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

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2019
or

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

For the transition period from _____ to _____
Commission File Number: 001-34186

VANDA PHARMACEUTICALS INC.
(Exact name of registrant as specified in its charter)

Delaware	**03-0491827**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2200 Pennsylvania Avenue, N.W., Suite 300 E **Washington, DC**	**20037**
(Address of principal executive offices)	**(Zip Code)**

(202) 734-3400
(Registrant's telephone number, including area code)

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

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

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No x

As of October 31, 2019, there were 53,337,085 shares of the registrant's common stock issued and outstanding.

Vanda Pharmaceuticals Inc.

Quarterly Report on Form 10-Q
For the Quarter Ended September 30, 2019

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q contains statements throughout this report are "forward-looking statements" within the meaning of the Section 27A of the Securities Act of 1933, as amended (Securities Act) and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act). Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "plan," "project," "target," "goal," "likely," "will," "would," and "could," or the negative of these terms and similar expressions or words, identify forward-looking statements. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Important factors that could cause actual results to differ materially from those reflected in our forward-looking statements include, among others:

- the ability of Vanda Pharmaceuticals Inc. (we, our, the Company or Vanda) to continue to commercialize HETLIOZ® (tasimelteon) for the treatment of non-24-hour sleep-wake disorder (Non-24) in the United States (U.S.) and Europe;
- uncertainty as to the ability to increase market awareness of Non-24 and the market acceptance of HETLIOZ®;
- our ability to continue to generate U.S. sales of Fanapt® (iloperidone) for the treatment of schizophrenia;
- our dependence on third-party manufacturers to manufacture HETLIOZ® and Fanapt® in sufficient quantities and quality;
- our level of success in commercializing HETLIOZ® and Fanapt® in new markets;
- our ability to prepare, file, prosecute, defend and enforce any patent claims and other intellectual property rights;
- 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;
- a loss of rights to develop and commercialize our products under our license agreements;
- our ability to obtain approval from the FDA for HETLIOZ® for the treatment of Jet Lag Disorder;
- the ability to obtain and maintain regulatory approval of our products, and the labeling for any approved products;
- the timing and success of preclinical studies and clinical trials;
- a failure of our products to be demonstrably safe and effective;
- limitations on our ability to utilize some or all of our prior net operating losses and orphan drug and research and development credits;
- the size and growth of the potential markets for our products and the ability to serve those markets;
- our expectations regarding trends with respect to our revenues, costs, expenses, liabilities and cash, cash equivalents and marketable securities;
- the scope, progress, expansion and costs of developing and commercializing our products;
- our failure to identify or obtain rights to new products;
- a loss of any of our key scientists or management personnel;
- the cost and effects of litigation;
- our ability to obtain the capital necessary to fund our research and development or commercial activities;
- regulatory developments in the United States, Europe and other foreign countries;
- potential losses incurred from product liability claims made against us; and
- 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 or referred to in this section. We caution investors not to rely too heavily on the forward-looking statements we make or that are made on our behalf. We undertake no obligation, and specifically decline any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

We encourage you to read *Management's Discussion and Analysis of Financial Condition and Results of Operations* and our unaudited condensed consolidated financial statements contained in this quarterly report on Form 10-Q. In addition to the risks described below and in Item 1A of Part I of our annual report on Form 10-K for the fiscal year ended December 31, 2018, other unknown or unpredictable factors also could affect our results. Therefore, the information in this quarterly report should be read

together with other reports and documents that we file with the Securities and Exchange Commission from time to time, including on Form 10-Q and Form 8-K, which may supplement, modify, supersede or update those risk factors. As a result of these factors, we cannot assure you that the forward-looking statements in this report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all.

Part I — FINANCIAL INFORMATION

ITEM 1 Financial Statements (Unaudited)

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

(in thousands, except for share and per share amounts)	September 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 39,208	$ 61,005
Marketable securities	198,577	196,355
Accounts receivable, net	26,824	28,780
Inventory	1,019	994
Prepaid expenses and other current assets	14,382	11,998
Total current assets	280,010	299,132
Marketable securities, non-current	61,827	—
Property and equipment, net	4,156	4,417
Operating lease right-of-use assets	11,436	—
Intangible assets, net	23,407	24,542
Deferred tax assets	89,072	—
Non-current inventory and other	4,541	4,039
Total assets	$ 474,449	$ 332,130
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 26,992	$ 21,584
Product revenue allowances	33,004	31,231
Milestone obligations under license agreements	—	200
Total current liabilities	59,996	53,015
Operating lease non-current liabilities	12,793	—
Other non-current liabilities	753	3,693
Total liabilities	73,542	56,708
Commitments and contingencies (Notes 9 and 15)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 20,000,000 shares authorized, and no shares issued or outstanding at September 30, 2019 and December 31, 2018	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized; 53,333,211 and 52,477,593 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	53	52
Additional paid-in capital	625,524	611,587
Accumulated other comprehensive income	211	1
Accumulated deficit	(224,881)	(336,218)
Total stockholders' equity	400,907	275,422
Total liabilities and stockholders' equity	$ 474,449	$ 332,130

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

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

(in thousands, except for share and per share amounts)	Three Months Ended		Nine Months Ended	
	September 30, 2019	September 30, 2018	September 30, 2019	September 30, 2018
Revenues:				
Net product sales	$ 59,485	$ 49,135	$ 166,258	$ 140,077
Total revenues	59,485	49,135	166,258	140,077
Operating expenses:				
Cost of goods sold excluding amortization	6,782	5,068	18,263	14,841
Research and development	11,347	11,390	35,575	30,672
Selling, general and administrative	30,221	26,047	92,718	80,829
Intangible asset amortization	376	397	1,135	1,147
Total operating expenses	48,726	42,902	147,691	127,489
Income from operations	10,759	6,233	18,567	12,588
Other income	1,517	1,030	4,651	2,440
Income before income taxes	12,276	7,263	23,218	15,028
Provision (benefit) for income taxes	(88,147)	92	(88,119)	180
Net income	$ 100,423	$ 7,171	$ 111,337	$ 14,848
Net income per share:				
Basic	$ 1.88	$ 0.14	$ 2.10	$ 0.30
Diluted	$ 1.84	$ 0.13	$ 2.03	$ 0.28
Weighted average shares outstanding:				
Basic	53,297,298	52,389,012	53,052,521	50,321,640
Diluted	54,541,625	54,709,749	54,803,851	52,315,642

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

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

(in thousands)	Three Months Ended		Nine Months Ended	
	September 30, 2019	September 30, 2018	September 30, 2019	September 30, 2018
Net income	$ 100,423	$ 7,171	$ 111,337	$ 14,848
Other comprehensive income (loss):				
Net foreign currency translation loss	(19)	(2)	(17)	(15)
Change in net unrealized gain (loss) on marketable securities	(89)	(7)	294	119
Tax provision on other comprehensive income (loss)	(67)	—	(67)	—
Other comprehensive income (loss), net of tax	(175)	(9)	210	104
Comprehensive income	$ 100,248	$ 7,162	$ 111,547	$ 14,952

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

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

(in thousands, except for share amounts)	Common Stock Shares	Common Stock Par Value	Additional Paid-in Capital	Other Comprehensive Income	Accumulated Deficit	Total
Balances at December 31, 2018	52,477,593	$ 52	$ 611,587	$ 1	$ (336,218)	$ 275,422
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	485,083	1	178	—	—	179
Stock-based compensation expense	—	—	3,282	—	—	3,282
Net loss	—	—	—	—	(612)	(612)
Other comprehensive income, net of tax	—	—	—	134	—	134
Balances at March 31, 2019	52,962,676	53	615,047	135	(336,830)	278,405
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	302,108	—	3,411	—	—	3,411
Stock-based compensation expense	—	—	3,101	—	—	3,101
Net income	—	—	—	—	11,526	11,526
Other comprehensive income, net of tax	—	—	—	251	—	251
Balances at June 30, 2019	53,264,784	53	621,559	386	(325,304)	296,694
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	68,427	—	558	—	—	558
Stock-based compensation expense	—	—	3,407	—	—	3,407
Net income	—	—	—	—	100,423	100,423
Other comprehensive loss, net of tax	—	—	—	(175)	—	(175)
Balances at September 30, 2019	53,333,211	$ 53	$ 625,524	$ 211	$ (224,881)	$ 400,907

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)

(in thousands, except for share amounts)	Common Stock Shares	Common Stock Par Value	Additional Paid-in Capital	Other Comprehensive Income (Loss)	Accumulated Deficit	Total
Balances at December 31, 2017	44,938,133	$ 45	$ 492,802	$ (34)	$ (361,426)	$ 131,387
Net proceeds from public offering of common stock	6,325,000	6	100,862	—	—	100,868
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	846,568	1	2,665	—	—	2,666
Stock-based compensation expense	—	—	3,151	—	—	3,151
Net income	—	—	—	—	3,066	3,066
Other comprehensive income, net of tax	—	—	—	6	—	6
Balances at March 31, 2018	52,109,701	52	599,480	(28)	(358,360)	241,144
Net proceeds from public offering of common stock	—	—	2	—	—	2
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	266,244	—	2,686	—	—	2,686
Stock-based compensation expense	—	—	2,721	—	—	2,721
Net income	—	—	—	—	4,611	4,611
Other comprehensive income, net of tax	—	—	—	107	—	107
Balances at June 30, 2018	52,375,945	52	604,889	79	(353,749)	251,271
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	24,764	—	112	—	—	112
Stock-based compensation expense	—	—	2,872	—	—	2,872
Net income	—	—	—	—	7,171	7,171
Other comprehensive loss, net of tax	—	—	—	(9)	—	(9)
Balances at September 30, 2018	52,400,709	$ 52	$ 607,873	$ 70	$ (346,578)	$ 261,417

