable securities.

*Provision for income taxes.* Income tax expense was \$3.0 million for the three months ended September 30, 2021 compared to \$2.5 million for the three months ended September 30, 2020. The income tax expense for the three months ended September 30, 2021 and 2020 was primarily driven by the estimated effective tax rate for the year, as well as discrete income tax expense of \$0.1 million and \$0.5 million, respectively.

#### ***Nine months ended September 30, 2021 compared to nine months ended September 30, 2020***

*Revenues.* Total revenues increased by \$20.1 million, or 11%, to \$200.7 million for the nine months ended September 30, 2021 compared to \$180.5 million for the nine months ended September 30, 2020. Revenues were as follows:

(in thousands)	Nine Months Ended			
	September 30, 2021	September 30, 2020	Net Change	Percent
HETLIOZ <sup>®</sup> net product sales	\$ 129,467	\$ 116,515	\$ 12,952	11 %
Fanapt <sup>®</sup> net product sales	71,196	64,000	7,196	11 %
Total net product sales	\$ 200,663	\$ 180,515	\$ 20,148	11 %

HETLIOZ<sup>®</sup> net product sales increased by \$13.0 million, or 11%, to \$129.5 million for the nine months ended September 30, 2021 compared to \$116.5 million for the nine months ended September 30, 2020. The increase to net product sales was attributable to an increase in price net of deductions partially offset by a decrease in volume.

Fanapt<sup>®</sup> net product sales increased by \$7.2 million, or 11%, to \$71.2 million for the nine months ended September 30, 2021 compared to \$64.0 million for the nine months ended September 30, 2020. The increase to net product sales was attributable to an increase in price net of deductions partially offset by a decrease in volume.

*Cost of goods sold.* Cost of goods sold increased by \$2.4 million, or 14%, to \$19.4 million for the nine months ended September 30, 2021 compared to \$17.0 million for the nine months ended September 30, 2020. Cost of goods sold includes third-party manufacturing costs of product sold, third-party royalty costs and distribution and other costs. Third-party royalty costs were 10% and 5% of HETLIOZ<sup>®</sup> net product sales in the U.S. and Germany, respectively. Third-party royalty costs on Fanapt<sup>®</sup> net product sales decreased from 9% to 6% beginning January 2020.

In addition to third-party royalty costs, HETLIOZ<sup>®</sup> and Fanapt<sup>®</sup> 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<sup>®</sup> manufacturing costs included in cost of goods sold will continue to be less than 2% of HETLIOZ<sup>®</sup> net product sales. We expect that, in the future, total Fanapt<sup>®</sup> manufacturing costs included in cost of goods sold will continue to be less than 3% of Fanapt<sup>®</sup> net product sales.

*Research and development expenses.* Research and development expenses increased by \$15.3 million, or 38%, to \$56.0 million for the nine months ended September 30, 2021 compared to \$40.7 million for the nine months ended September 30, 2020. The increase in research and development expenses was associated with our Fanapt<sup>®</sup>, HETLIOZ<sup>®</sup> and tradipitant development programs, as well as our other development programs, including VQW-765 and P88.

The following table summarizes the costs of our product development initiatives for the nine months ended September 30, 2021 and 2020:

(in thousands)	Nine Months Ended	
	September 30, 2021	September 30, 2020
Direct project costs (1)		
HETLIOZ <sup>®</sup>	\$ 8,419	\$ 6,562
Fanapt <sup>®</sup>	15,126	6,386
Tradipitant	18,456	17,367
VTR-297	1,431	979
CFTR	2,660	2,439
Other	4,158	1,488
Total direct project costs	50,250	35,221
Indirect project costs (1)		
Stock-based compensation	2,970	2,864
Other indirect overhead	2,812	2,643
Total indirect project costs	5,782	5,507
Total research and development expense	\$ 56,032	\$ 40,728

(1) We record direct costs, including personnel costs and related benefits, on a project-by-project basis. Many of our research and development costs are not attributable to any individual project because we share resources across several

development projects. We record indirect costs that support a number of our research and development activities in the aggregate, including stock-based compensation.

We expect to incur significant research and development expenses as we continue to develop our products. In addition, we expect to incur licensing costs in the future that could be substantial, as we continue our efforts to expand our product pipeline.