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

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

(in thousands)	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Cash flows from operating activities		
Net income	$ 111,337	$ 14,848
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation of property and equipment	1,022	1,057
Stock-based compensation	9,790	8,744
Amortization of discounts on marketable securities	(2,627)	(1,386)
Intangible asset amortization	1,135	1,147
Deferred income taxes	(89,155)	—
Other non-cash adjustments, net	1,517	153
Changes in operating assets and liabilities:		
Accounts receivable	1,914	(7,686)
Prepaid expenses and other assets	(2,956)	(3,936)
Inventory	(896)	215
Accounts payable and other liabilities	3,191	(3,182)
Product revenue allowances	1,884	4,749
Net cash provided by operating activities	36,156	14,723
Cash flows from investing activities		
Acquisition of intangible asset	—	(25,000)
Purchases of property and equipment	(951)	(346)
Purchases of marketable securities	(291,333)	(201,940)
Maturities of marketable securities	230,205	133,430
Net cash used in investing activities	(62,079)	(93,856)
Cash flows from financing activities		
Net proceeds from offering of common stock	—	100,870
Proceeds from the exercise of stock options	4,148	5,464
Net cash provided by financing activities	4,148	106,334
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(24)	(14)
Net change in cash, cash equivalents and restricted cash	(21,799)	27,187
Cash, cash equivalents and restricted cash		
Beginning of period	61,749	34,335
End of period	$ 39,950	$ 61,522

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

VANDA PHARMACEUTICALS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

1. Business Organization and Presentation

Business organization

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

- HETLIOZ® (tasimelteon), a product for the treatment of non-24-hour sleep-wake disorder (Non-24), was approved by the U.S. Food and Drug Administration (FDA) in January 2014 and launched commercially in the U.S. in April 2014. In July 2015, the European Commission (EC) granted centralized marketing authorization with unified labeling for HETLIOZ® for the treatment of Non-24 in totally blind adults. HETLIOZ® was commercially launched in Germany in August 2016. HETLIOZ® has potential utility in a number of other circadian rhythm disorders and is presently in clinical development for the treatment of Jet Lag Disorder, Smith-Magenis Syndrome (SMS) and pediatric Non-24. An assessment of new HETLIOZ® clinical opportunities, including the treatment of delayed sleep phase disorder and for sleep disorders in patients with neurodevelopmental disorders, is ongoing.
- Fanapt® (iloperidone), a product for the treatment of schizophrenia, the oral formulation of which was approved by the FDA in May 2009 and launched commercially in the U.S. by Novartis Pharma AG (Novartis) in January 2010. Novartis transferred all the U.S. and Canadian commercial rights to the Fanapt® franchise to the Company on December 31, 2014. Additionally, the Company's distribution partners launched Fanapt® in Israel in 2014. Fanapt® has potential utility in a number of other disorders. Initial clinical work studying a long acting injectable (LAI) formulation of Fanapt® began in 2018. An assessment of new Fanapt® clinical opportunities, including the treatment of bipolar disorder, is ongoing.
- Tradipitant (VLY-686), a small molecule neurokinin-1 receptor (NK-1R) antagonist, which is presently in clinical development for the treatment of chronic pruritus in atopic dermatitis, gastroparesis and motion sickness.
- VTR-297, a small molecule histone deacetylase (HDAC) inhibitor presently in clinical development for the treatment of hematologic malignancies.
- Portfolio of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) activators and inhibitors. An early stage CFTR activator program is planned for the treatment of dry eye and ocular inflammation. In addition, an early stage CFTR inhibitor program is planned for the treatment of secretory diarrhea disorders, including cholera.
- VQW-765, a Phase II alpha-7 nicotinic acetylcholine receptor partial agonist.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the Company's consolidated financial statements and accompanying notes included in the Company's annual report on Form 10-K for the fiscal year ended December 31, 2018. The financial information as of September 30, 2019 and for the three and nine months ended September 30, 2019 and 2018 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, 2018 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

With the exception of the adoption of Accounting Standards Update (ASU) No. 2016-02, *Leases* and all related amendments (collectively, Accounting Standards Codification (ASC) 842) on January 1, 2019, discussed below, there have been no material changes to the significant accounting policies previously disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

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.

Leases

In accordance with ASC 842, *Leases*, effective January 1, 2019, the Company determines if an arrangement contains a lease at inception. Right-of-use (ROU) assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from that lease. For leases with a term greater than 12 months, ROU assets and liabilities are recognized at the lease commencement date based on the estimated present value of lease payments over the lease term. The lease term includes the option to extend the lease when it is reasonably certain the Company will exercise that option. When available, the Company uses the rate implicit in the lease to discount lease payments to present value. In the case the implicit rate is not available, the Company uses its incremental borrowing rate based on information available at the lease commencement date, including publicly available data for instruments with similar characteristics, to determine the present value of lease payments. The Company does not combine lease and non-lease elements for office leases. For existing leases as of January 1, 2019, executory costs are excluded from lease expense, which is consistent with the Company's accounting under ASC 840, *Leases*. For all leases entered into after January 1, 2019, executory costs are allocated between lease and non-lease elements based upon their relative stand-alone prices.

Revenue from Net Product Sales

The Company's revenues consist of net product sales of HETLIOZ® and net product sales of Fanapt®. Net sales by product for the three and nine months ended September 30, 2019 and 2018 were as follows:

	Three Months Ended		Nine Months Ended	
(in thousands)	September 30, 2019	September 30, 2018	September 30, 2019	September 30, 2018
HETLIOZ® product sales, net	$ 37,589	$ 29,923	$ 104,381	$ 83,391
Fanapt® product sales, net	21,896	19,212	61,877	56,686
Total net product sales	$ 59,485	$ 49,135	$ 166,258	$ 140,077

Major Customers

HETLIOZ® is available in the U.S. for distribution through a limited number of specialty pharmacies, and is not available in retail pharmacies. Fanapt® is available in the U.S. for distribution through a limited number of wholesalers and is available in retail pharmacies. The Company invoices and records revenue when its customers, specialty pharmacies and wholesalers, receive product from the third-party logistics warehouse which is the point at which control is transferred to the customer. There were five major customers that each accounted for more than 10% of total revenues and, as a group, represented 96% of total revenues for the nine months ended September 30, 2019. 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, 2019. The Company evaluates outstanding receivables to assess collectability. In performing this evaluation, the Company analyzes economic conditions, the aging of receivables and customer specific risks. Using this information, the Company reserves an amount that it estimates may not be collected.

Supplemental Cash Flows Information

Cash, Cash Equivalents and Restricted Cash

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

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

(in thousands)	September 30, 2019	September 30, 2018
Cash and cash equivalents	$ 39,208	$ 60,778
Restricted cash included in:		
Prepaid expenses and other current assets	157	157
Non-current inventory and other	585	587
Total cash, cash equivalents and restricted cash	$ 39,950	$ 61,522

Recent Accounting Pronouncements

In August 2018, the U.S. Securities and Exchange Commission (SEC) adopted the final rule under SEC Release No. 33-10532, *Disclosure Update and Simplification.* This final rule amends certain disclosure requirements that are redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expand the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule is effective for the Company for all filings made on or after November 5, 2018. The SEC staff clarified that the first presentation of the changes in shareholders' equity may be included in the first Form 10-Q for the quarter that begins after the effective date of the amendments. The adoption of the final rule did not have a material impact on the Company's condensed consolidated financial statements. The Company updated the disclosure of its Condensed Consolidated Statements of Changes in Stockholders' Equity in 2019 to include a reconciliation for the quarter-to-date and year-to-date comparative periods.

In June 2016, the Financial Accounting Standards Board (FASB) issued ASU 2016-13, *Financial Instruments – Credit Losses,* which changes the impairment model for most financial assets and certain other financial instruments. The standard will require the use of a forward-looking "expected loss" model for instruments measured at amortized cost that generally will result in the earlier recognition of allowances for losses. The standard is effective for years beginning after December 15, 2019, and interim periods within annual periods beginning after December 15, 2019. The Company is evaluating this standard to determine if adoption will have a material impact on the Company's accounts receivable and marketable securities balances and related financial statement disclosures.

In February 2016, the FASB issued ASU 2016-2, *Leases (Topic 842)*, which was further clarified by ASU 2018-10, *Codification Improvements to Topic 842, Leases*, and ASU 2018-11, *Leases - Targeted Improvements*, issued in July 2018. ASC 842 supersedes existing lease guidance, including ASC 840 *Leases*. The new leasing standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The new leasing standard requires that lessees will need to recognize an ROU asset and a lease liability for virtually all of their leases, and allows companies to make a policy election as to whether short term leases will be recognized under the requirements of the new standard. The Company elected to exclude short-term leases in the application of the new standard. The lease liability is equal to the present value of lease payments. The ROU asset is based on the liability subject to certain adjustments. For income statement purposes, the FASB retained a dual model, requiring leases to be classified as either operating or finance. Operating leases will result in straight-line expense, similar to accounting for operating leases under ASC 840, while finance leases will result in a front-loaded expense pattern, similar to accounting for capital leases under ASC 840.

The Company adopted the new leasing standard in the first quarter of 2019, using a modified retrospective transition. There was no impact to the opening balance of retained earnings as of the effective date of January 1, 2019 as a result of adoption. Prior period financial statements were not recast. The Company elected the package of transition provisions available for expired or existing contracts, which allowed it to carryforward its historical assessments of (1) whether contracts are or contain leases, (2) lease classification and (3) initial direct costs. The adoption of the new leasing standard on January 1, 2019 resulted in the recognition of $15.8 million of operating lease liabilities, $2.2 million of which were classified as current liabilities, with corresponding ROU assets of $12.2 million, net of lease prepayments and the balance of deferred lease incentives. The Company does not have any financing leases.

3. Marketable Securities

The following is a summary of the Company's available-for-sale marketable securities as of September 30, 2019:

September 30, 2019 *(in thousands)*	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Current:				
U.S. Treasury and government agencies	$ 72,767	$ 83	$ (4)	$ 72,846
Corporate debt	110,119	176	—	110,295
Asset-backed securities	15,410	28	(2)	15,436
Total marketable securities, current	$ 198,296	$ 287	$ (6)	$ 198,577
Non-current:				
U.S. Treasury and government agencies	$ 14,499	$ —	$ (20)	$ 14,479
Corporate debt	15,852	28	(2)	15,878
Asset-backed securities	31,469	15	(14)	31,470
Total marketable securities, non-current	61,820	43	(36)	61,827
Total marketable securities	$ 260,116	$ 330	$ (42)	$ 260,404

Current marketable securities have a remaining maturity of less than one year. Non-current marketable securities have a remaining maturity of between one and two years.

The following is a summary of the Company's available-for-sale marketable securities as of December 31, 2018, which all have contract maturities of less than one year:

December 31, 2018 *(in thousands)*	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Current:				
U.S. Treasury and government agencies	$ 69,275	$ 12	$ (17)	$ 69,270
Corporate debt	105,897	38	(25)	105,910
Asset-backed securities	21,189	—	(14)	21,175
Total marketable securities, current	$ 196,361	$ 50	$ (56)	$ 196,355

4. Fair Value Measurements

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

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

Marketable securities classified in Level 1 and Level 2 as of September 30, 2019 and December 31, 2018 consist of available-for-sale marketable securities. The valuation of Level 1 instruments is determined using a market approach, and is based upon unadjusted quoted prices for identical assets in active markets. The valuation of investments classified in Level 2 is also determined using a market approach based upon quoted prices for similar assets in active markets, or other inputs that are observable for substantially the full term of the financial instrument. Level 2 securities include certificates of deposit, commercial paper, corporate notes and asset-backed securities that use as their basis readily observable market parameters. The Company did not transfer any assets between Level 2 and Level 1 during the nine months ended September 30, 2019 and 2018.

As of September 30, 2019, the Company held certain assets that are required to be measured at fair value on a recurring basis, as follows:

		Fair Value Measurement as of September 30, 2019 Using		
(in thousands)	Total Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
U.S. Treasury and government agencies	$ 87,325	$ 87,325	$ —	$ —
Corporate debt	126,173	—	126,173	—
Asset-backed securities	46,906	—	46,906	—
Total assets measured at fair value	$ 260,404	$ 87,325	$ 173,079	$ —

As of December 31, 2018, the Company held certain assets that are required to be measured at fair value on a recurring basis, as follows:

		Fair Value Measurement as of December 31, 2018 Using		
(in thousands)	Total Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
U.S. Treasury and government agencies	$ 69,270	$ 69,270	$ —	$ —
Corporate debt	105,910	—	105,910	—
Asset-backed securities	21,175	—	21,175	—
Total assets measured at fair value	$ 196,355	$ 69,270	$ 127,085	$ —

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

5. Inventory

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

Inventory consisted of the following as of September 30, 2019 and December 31, 2018:

(in thousands)	September 30, 2019	December 31, 2018
Current:		
Work-in-process	$ —	$ 48
Finished goods	1,019	946
Total inventory, current	$ 1,019	$ 994
Non-Current:		
Raw materials	$ 662	$ 86
Work-in-process	1,131	2,290
Finished goods	1,286	516
Total inventory, non-current	3,079	2,892
Total inventory	$ 4,098	$ 3,886

6. Leases

The Company's long-term leases primarily include operating leases and subleases for office space in Washington, D.C. and London, England. The Company recognized ROU assets and lease liabilities related to fixed payments for these long-term operating leases in its Condensed Consolidated Balance Sheet as of September 30, 2019. The Company also has short-term leases, including office space in Berlin, Germany.

In June 2011, the Company entered into an operating lease agreement under which it leases 33,534 square feet of office space for its headquarters at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. Subject to the prior rights of other tenants, the Company has the right to renew the lease for five years following its expiration in July 2028. As of September 30, 2019, the renewal period has not been included in the lease term. The Company has the right to sublease or assign all or a portion of the premises, subject to standard conditions. The lease may be terminated early by the Company or the landlord under certain circumstances.

In June 2016, the Company entered into a sublease agreement under which it subleases an additional 9,928 square feet of office space for its headquarters at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. The sublease term began in January 2017 and ends in July 2026, but may be terminated earlier by either party under certain circumstances. The Company has the right to sublease or assign all or a portion of the premises, subject to standard conditions.

In May 2016, the Company entered into an operating lease agreement under which it leases 2,880 square feet of office space for its European headquarters in London, England. The Company has the right to renew the lease for five years following its expiration in 2021. As of September 30, 2019, the renewal period has not been included in the lease term.

The following is a summary of the Company’s ROU assets and operating lease liabilities as of September 30, 2019:

(in thousands)	Classification on the Balance Sheet	September 30, 2019
Assets		
Operating lease assets	Operating lease right-of-use assets	$ 11,436
Liabilities		
Operating lease current liabilities	Accounts payable and accrued liabilities	$ 2,123
Operating lease non-current liabilities	Operating lease non-current liabilities	12,793
Total lease liabilities		$ 14,916
Weighted average remaining lease term		8.3 Years
Weighted average discount rate[(1)]		8.1%

(1) Upon adoption of the new lease standard, discount rates used for existing leases were established at January 1, 2019.

For the three and nine months ended September 30, 2019, the Company recognized operating lease cost of $0.6 million and $1.7 million, respectively, and short-term operating lease cost of $0.1 million and $0.3 million, respectively. The Company also recognized $0.4 million and $1.0 million, respectively, of expense related to non-lease elements, such as building maintenance services and utilities, and executory costs associated with the operating leases. For existing leases as of January 1, 2019, executory costs are excluded from operating lease expense, which is consistent with the Company's accounting under ASC 840. For all leases entered into after January 1, 2019, executory costs are allocated between lease and non-lease elements based upon their relative stand-alone prices. For the three and nine months ended September 30, 2018, the Company recognized $0.9 million and $2.7 million of rent expense, respectively, inclusive of lease expense, non-lease elements, and executory costs for short and long-term operating leases.

Cash paid for amounts included in the measurement of operating lease liabilities is included in operating cash flows was $1.8 million for the nine months ended September 30, 2019.

The table below reconciles the Company's future cash obligations to operating lease liabilities recorded on the balance sheet as of September 30, 2019:

(in thousands)	Operating Leases
2019	$ 633
2020	2,309
2021	2,329
2022	2,355
2023	2,420
Thereafter	10,669
Total minimum lease payments	20,715
Less: amount of lease payments representing interest	(5,799)
Present value of future minimum lease payments	14,916
Less: current obligations under leases	(2,123)
Operating lease non-current liabilities	$ 12,793

At December 31, 2018, future minimum payments under noncancellable operating leases under ASC 840 were as follows:

	Cash Payments Due by Year						
(in thousands)	Total	2019	2020	2021	2022	2023	Thereafter
Operating leases	22,757	2,483	2,495	2,335	2,355	2,420	10,669

7. Intangible Assets

HETLIOZ®. In January 2014, the Company announced that the FDA had approved the New Drug Application (NDA) for HETLIOZ®. As a result of this approval, the Company met a milestone under its license agreement with Bristol-Myers Squibb (BMS) that required the Company to make a license payment of $8.0 million to BMS. The $8.0 million is being amortized on a straight-line basis over the estimated economic useful life of the related product patents, the latest of which expires in July 2035.

In April 2018, the Company met its final milestone under its license agreement when cumulative worldwide sales of HETLIOZ® reached $250.0 million. As a result of the achievement of this milestone, the Company made a payment to BMS of $25.0 million in the second quarter of 2018. The $25.0 million was determined to be additional consideration for the acquisition of the HETLIOZ® intangible asset and is being amortized on a straight-line basis over the estimated economic useful life of the related product patents, the latest of which expires in July 2035.

The estimated economic useful life of both the $8.0 million and the $25.0 million intangible assets were changed from February 2035 to July 2035 based on the July 2035 expiration date of U.S. patent number 10,376,487 ('487 Patent) issued by the U.S. Patent and Trademark Office in August 2019. The estimated economic useful life of these intangible assets were previously changed from May 2034 to February 2035 based on the February 2035 expiration date of U.S. patent number 10,071,977 ('977 Patent) issued by the U.S. Patent and Trademark Office in September 2018.

The following is a summary of the Company’s intangible assets as of September 30, 2019:

		September 30, 2019		
(in thousands)	Estimated Useful Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	July 2035	$ 33,000	$ 9,593	$ 23,407

The following is a summary of the Company's intangible assets as of December 31, 2018:

(in thousands)	Estimated Useful Life (Years)	December 31, 2018 Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	February 2035	$ 33,000	$ 8,458	$ 24,542

As of September 30, 2019 and December 31, 2018, 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, 2019 and 2018. Amortization expense was $1.1 million for each of the nine months ended September 30, 2019 and 2018. The following is a summary of the future intangible asset amortization schedule as of September 30, 2019:

(in thousands)	Total	2019	2020	2021	2022	2023	Thereafter
HETLIOZ®	$ 23,407	$ 370	$ 1,478	$ 1,478	$ 1,478	$ 1,478	$ 17,125

8. Accounts Payable and Accrued Liabilities

The following is a summary of the Company's accounts payable and accrued liabilities as of September 30, 2019 and December 31, 2018:

(in thousands)	September 30, 2019	December 31, 2018
Consulting and other professional fees	$ 4,579	$ 2,924
Research and development expenses	6,709	5,593
Royalties payable	5,783	5,172
Compensation and employee benefits	5,490	6,363
Operating lease liabilities	2,123	—
Other	2,308	1,532
Total accounts payable and accrued liabilities	$ 26,992	$ 21,584

9. Commitments and Contingencies

The following is a summary of the Company's noncancellable long-term contractual cash obligations as of September 30, 2019. See footnote 6, *Leases*, for the maturities of the Company's operating lease liabilities as of September 30, 2019.