*Selling, general and administrative expenses.* Selling, general and administrative expenses decreased by \$14.3 million, or 14%, to \$90.6 million for the nine months ended September 30, 2021 compared to \$104.9 million for the nine months ended September 30, 2020. The decrease in selling, general and administrative expenses was primarily the result of a decrease in spending on marketing activities for our commercial products.

*Intangible asset amortization.* Intangible asset amortization was \$1.1 million for each of the nine months ended September 30, 2021 and September 30, 2020.

*Other income.* Other income was \$0.2 million for the nine months ended September 30, 2021 compared to \$3.9 million for the nine months ended September 30, 2020. Other income primarily consists of investment income, which decreased beginning in the second half of 2020 as a result of lower yields on our marketable securities.

*Provision for income taxes.* Income tax expense was \$7.7 million for the nine months ended September 30, 2021 compared to \$5.6 million for the nine months ended September 30, 2020. The income tax expense for the nine months ended September 30, 2021 and 2020 was primarily driven by the estimated effective tax rate for the year, as well as discrete income tax expense of \$0.2 million and \$1.6 million, respectively.

### Liquidity and Capital Resources

As of September 30, 2021, our total cash and cash equivalents and marketable securities were \$406.0 million compared to \$367.7 million at December 31, 2020. Our cash and cash equivalents are deposits in operating accounts and highly liquid investments with an original maturity of 90 days or less at date of purchase and consist of investments in money market funds with commercial banks and financial institutions and commercial paper of high-quality corporate issuers. Our marketable securities consist of investments in government sponsored and corporate enterprises and commercial paper.

Our liquidity resources as of September 30, 2021 and December 31, 2020 are summarized as follows:

<i>(in thousands)</i>	September 30, 2021	December 31, 2020
Cash and cash equivalents	\$ 50,522	\$ 61,031
Marketable securities:		
U.S. Treasury and government agencies	177,098	166,092
Corporate debt	178,348	140,617
<b>Total marketable securities</b>	<b>355,446</b>	<b>306,709</b>
<b>Total cash, cash equivalents and marketable securities</b>	<b>\$ 405,968</b>	<b>\$ 367,740</b>

As of September 30, 2021, we maintained all of our cash, cash equivalents and marketable securities in two financial institutions. Deposits held with these institutions may exceed the amount of insurance provided on such deposits, but we do not anticipate any losses with respect to such deposits.

Based on our current operating plans, which include costs and expenses in connection with our continued clinical development of tradipitant and our other products, U.S. commercial activities for HETLIOZ<sup>®</sup> and Fanapt<sup>®</sup>, pursuit of market approval of HETLIOZ<sup>®</sup> and Fanapt<sup>®</sup> in other regions, and payments due upon achievement of milestones under our license agreements, we believe that our cash, cash equivalents and marketable securities and cash received from product sales will be sufficient for at least the next 12 months. Our future capital requirements and the adequacy of our available funds will depend on many factors, 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 nine months ended September 30, 2021 and 2020:

<i>(in thousands)</i>	Nine Months Ended		
	September 30, 2021	September 30, 2020	Net Change
<b>Net cash provided by (used in):</b>			
Operating activities:			
Net income	\$ 26,074	\$ 15,147	\$ 10,927
Non-cash charges	21,828	17,049	4,779
Net change in operating assets and liabilities	(10,295)	277	(10,572)
Operating activities	37,607	32,473	5,134
Investing activities:			
Purchases of property and equipment	(418)	(829)	411
Net purchases, sales and maturities of marketable securities	(50,280)	(23,984)	(26,296)
Investing activities	(50,698)	(24,813)	(25,885)
Financing activities:			
Proceeds from the exercise of stock options	2,509	4,202	(1,693)
Financing activities	2,509	4,202	(1,693)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	10	41	(31)
Net change in cash, cash equivalents and restricted cash	<u>\$ (10,572)</u>	<u>\$ 11,903</u>	<u>\$ (22,475)</u>

*Operating Activities:* Cash flows provided by operating activities during the nine months ended September 30, 2021 were \$37.6 million, an increase of \$5.1 million compared to cash flows provided by operating activities of \$32.5 million for the nine months ended September 30, 2020. The increase primarily reflects an increase of \$10.9 million in net income and an increase of \$4.8 million in non-cash charges, partially offset by a decrease of \$10.6 million from the net change in operating assets and liabilities. The decrease of \$10.6 million from the net change in operating assets and liabilities primarily relates to an increase in accounts receivable attributable to the timing of shipments and payments.