	Cash Payments Due by Year						
(in thousands)	Total	2019	2020	2021	2022	2023	Thereafter
Purchase commitments	12,872	225	11,200	966	481	—	—

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 a result of the FDA's approval of the HETLIOZ® NDA in January 2014, the Company made an $8.0 million milestone payment to BMS in the first quarter of 2014 under the license agreement that was capitalized as an intangible asset and is being amortized over the estimated economic useful life of the related product patents for HETLIOZ® in the U.S. In April 2018, the Company met another milestone under its license agreement when cumulative worldwide sales of HETLIOZ® reached $250.0 million. As a result of the achievement of this milestone, the Company made a payment to BMS of $25.0 million in the second quarter of 2018. The $25.0 million milestone obligation was capitalized as an intangible asset in the first quarter of 2015 and is being amortized over the estimated economic useful life of the related product patents for HETLIOZ® in the U.S. The Company has no remaining milestone obligations to BMS. Additionally, the Company is obligated to make royalty payments on HETLIOZ® net sales to BMS in any territory where the Company commercializes HETLIOZ® for a period equal to the greater of 10 years following the first commercial sale in the territory or the expiry of the new chemical entity (NCE) patent in that territory. During the period prior to the expiry of the NCE patent in a territory, the Company is obligated to pay a 10% royalty on net sales in that territory. The royalty rate is decreased by half for countries in which no NCE patent existed or for the remainder of the 10 years after the expiry of the NCE patent. The Company is also obligated under the license agreement to pay BMS a percentage of any sublicense fees, upfront payments and milestone and other payments (excluding royalties) that it receives from a third party in connection with any sublicensing arrangement, at a rate which is in the mid-twenties. The Company has agreed with BMS in the license agreement for HETLIOZ® to use its commercially reasonable efforts to develop and commercialize HETLIOZ®.

Fanapt®. Pursuant to the terms of a settlement agreement with Novartis, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to the Company on December 31, 2014. The Company pays directly to Sanofi S.A (Sanofi) a fixed royalty of 3% of net sales through December 2019 related to manufacturing know-how. No further royalties on manufacturing know-how will be payable by the Company after December 2019. The Company is also obligated to pay Sanofi a fixed royalty on Fanapt® net sales equal to 6% on Sanofi know-how not related to manufacturing under certain conditions for a period of up to 10 years in markets where the NCE patent has expired or was not issued. The Company is obligated to pay this 6% royalty on net sales in the U.S. through November 2026. No further royalties on know-how not related to manufacturing will be payable by the Company for net sales in the U.S. after November 2026.

Tradipitant. In April 2012, the Company entered into a license agreement with Eli Lilly and Company (Lilly) pursuant to which the Company acquired an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize an NK-1R antagonist, tradipitant, for all human indications. The patent describing tradipitant as an NCE expires in April 2023, except in the U.S., where it expires in June 2024 absent any applicable patent term adjustments. Lilly is eligible to receive future payments based upon achievement of specified development and commercialization milestones as well as tiered-royalties on net sales at percentage rates up to the low double digits. As of September 30, 2019, remaining milestone obligations include a $2.0 million pre-NDA approval milestone due upon the filing of the first marketing authorization for tradipitant in either the U.S. or European Union, $10.0 million and $5.0 million for the first approval of a marketing authorization for tradipitant in the U.S. and European Union, respectively, and up to $80.0 million for sales milestones. In the third quarter of 2018, the Company also made a $2.0 million milestone payment to Lilly as a result of enrolling the first subject into a Phase III study for tradipitant in July 2018. The likelihood of achieving this milestone was determined to be probable during 2017 and the obligation of $2.0 million tied to such milestone was recorded as research and development expense in the consolidated statement of operations during the year ended December 31, 2017. The Company is obligated to use its commercially reasonable efforts to develop and commercialize tradipitant.

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

Portfolio of CFTR activators and inhibitors. In March 2017, the Company entered into a license agreement with the University of California San Francisco (UCSF), under which the Company acquired an exclusive worldwide license to develop and commercialize a portfolio of CFTR activators and inhibitors. Pursuant to the license agreement, the Company will develop and

commercialize the CFTR activators and inhibitors and is responsible for all development costs under the license agreement, including current pre-investigational new drug development work. UCSF is eligible to receive future payments based upon achievement of specified development and commercialization milestones as well as single-digit royalties on net sales. As of September 30, 2019, remaining milestone obligations include annual maintenance fees, $12.2 million for pre-NDA approval milestones and $33.0 million for future regulatory approval and sales milestones. Included in the $12.2 million pre-NDA approval milestones is a $350,000 milestone due upon the conclusion of a Phase I study for each licensed product but not to exceed $1.1 million in total for the CFTR portfolio. In the first quarter of 2019, the Company also made a $0.2 million pre-NDA approval milestone payment to UCSF, which was determined to be probable and accrued as a current liability in the fourth quarter of 2018. Additionally, the Company paid an initial license fee of $1.0 million in 2017.

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-for-service arrangements. The Company's current agreements for clinical, marketing, and other services generally may be terminated on 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. Purchase commitments included in the noncancellable long-term contractual cash obligations table above include noncancellable purchase commitments longer than one year and primarily relate to commitments for advertising and data services.

10. Public Offering of Common Stock

In March 2018, the Company completed a public offering of 6,325,000 shares of its common stock, including the exercise of the underwriters' option to purchase an additional 825,000 shares of common stock, at a price to the public of $17.00 per share. Net cash proceeds from the public offering were $100.9 million after deducting the underwriting discounts and commissions and offering expenses.

11. 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, 2019 and December 31, 2018:

(in thousands)	September 30, 2019	December 31, 2018
Foreign currency translation	$ (10)	$ 7
Unrealized gain (loss) on marketable securities	221	(6)
Accumulated other comprehensive income	$ 211	$ 1

There were no reclassifications out of accumulated other comprehensive income for either of the nine months ended September 30, 2019 or 2018.

12. Stock-Based Compensation

As of September 30, 2019, there were 6,324,304 shares that were subject to outstanding options and restricted stock units (RSUs) under the 2006 Equity Incentive Plan (2006 Plan) and the Amended and Restated 2016 Equity Incentive Plan (2016 Plan, and together with the 2006 Plan, Plans). The 2006 Plan expired by its terms in April 2016, and the Company adopted the 2016 Plan. Outstanding options and RSUs under the 2006 Plan remain in effect and the terms of the 2006 Plan continue to apply, but no additional awards can be granted under the 2006 Plan. In June 2016, the Company's stockholders approved the 2016 Plan. The 2016 Plan has been amended and restated twice to increase the number of shares reserved for issuance, among other administrative changes. Both amendments and restatements of the 2016 Plan were approved by the Company's stockholders. There are a total of 7,100,000 shares of common stock reserved for issuance under the 2016 Plan, 3,063,197 shares of which remained available for future grant as of September 30, 2019.

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 Company's 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 on the first anniversary of the grant date with respect to 25% of the shares subject to service option awards. The remaining 75% of the shares subject to the service option awards vest and become exercisable monthly in equal installments thereafter over three years. Subsequent annual service option awards granted to directors vest and become exercisable in either equal monthly installments over a period of one year or on the first anniversary of the grant date. Certain service option awards to executives and directors provide for accelerated vesting if there is a change in control of the Company. Certain service option awards to employees and executives provide for accelerated vesting if the respective employee's or executive's service is terminated by the Company for any reason other than cause or permanent disability.

As of September 30, 2019, $10.7 million of unrecognized compensation costs related to unvested service option awards are expected to be recognized over a weighted average period of 1.5 years. No option awards are classified as a liability as of September 30, 2019.

A summary of option activity under the Plans for the nine months ended September 30, 2019 follows:

2006 and 2016 Plans *(in thousands, except for share and per share amounts)*	**Number of Shares**	**Weighted Average Exercise Price at Grant Date**	**Weighted Average Remaining Term (Years)**	**Aggregate Intrinsic Value**
Outstanding at December 31, 2018	4,369,042	$ 11.15	5.28	$ 65,438
Granted	652,500	18.60		
Forfeited	—	—		
Expired	(15,000)	14.78		
Exercised	(338,317)	12.26		1,083
Outstanding at September 30, 2019	4,668,225	12.10	5.56	12,673
Exercisable at September 30, 2019	3,489,627	10.21	4.46	12,343
Vested and expected to vest at September 30, 2019	4,459,638	11.81	5.38	12,652

The weighted average grant-date fair value of options granted was $10.34 and $10.66 per share for the nine months ended September 30, 2019 and 2018, respectively. Proceeds from the exercise of stock options amounted to $4.1 million and $5.5 million for the nine months ended September 30, 2019 and 2018, 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 generally vest over 4 years in equal annual installments provided that the employee remains employed with the Company. Annual service RSUs granted to directors vest on the first anniversary of the grant date.

As of September 30, 2019, $25.3 million of unrecognized compensation costs related to unvested service RSUs are expected to be recognized over a weighted average period of 1.9 years. No RSUs are classified as a liability as of September 30, 2019.

A summary of RSU activity under the Plans for the nine months ended September 30, 2019 follows:

2006 and 2016 Plans	**Number of Shares Underlying RSUs**	**Weighted Average Grant Date Fair Value**
Unvested at December 31, 2018	1,313,576	$ 15.68
Granted	915,328	19.58
Forfeited	(55,024)	18.93
Vested	(517,801)	14.49
Unvested at September 30, 2019	1,656,079	18.09

The grant date fair value for the 517,801 shares underlying RSUs that vested during the nine months ended September 30, 2019 was $7.5 million.