*Investing Activities:* Cash flows used in investing activities during the nine months ended September 30, 2021 were \$50.7 million, a decrease of \$25.9 million compared to cash flows used in investing activities of \$24.8 million for the nine months ended September 30, 2020. Investing activities primarily include purchases, sales and maturities of marketable securities.

*Financing Activities:* Cash flows provided by financing activities during the nine months ended September 30, 2021 were \$2.5 million, a decrease of \$1.7 million compared to \$4.2 million for the nine months ended September 30, 2020. 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 non-cancellable long-term contractual cash obligations as of September 30, 2021:

(in thousands)	Cash payments due by year (4)						
	Total	2021	2022	2023	2024	2025	Thereafter
Operating leases (1)	\$ 16,376	\$ 640	\$ 2,606	\$ 2,461	\$ 2,488	\$ 2,557	\$ 5,624
Milestone obligation (2)	350	350	—	—	—	—	—
Purchase commitments (3)	956	475	481	—	—	—	—
Total non-cancellable long-term contractual cash obligations	<u>\$ 17,682</u>	<u>\$ 1,465</u>	<u>\$ 3,087</u>	<u>\$ 2,461</u>	<u>\$ 2,488</u>	<u>\$ 2,557</u>	<u>\$ 5,624</u>

- (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) This table includes a probable future \$350,000 milestone obligation under our license agreement with University of California San Francisco. 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 September 30, 2021. See Note 8, *Commitments and Contingencies*, to the condensed consolidated financial statements included in Part I of this Quarterly Report, for a description of our licensing arrangements and remaining milestone obligations.
- (3) Purchase commitments include non-cancellable 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 cancellable 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.
- (4) This table does not include liabilities related to uncertain tax positions taken as of September 30, 2021. 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 that are generally investment grade, liquid, short-term fixed income securities and money-market instruments denominated in U.S. dollars. Our marketable securities consist of commercial paper, corporate notes and U.S. government agency notes.

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 92% of total revenues for the nine months ended September 30, 2021. 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 September 30, 2021. 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 September 30, 2021. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of September 30, 2021, 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 third quarter of 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II — OTHER INFORMATION**

### **ITEM 1        Legal Proceedings**

Information with respect to this item may be found in Note 13, *Legal Matters*, to the condensed consolidated financial statements in Part I of this quarterly report on Form 10-Q, which is incorporated herein by reference.

### **ITEM 1A      Risk Factors**

We previously disclosed in Part I, Item 1A of our annual report on Form 10-K (Annual Report) for the year ended December 31, 2020, filed with the Securities and Exchange Commission on February 11, 2021, 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. There have been no material changes in our risk factors subsequent to the filing of our Annual Report for the fiscal year ended December 31, 2020.

### **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	<a href="#">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).</a>
3.2	<a href="#">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).</a>
31.1	<a href="#">Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.</a>
31.2	<a href="#">Certification of the Chief Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.</a>
32.1	<a href="#">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.</a>
101	The following financial information from this quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2021 formatted in Inline Extensible Business Reporting Language (iXBRL) and filed electronically herewith: (i) Condensed Consolidated Balance Sheets as of September 30, 2021 and December 31, 2020; (ii) Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2021 and 2020; (iii) Condensed Consolidated Statements of Comprehensive Income for the three and nine months ended September 30, 2021 and 2020; (iv) Condensed Consolidated Statements of Changes in Stockholders' Equity for the three and nine months ended September 30, 2021 and 2020; (v) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2021 and 2020; 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.**

November 4, 2021

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

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

November 4, 2021

/s/ Kevin Moran

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

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

I, Mihael H. Polymeropoulos, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Vanda Pharmaceuticals Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 4, 2021

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

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

**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.

November 4, 2021

/s/ Kevin Moran

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**Kevin Moran**

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

## 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 September 30, 2021 (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.

November 4, 2021

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

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

November 4, 2021

/s/ Kevin Moran

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**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.*