Stock-Based Compensation

Stock-based compensation expense recognized for the three and nine months ended September 30, 2019 and 2018 was comprised of the following:

	Three Months Ended		Nine Months Ended	
(in thousands)	September 30, 2019	September 30, 2018	September 30, 2019	September 30, 2018
Research and development	$ 827	$ 326	$ 2,311	$ 963
Selling, general and administrative	2,580	2,546	7,479	7,781
Total stock-based compensation expense	$ 3,407	$ 2,872	$ 9,790	$ 8,744

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 not paid dividends to its stockholders since its inception (other than a dividend of preferred share purchase rights, which was declared in September 2008) and does not plan to pay dividends in the foreseeable future. Assumptions used in the Black-Scholes-Merton option pricing model for stock options granted during the nine months ended September 30, 2019 and 2018 were as follows:

	Nine Months Ended	
	September 30, 2019	September 30, 2018
Expected dividend yield	0%	0%
Weighted average expected volatility	58%	58%
Weighted average expected term (years)	5.94	5.90
Weighted average risk-free rate	2.29%	2.68%

13. Income Taxes

For the three months ended September 30, 2019 and 2018, the Company recorded income tax benefit of $88.1 million and income tax expense of $0.1 million, respectively. For the nine months ended September 30, 2019 and 2018, the Company recorded income tax benefit of $88.1 million and income tax expense of $0.2 million, respectively. The income tax benefit for the three and nine months ended September 30, 2019 was primarily due to the reduction of the Company's tax valuation allowance against substantially all of its deferred tax assets in the U.S. recognized during the three months ended September 30, 2019. Net income tax benefit of $1.6 million was also recorded related to the generation of 2019 research and development and orphan drug credits, current taxes payable to certain U.S. state and foreign jurisdictions and uncertain tax positions for the three and nine months ended September 30, 2019. As a result of the tax valuation allowance against deferred tax assets in the U.S., there was no expense for federal income taxes associated with the income before taxes for the three and nine months ended September 30, 2018. Income taxes were recorded related to certain U.S. state and foreign jurisdictions for the three and nine months ended September 30, 2018.

The Company assesses the need for a valuation allowance against its deferred tax asset each quarter through the review of all available positive and negative evidence. Deferred tax assets are reduced by a tax valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. As of December 31, 2018, there was a full tax valuation allowance against all deferred tax assets in the U.S. During the three months ended September 30, 2019, after considering all available positive and negative evidence, including but not limited to cumulative income in recent periods, historical and current projected results, and significant risks and uncertainties related to forecasts, the Company concluded that it was more likely than not that substantially all of its deferred taxes are realizable in future periods.

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. As of September 30, 2019, the total amount of unrecognized tax benefits (UTB) was $9.7 million. As of December 31, 2018, the Company had no UTB. The UTB recognized in 2019 is primarily related to prior year tax positions and has no impact on tax expense as, prior to 2019, a tax valuation allowance was recorded against deferred tax assets in the U.S.

The Company does not expect its unrecognized tax benefits as of September 30, 2019 to change significantly over the next twelve months.

Certain tax attributes of the Company, including net operating losses (NOLs) and credits, would be subject to a limitation should an ownership change as defined under the Internal Revenue Code of 1986, as amended, Section 382, occur. The limitations resulting from a change in ownership could affect the Company's ability to utilize its NOLs and credit carryforward (tax attributes). Ownership changes occurred in the years ended December 31, 2014 and December 31, 2008. The Company believes that the ownership changes in 2014 and 2008 will not impact its ability to utilize NOL and credit carryforwards; however, future ownership changes may cause the Company's existing tax attributes to have additional limitations.

The Tax Cuts and Jobs Act (TCJA) was enacted in December 2017. During the fourth quarter of 2018, the Company completed its accounting for the tax effects of the TCJA. No material measurement period adjustments were recorded in 2018 to adjust estimated effects of the TCJA that were recorded in 2017. Immaterial measurement period adjustments that were recorded resulted in no tax expense as they were fully offset by a change in the Company's valuation allowance.

14. 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, 2019 and 2018:

	Three Months Ended		Nine Months Ended	
(in thousands, except for share and per share amounts)	September 30, 2019	September 30, 2018	September 30, 2019	September 30, 2018
Numerator:				
Net income	$ 100,423	$ 7,171	$ 111,337	$ 14,848
Denominator:				
Weighted average shares outstanding, basic	53,297,298	52,389,012	53,052,521	50,321,640
Effect of dilutive securities	1,244,327	2,320,737	1,751,330	1,994,002
Weighted average shares outstanding, diluted	54,541,625	54,709,749	54,803,851	52,315,642
Net income per share, basic and diluted:				
Basic	$ 1.88	$ 0.14	$ 2.10	$ 0.30
Diluted	$ 1.84	$ 0.13	$ 2.03	$ 0.28
Antidilutive securities excluded from calculations of diluted net income per share	2,646,933	752,194	1,826,279	1,058,058

15. Legal Matters

Fanapt®. The Company has been involved in litigation with Roxane Laboratories, Inc. (Roxane) and its affiliates, West-Ward Pharmaceuticals International Limited and West-Ward Pharmaceuticals Corp (West-Ward), since the Company filed a lawsuit against Roxane in the U.S. District Court for the District of Delaware (Delaware District Court) for patent infringement in June 2014. The lawsuit was filed in response to Roxane's submission to the U.S. Food and Drug Administration (FDA) of an Abbreviated New Drug Application (ANDA) for a generic version of Fanapt® prior to the expiration of certain of the Company's patents covering Fanapt®, including U.S. Patent No. 8,586,610 ('610 Patent). In August 2016, the Delaware District Court ruled in the Company's favor, permanently enjoining Roxane from manufacturing, using, selling, offering to sell, distributing or importing any generic iloperidone product described in Roxane's ANDA until the expiration of the '610 Patent in November 2027, or May 2028 if the Company obtains pediatric exclusivity. In April 2018, following an appeal by Roxane of the Delaware District Court's decision to the Federal Circuit Court of Appeals (Federal Circuit), the Federal Circuit affirmed the Delaware District Court's ruling. In June 2018, West-Ward, having replaced Roxane as defendants following the acquisition of Roxane by West-Ward's parent company, Hikma Pharmaceuticals PLC, petitioned the Federal Circuit for a rehearing en banc. In August 2018, the Federal Circuit denied West-Ward's petition. In January 2019, West-Ward filed a petition in the U.S.

Supreme Court for a writ of certiorari seeking reversal of the Federal Circuit's decision. In March 2019, the U.S. Supreme Court invited the Solicitor General of the U.S. to file a brief in the matter expressing the views of the U.S.

In 2015, the Company filed six separate patent infringement lawsuits in the Delaware District Court against Roxane, Inventia Healthcare Pvt. Ltd. (Inventia), Lupin Ltd. and Lupin Pharmaceuticals, Inc. (Lupin), Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd. (Taro), and Apotex Inc. and Apotex Corp. (Apotex, and collectively with Roxane, Inventia, Lupin and Taro, the Fanapt® Defendants). These lawsuits were filed in response to the submission to the FDA by each of the Fanapt® Defendants of ANDAs for generic versions of Fanapt® prior to the expiration of the '610 Patent in November 2027 or the U.S. Patent No. 9,138,432 in September 2025. The Company entered into separate confidential stipulations with each of Inventia and Lupin regarding any potential launch of their generic versions of Fanapt®. The remaining lawsuits against the other Fanapt® Defendants have been stayed until 14 days after final disposition by the U.S. Supreme Court of the petition for a writ of certiorari filed by West-Ward.

HETLIOZ®. In April and May 2018, the Company filed three separate patent infringement lawsuits in the Delaware District Court against Teva Pharmaceuticals USA, Inc. (Teva), MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited (MSN) and Apotex (collectively with Teva and MSN, the HETLIOZ® Defendants) after having received Paragraph IV certification notice letters (Paragraph IV Letters) from each of the HETLIOZ® Defendants alleging that certain of the Company's patents covering HETLIOZ® (collectively, the HETLIOZ® Patents) were invalid, unenforceable and/or would not be infringed by the manufacture, use or sale of their generic versions of HETLIOZ®, as described in the ANDAs submitted to the FDA by each of the HETLIOZ® Defendants, prior to the expiration of the latest to expire of the HETLIOZ® Patents in 2034. Each of the HETLIOZ® Patents are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book). In December 2018, the Company filed amended complaints against each of the HETLIOZ® Defendants following the receipt of additional Paragraph IV Letters from Teva and Apotex concerning its Orange Book listed '977 Patent, which expires in 2035. These lawsuits are scheduled for trial in October 2020.

In March 2019, April 2019, and May 2019, the Company filed three additional patent infringement lawsuits in the Delaware District Court against the HETLIOZ® Defendants following the receipt of additional Paragraph IV Letters from each concerning its Orange Book listed U.S. Patent No. 10,149,829, which expires in 2033. A trial date has not yet been scheduled for these lawsuits.

In October 2019, the Company received an additional Paragraph IV certification notice letter from Teva concerning its Orange Book listed '487 Patent, which expires in July 2035. In its notice letter, Teva alleges that the '487 Patent, which covers a method of treatment using HETLIOZ®, is invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of its generic version of HETLIOZ® as described in its ANDA. The Company intends to vigorously pursue a patent infringement lawsuit permanently enjoining Teva from infringing the claims of the '487 Patent.

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

On February 5, 2019, the Company filed a lawsuit against the FDA in the U.S. District Court for the District of Columbia (DC District Court), challenging the FDA's legal authority to issue the PCH, and seeking an order to set it aside. In February 2019, the FDA filed a Motion for Voluntary Remand to the Agency and for a Stay of the Case. In March 2019, the DC District Court granted the FDA's request for voluntary remand and returned the matter to the FDA for further consideration. In April 2019, the FDA provided its remand response, in which it indicated that, upon review of scientific literature and tradipitant data, it believes that a partial clinical hold continues to be appropriate until the Company has adequate safety data from a 9-month non-rodent toxicity study. After reviewing the FDA's remand response, the Company continues to believe that additional chronic toxicity studies are unjustified, and that it has provided the FDA with sufficient information regarding the safety of tradipitant to justify the continued study of tradipitant in patients beyond 12 weeks, in accordance with applicable law and FDA regulations. In May 2019, the Company filed an amended complaint, and in July 2019, the Company filed a Motion for

Summary Judgment. The FDA filed a reply and cross-motion for summary judgment in October 2019. A hearing has been set for December 13, 2019. The Company intends to continue vigorously pursuing its interests in the matter.

In February 2019, a qui tam action filed against the Company was unsealed by order of the DC District Court. The qui tam action, which was filed under seal in March 2017, was brought by a former Company employee on behalf of the U.S., 28 states and the District of Columbia (collectively, the Plaintiff States) and the policyholders of certain insurance companies under the Federal False Claims Act and state law equivalents to the Federal False Claims Act and related state laws. The complaint alleged that the Company violated these laws through the promotion and marketing of its products Fanapt® and HETLIOZ® and sought, among other things, treble damages, civil penalties for each alleged false claim, and attorneys' fees and costs. By virtue of the DC District Court having unsealed the original complaint, the Company learned that in January 2019, the U.S. Department of Justice (the DOJ), as well as the Plaintiff States, elected not to intervene in the qui tam action at that time. In May 2019, the plaintiff filed an amended complaint under seal repeating the same allegations and seeking the same relief. In August 2019, the Company filed a motion to dismiss, and in October 2019 the plaintiff filed a reply. According to a filing unsealed in June 2019, the DOJ reaffirmed its decision not to intervene and incorporated its prior filing, indicating that neither the DOJ nor the Plaintiff States were intervening regarding the original complaint. Although the DOJ and the Plaintiff States have elected not to intervene, the plaintiff may litigate this action and the DOJ and the Plaintiff States may later seek to intervene in the action. The Company intends to vigorously defend itself in the case.

In February 2019, a securities class action, *Gordon v. Vanda Pharmaceuticals Inc.*, was filed in the U.S. District Court for the Eastern District of New York naming the Company and certain of its officers as defendants. An amended complaint was filed in July 2019. The amended complaint, filed on behalf of a purported stockholder, asserts claims on behalf of a putative class of all persons who purchased the Company's publicly traded securities between November 4, 2015 and February 11, 2019, for alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder. The amended complaint alleges that the defendants made false and misleading statements and/or omissions regarding Fanapt®, HETLIOZ® and the Company's interactions with the FDA regarding tradipitant between November 3, 2015 and February 11, 2019. The Company believes that it has meritorious defenses and intends to vigorously defend this lawsuit. The Company does not anticipate that this litigation will have a material adverse effect on its business, results of operations or financial condition. However, this lawsuit is subject to inherent uncertainties, the actual cost may be significant, and the Company may not prevail. The Company believes it is entitled to coverage under its relevant insurance policies, subject to a retention, but coverage could be denied or prove to be insufficient.

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

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 commenced operations in 2003 and our product portfolio includes:

- HETLIOZ® (tasimelteon), a product for the treatment of non-24-hour sleep-wake disorder (Non-24), was approved by the U.S. Food and Drug Administration (FDA) in January 2014 and launched commercially in the U.S. in April 2014. In July 2015, the European Commission (EC) granted centralized marketing authorization with unified labeling for HETLIOZ® for the treatment of Non-24 in totally blind adults. HETLIOZ® was commercially launched in Germany in August 2016. HETLIOZ® has potential utility in a number of other circadian rhythm disorders and is presently in clinical development for the treatment of Jet Lag Disorder, Smith-Magenis Syndrome (SMS) and pediatric Non-24. An assessment of new HETLIOZ® clinical opportunities including the treatment of delayed sleep phase disorder (DSPD) and for sleep disorders in patients with neurodevelopmental disorders is ongoing.
- Fanapt® (iloperidone), a product for the treatment of schizophrenia, the oral formulation of which was approved by the FDA in May 2009 and launched commercially in the U.S. by Novartis Pharma AG (Novartis) in January 2010. Novartis transferred all the U.S. and Canadian commercial rights to the Fanapt® franchise to us on December 31, 2014. Additionally, our distribution partners launched Fanapt® in Israel in 2014. Fanapt® has potential utility in a number of other disorders. Initial clinical work studying a long acting injectable (LAI) formulation of Fanapt® began in 2018. An assessment of new Fanapt® clinical opportunities including the treatment of bipolar disorder is ongoing.
- Tradipitant (VLY-686), a small molecule neurokinin-1 receptor (NK-1R) antagonist, which is presently in clinical development for the treatment of chronic pruritus in atopic dermatitis, gastroparesis and motion sickness.
- VTR-297, a small molecule histone deacetylase (HDAC) inhibitor presently in clinical development for the treatment of hematologic malignancies.
- Portfolio of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) activators and inhibitors. An early stage CFTR activator program is planned for the treatment of dry eye and ocular inflammation. In addition, an early stage CFTR inhibitor program is planned for the treatment of secretory diarrhea disorders, including cholera.
- VQW-765, a Phase II alpha-7 nicotinic acetylcholine receptor partial agonist.

Operational Highlights

Tradipitant

- Enrollment in EPIONE, the Phase III clinical study of tradipitant in atopic dermatitis, is complete. Results from EPIONE are expected in the first quarter of 2020.
- In October 2019, EPIONE II, a second Phase III clinical study of tradipitant in atopic dermatitis, began enrolling patients.
- Enrollment in the Phase III study of tradipitant in gastroparesis is ongoing as Vanda continues to engage with the FDA on tradipitant's regulatory path.
- Vanda plans to initiate the Phase III program of tradipitant in motion sickness in the fourth quarter of 2019. Vanda expects to file a New Drug Application with the FDA for tradipitant for the treatment of motion sickness in 2020.

HETLIOZ®

- Vanda received a complete response letter (CRL) on August 16, 2019 from the FDA related to the supplemental New Drug Application (sNDA) of HETLIOZ® for the treatment of Jet Lag Disorder. Vanda met with the FDA to discuss the CRL in a Post Action meeting and is determining its next steps.
- Vanda plans to meet with the FDA in the fourth quarter of 2019 to discuss the HETLIOZ® SMS clinical study results and expects to submit an sNDA by year-end 2019.
- An observational study of DSPD is ongoing. Vanda plans to initiate a Phase III clinical study of HETLIOZ® in DSPD patients by year-end 2019.

Fanapt®

- A pharmacokinetic study for the once-a-month LAI formulation of Fanapt® is ongoing.
- A study of Fanapt® in bipolar disorder is planned to begin by year-end 2019.

VTR-297

- Enrollment in the Phase I clinical study (1101) of VTR-297 in hematologic malignancies is ongoing.

Corporate

- Vanda announced the appointment of Anne Sempowski Ward to its Board of Directors, effective October 28, 2019, increasing the total number of members on the Board to six.
- Vanda announced the hiring of Scott L. Howell as its Chief People Officer, Aranthan "AJ" Jones II as its Chief Corporate Affairs and Communications Officer and Joakim "Kim" Wijkstrom as its Chief Marketing Officer, further bolstering the executive leadership team.

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 ability to successfully commercialize HETLIOZ® and Fanapt® in the U.S. and Europe, on our ability, alone or with others, to complete the development of our products, and to obtain the regulatory approvals for and to manufacture, market and sell our products. The results of our operations will vary significantly from year-to-year and quarter-to-quarter and depend on a number of factors, including risks related to our business, risks related to our industry, and other risks which are detailed in *Risk Factors* reported in Item 1A of Part I of our annual report on Form 10-K for the year ended December 31, 2018 and Item 1A of Part II of this quarterly report on Form 10-Q.

As described in Part II, Item 1, *Legal Proceedings*, of this quarterly report on Form 10-Q, we have initiated lawsuits to enforce our patent rights against certain generic pharmaceutical companies.

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.

With the exception of the accounting related to our lease agreements as a result of adoption of the new lease accounting standard on January 1, 2019, there have been no significant changes in our critical accounting policies including estimates, assumptions and judgments from those described in Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations*, included in our annual report on Form 10-K for the fiscal year ended December 31, 2018. A summary of our significant accounting policies appears in the notes to our audited consolidated financial statements included in our annual report on Form 10-K for the fiscal year ended December 31, 2018. 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.

Leases. In accordance with Accounting Standards Codification (ASC) 842, *Leases*, effective January 1, 2019, we determine if an arrangement contains a lease at inception. Right-of-use (ROU) assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from that lease. For leases with a term greater than 12 months, ROU assets and liabilities are recognized at the lease commencement date based on the estimated present value of lease payments over the lease term. The lease term includes the option to extend the lease when it is reasonably certain we will exercise that option. We do not combine lease and non-lease elements for office leases. For existing leases as of January 1, 2019, executory costs are excluded from lease expense, which is consistent with our accounting under ASC 840, *Leases*. For all leases entered into after January 1, 2019, executory costs are allocated between lease and non-lease elements based upon their relative stand-alone prices.

When available, we use the rate implicit in the lease to discount lease payments to present value; however, most of our leases do not provide a readily determinable implicit rate. Therefore, we use our incremental borrowing rate based on information available at the lease commencement date in determining the present value of lease payments. Our incremental borrowing rate is derived from information available at the lease commencement date in determining the present value of lease payments. Since we do not have outstanding debt that could provide an indication of the appropriate discount rate we used publicly available data for instruments with similar characteristics when calculating our incremental borrowing rates. In making this estimation we considered market comparable data on companies with similar credit rating, secured contracts and contract length terms. We use the lease term to determine the incremental borrowing rate.

Net Product Sales. Our net product sales consist of sales of HETLIOZ® and sales of Fanapt®. In accordance with ASC 606, *Revenue from Contracts with Customers*, which we adopted January 1, 2018, 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. Sales, value-added, and usage-based taxes are excluded from revenues.

HETLIOZ® is available in the U.S. for distribution through a limited number of specialty pharmacies, and is not available in retail pharmacies. Fanapt® is available in the U.S. for distribution through a limited number of wholesalers and is available in retail pharmacies. We invoice and record revenue when customers, specialty pharmacies and wholesalers, receive product from the third-party logistics warehouse which is the point at which control is transferred to the customer. Revenues and accounts receivable are concentrated with these customers. Outside the U.S., we commercially launched HETLIOZ® in Germany in August 2016. We have also entered into a distribution agreement with Megapharm Ltd. for the commercialization of Fanapt® in Israel.

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 discounts, rebates, chargebacks, service fees, co-pay assistance and product returns that are applicable for various government and commercial payors. We estimate the amount of variable consideration that should be included in the transaction price utilizing the most likely amount method and update our estimate at each reporting date.

Variable consideration is included in the transaction price if, in our judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Reserves for variable consideration for rebates, chargebacks and co-pay assistance are based upon the insurance benefits of the end customer, which are estimated using historical activity and, where available, actual and pending prescriptions for which we have validated the insurance benefits. Reserves for variable consideration are classified as product revenue allowances on our Condensed Consolidated Balance Sheets, with the exception of prompt-pay discounts which are classified as reductions of accounts receivable. The reserve for product returns for which the product may not be returned for a period of greater than one year from the balance sheet date is classified as other non-current liabilities on our Condensed Consolidated Balance Sheets. Uncertainties related to variable consideration are generally resolved in the quarter subsequent to period end, with the exception of product returns which are resolved during the product expiry period specified in the customer contract. We currently record sales allowances for the following:

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

Rebates: Allowances for rebates include mandated and supplemental 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 expected patient utilization.

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

Medicare Part D Coverage Gap: Medicare Part D prescription drug benefit mandates manufacturers to fund approximately 50% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients through 2018. Public Law No. 115-123, also known as the Bipartisan Budget Act of 2018 enacted on February 9, 2018 increased the manufacturer discount from 50% to 70% effective on January 1, 2019 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 for which we have validated the insurance benefits.

Service Fees: We receive sales order management, data and distribution services from certain customers. These fees are based on contracted terms and are known amounts. We accrue service fees at the time of revenue recognition, resulting in a reduction of product sales and the recognition of an accrued liability, unless it is a payment for a distinct good or service

from the customer in which case the fair value of those distinct goods or services are recorded as selling, general and administrative expense.

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

Product Returns: Consistent with industry practice, we generally offer direct customers a limited right to return as defined within our returns policy. We consider several factors in the estimation process, including historical return activity, expiration dates of product shipped to specialty pharmacies, inventory levels within the distribution channel, product shelf life, 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, 2019 or December 31, 2018.

The following table summarizes sales discounts and allowance activity for the nine months ended September 30, 2019:

(in thousands)	Rebates & Chargebacks	Discounts, Returns and Other	Total
Balances at December 31, 2018	$ 22,134	$ 9,700	$ 31,834
Provision related to current period sales	44,501	19,903	64,404
Adjustments for prior period sales	85	(53)	32
Credits/payments made	(43,774)	(18,824)	(62,598)
Balances at September 30, 2019	$ 22,946	$ 10,726	$ 33,672

The provision of $44.5 million for rebates and chargebacks for the nine months ended September 30, 2019 primarily represents Medicaid rebates applicable to sales of Fanapt® and HETLIOZ®. The provision of $19.9 million for discounts, returns and other for the nine months ended September 30, 2019 primarily represents wholesaler distribution fees applicable to sales of Fanapt® and, to a lesser extent, co-pay assistance costs and prompt pay discounts applicable to the sales of both HETLIOZ® and Fanapt® as well as estimated product returns of 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 not paid dividends to our stockholders since our inception (other than a dividend of preferred share purchase rights which was declared in September 2008) and do not plan to pay dividends in the foreseeable future. As stock-based compensation expense recognized in the Condensed Consolidated Statements of Operations is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

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

Clinical trials are inherently complex, often involve multiple service providers, and can include payments made to investigator physicians at study sites. Because billing for services often lags delivery of service by a substantial amount of time, we often are required to estimate a significant portion of our accrued clinical expenses. Our assessments include, but are not limited to:

(i) an evaluation by the project manager of the work that has been completed during the period, (ii) measurement of progress prepared internally and/or provided by the third-party service provider, (iii) analyses of data that justify the progress, and (iv) management's judgment. In the event that we do not identify certain costs that have begun to be incurred or we under- or over-estimate the level of services performed or the costs of such services, our reported expenses for such period would be too low or too high.

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

Income taxes. We assess the need for a valuation allowance against our deferred tax asset each quarter through the review of all available positive and negative evidence. Deferred tax assets are reduced by a tax valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. As of December 31, 2018, there was a full tax valuation allowance against all deferred tax assets in the U.S. During the three months ended September 30, 2019, after considering all available positive and negative evidence, including but not limited to cumulative income in recent periods, historical and current projected results, and significant risks and uncertainties related to forecasts, we concluded that it was more likely than not that substantially all of our deferred taxes are realizable in future periods. Tax benefits are recognized from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax benefit recognized in the financial statements for a particular tax position is based on the largest benefit that is more likely than not to be realized upon settlement.

Recent Accounting Pronouncements

See *Summary of Significant Accounting Policies* footnote to the condensed consolidated financial statements included in Part I of this quarterly report on Form 10-Q for information on recent accounting pronouncements.

Results of Operations

We anticipate that our results of operations will fluctuate for the foreseeable future due to several factors, including our and our partners' ability to successfully commercialize our products, any possible payments made or received pursuant to license or collaboration agreements, progress of our research and development efforts, the timing and outcome of clinical trials and related possible regulatory approvals. Since our inception, we have incurred significant losses resulting in an accumulated deficit of $224.9 million as of September 30, 2019. Our total stockholders' equity was $400.9 million as of September 30, 2019.

Three months ended September 30, 2019 compared to three months ended September 30, 2018

Revenues. Total revenues increased by $10.4 million, or 21%, to $59.5 million for the three months ended September 30, 2019 compared to $49.1 million for the three months ended September 30, 2018. Revenues were as follows:

	Three Months Ended			
(in thousands)	September 30, 2019	September 30, 2018	Net Change	Percent
HETLIOZ® product sales, net	$ 37,589	$ 29,923	$ 7,666	26%
Fanapt® product sales, net	21,896	19,212	2,684	14%
Total net product sales	$ 59,485	$ 49,135	$ 10,350	21%

HETLIOZ® product sales, net increased by $7.7 million, or 26%, to $37.6 million for the three months ended September 30, 2019 compared to $29.9 million for the three months ended September 30, 2018. The increase to net product sales was attributable to an increase in volume and an increase in price net of deductions.

Fanapt® product sales, net increased by $2.7 million, or 14%, to $21.9 million for the three months ended September 30, 2019 compared to $19.2 million for the three months ended September 30, 2018. The increase to net product sales was attributable to an increase in price net of deductions.

Cost of goods sold. Cost of goods sold increased by $1.7 million, or 34%, to $6.8 million for the three months ended September 30, 2019 compared to $5.1 million for the three months ended September 30, 2018. Cost of goods sold includes third party manufacturing costs of product sold, third party royalty costs and distribution and other costs. Third party royalty costs were 10% and 5% of net product sales of HETLIOZ® in the U.S. and Germany, respectively, and 9% of net product sales of Fanapt®. Third party royalty costs on net product sales of Fanapt® will decrease to 6% beginning January 2020.

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

Research and development expenses. Research and development expenses were $11.3 million and $11.4 million for the three months ended September 30, 2019 and 2018, respectively. The decrease in clinical trial expenses associated with our HETLIOZ® and tradipitant development programs were offset by an increase in clinical trial expenses associated with our Fanapt® development programs as well as an increase in stock-based compensation expense. The following table summarizes the costs of our product development initiatives for the three months ended September 30, 2019 and 2018:

	Three Months Ended	
(in thousands)	**September 30, 2019**	**September 30, 2018**
Direct project costs (1)		
HETLIOZ®	$ 2,472	$ 2,964
Fanapt®	1,119	462
Tradipitant	4,368	5,113
VTR-297	369	390
CFTR	1,208	1,465
Other	265	174
	9,801	10,568
Indirect project costs (1)		
Stock-based compensation	827	326
Other indirect overhead	719	496
	1,546	822
Total research and development expense	$ 11,347	$ 11,390

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

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

Selling, general and administrative expenses. Selling, general and administrative expenses increased by $4.2 million, or 16%, to $30.2 million for the three months ended September 30, 2019 compared to $26.0 million for the three months ended September 30, 2018. The increase was primarily the result of increased spending on corporate and legal related activities and investment in U.S. commercial capabilities.

Intangible asset amortization. Intangible asset amortization was $0.4 million for each of the three months ended September 30, 2019 and 2018.

Other income. Other income was $1.5 million for the three months ended September 30, 2019 compared to $1.0 million for the three months ended September 30, 2018. Other income primarily relates to investment income on our marketable securities.

Provision (benefit) for income taxes. For the three months ended September 30, 2019 and 2018, we recorded income tax benefit of $88.1 million and income tax expense of $0.1 million, respectively. The income tax benefit for the three months ended September 30, 2019 was primarily due to the reduction of our tax valuation allowance against substantially all of our deferred tax assets in the U.S. Net income tax benefit of $1.6 million was also recorded related to the generation of 2019 research and development and orphan drug credits, current taxes payable to certain U.S. state and foreign jurisdictions and uncertain tax positions. As a result of the tax valuation allowance against deferred tax assets in the U.S., there was no expense (benefit) for federal income taxes associated with the income before taxes for the three months ended September 30, 2018. Income taxes were recorded related to certain U.S. state and foreign jurisdictions for the three months ended September 30, 2018.

Nine months ended September 30, 2019 compared to nine months ended September 30, 2018

Revenues. Total revenues increased by $26.2 million, or 19%, to $166.3 million for the nine months ended September 30, 2019 compared to $140.1 million for the nine months ended September 30, 2018. Revenues were as follows:

	Nine Months Ended			
(in thousands)	September 30, 2019	September 30, 2018	Net Change	Percent
HETLIOZ® product sales, net	$ 104,381	$ 83,391	$ 20,990	25%
Fanapt® product sales, net	61,877	56,686	5,191	9%
Total net product sales	$ 166,258	$ 140,077	$ 26,181	19%

HETLIOZ® product sales, net increased by $21.0 million, or 25%, to $104.4 million for the nine months ended September 30, 2019 compared to $83.4 million for the nine months ended September 30, 2018. The increase to net product sales was attributable to an increase in volume and an increase in price net of deductions.

Fanapt® product sales, net increased by $5.2 million, or 9%, to $61.9 million for the nine months ended September 30, 2019 compared to $56.7 million for the nine months ended September 30, 2018. The increase to net product sales was attributable to an increase in price net of deductions.

Cost of goods sold. Cost of goods sold increased by $3.4 million, or 23%, to $18.3 million for the nine months ended September 30, 2019 compared to $14.8 million for the nine months ended September 30, 2018. Cost of goods sold includes third party manufacturing costs of product sold, third party royalty costs and distribution and other costs. Third party royalty costs were 10% and 5% of net product sales of HETLIOZ® in the U.S. and Germany, respectively, and 9% of net product sales of Fanapt®. Third party royalty costs on net product sales of Fanapt® will decrease to 6% beginning January 2020.

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

Research and development expenses. Research and development expenses increased by $4.9 million, or 16%, to $35.6 million for the nine months ended September 30, 2019 compared to $30.7 million for the nine months ended September 30, 2018. The increase was primarily due to an increase in clinical trial expenses associated with our tradipitant and Fanapt® development programs and preclinical expenses associated with the CFTR programs as well as an increase in stock-based compensation expense, partially offset by a decrease in expenses associated with the HETLIOZ® development programs. The following table summarizes the costs of our product development initiatives for the nine months ended September 30, 2019 and 2018:

(in thousands)	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Direct project costs (1)		
HETLIOZ®	$ 6,636	$ 9,009
Fanapt®	3,244	2,018
Tradipitant	15,726	11,762
VTR-297	1,078	1,682
CFTR	3,674	2,764
Other	467	527
	30,825	27,762
Indirect project costs (1)		
Stock-based compensation	2,311	963
Other indirect overhead	2,439	1,947
	4,750	2,910
Total research and development expense	$ 35,575	$ 30,672

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

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

Selling, general and administrative expenses. Selling, general and administrative expenses increased by $11.9 million, or 15%, to $92.7 million for the nine months ended September 30, 2019 compared to $80.8 million for the nine months ended September 30, 2018. The increase was primarily the result of increased spending on corporate and legal related activities and investment in U.S. commercial capabilities.

Intangible asset amortization. Intangible asset amortization was $1.1 million for each of the nine months ended September 30, 2019 and September 30, 2018.

Other income. Other income was $4.7 million for the nine months ended September 30, 2019 compared to $2.4 million for the nine months ended September 30, 2018. Other income primarily relates to investment income on our marketable securities.

Provision (benefit) for income taxes. For the nine months ended September 30, 2019 and 2018, we recorded income tax benefit of $88.1 million and income tax expense of $0.2 million, respectively. The income tax benefit for the nine months ended September 30, 2019 was primarily due to the reduction of our tax valuation allowance against substantially all of our deferred tax assets in the U.S. Net income tax benefit of $1.6 million was also recorded related to the generation of 2019 research and development and orphan drug credits, current taxes payable to certain U.S. state and foreign jurisdictions and uncertain tax positions. As a result of the tax valuation allowance against deferred tax assets in the U.S., there was no expense (benefit) for federal income taxes associated with the income before taxes for the nine months ended September 30, 2018. Income taxes were recorded related to certain U.S. state and foreign jurisdictions for the nine months ended September 30, 2018.

Liquidity and Capital Resources

As of September 30, 2019, our total cash and cash equivalents and marketable securities (Cash) was $299.6 million compared to $257.4 million at December 31, 2018. 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, government agencies and commercial paper of high-quality corporate issuers. Our marketable securities consist of investments in government sponsored and corporate enterprises, commercial paper and asset-backed securities.

Our liquidity resources as of September 30, 2019 and December 31, 2018 are summarized as follows:

(in thousands)	September 30, 2019	December 31, 2018
Cash and cash equivalents	$ 39,208	$ 61,005
Marketable securities:		
U.S. Treasury and government agencies	87,325	69,270
Corporate debt	126,173	105,910
Asset-backed securities	46,906	21,175
Total marketable securities	260,404	196,355
Total cash, cash equivalents and marketable securities	$ 299,612	$ 257,360

As of September 30, 2019, we maintained all of our Cash in two financial institutions. Deposits held with these institutions may exceed the amount of insurance provided on such deposits, but we do not anticipate any losses with respect to such deposits.

We expect to incur substantial costs and expenses throughout the remainder of 2019 and beyond in connection with our continued clinical development of tradipitant and our other products, U.S. commercial activities for HETLIOZ® and Fanapt®, the European commercial launch activities for HETLIOZ® and payments due upon achievement of milestones under our license agreements. Additionally, we continue to pursue market approval of HETLIOZ® and Fanapt® in other regions. The actual costs to advance tradipitant and our research and development projects and commercial activities for HETLIOZ® and Fanapt® may vary significantly. We believe that the upcoming activities associated with our tradipitant and other development programs will result in an increase in research and development expenses in the near term. We believe that our existing funds will be sufficient to meet our operating plans for at least the next twelve months. Our future capital requirements and the adequacy of our available funds will depend on many factors, primarily including our ability to generate revenue, the scope and costs of our commercial, manufacturing and process development activities, the magnitude of our discovery, preclinical and clinical development programs, and potential costs to acquire or license the rights to additional products.

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

Cash Flow

The following table summarizes our net cash flows from operating, investing and financing activities for the nine months ended September 30, 2019 and 2018:

	Nine Months Ended		
(in thousands)	September 30, 2019	September 30, 2018	Net Change
Net cash provided by (used in):			
Operating activities:			
Net income	$ 111,337	$ 14,848	$ 96,489
Non-cash charges	(78,318)	9,715	(88,033)
Net change in operating assets and liabilities	3,137	(9,840)	12,977
Operating activities	36,156	14,723	21,433
Investing activities:			
Acquisition of intangible asset	—	(25,000)	25,000
Purchases of property and equipment	(951)	(346)	(605)
Net purchases of marketable securities	(61,128)	(68,510)	7,382
Investing activities	(62,079)	(93,856)	31,777
Financing activities:			
Net proceeds from offering of common stock	—	100,870	(100,870)
Proceeds from the exercise of stock options	4,148	5,464	(1,316)
Financing activities	4,148	106,334	(102,186)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(24)	(14)	(10)
Net change in cash, cash equivalents and restricted cash	$ (21,799)	$ 27,187	$ (48,986)

The increase of $21.4 million in net cash provided by operating activities reflects an increase of $13.0 million from the net change in operating assets and liabilities and an increase of $96.5 million in net income, partially offset by a decrease of $88.0 million in non-cash charges primarily due to the reduction of our tax valuation allowance against substantially all of our deferred tax assets in the U.S. during the three months ended September 30, 2019. The increase of $13.0 million from the net change in operating assets and liabilities primarily relates to a decrease in accounts receivable attributable to the timing of shipments and payments and an increase in accounts payable and other liabilities attributable to the timing of activities and payments. For the nine months ended September 30, 2019, the net decrease in cash, cash equivalents and restricted cash of $21.8 million includes net reinvestment of $61.1 million of available cash and cash equivalents in our portfolio of marketable securities.

Off-Balance Sheet Arrangements

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

Contractual Obligations and Commitments

The following is a summary of our noncancellable long-term contractual cash obligations as of September 30, 2019:

	Cash Payments Due by Year (1)(2)(3)						
(in thousands)	Total	2019	2020	2021	2022	2023	Thereafter
Operating leases(4)	$ 20,715	$ 633	$ 2,309	$ 2,329	$ 2,355	$ 2,420	$ 10,669
Purchase commitments(5)	12,872	225	11,200	966	481	—	—
Total noncancellable long-term contractual cash obligations	$ 33,587	$ 858	$ 13,509	$ 3,295	$ 2,836	$ 2,420	$ 10,669

(1) This table does not include potential future milestone obligations under our license agreement with Lilly for the exclusive rights to develop and commercialize tradipitant. As of September 30, 2019, remaining milestone obligations include a $2.0 million pre-NDA approval milestone due upon the filing of the first marketing authorization for tradipitant in either the U.S. or European Union, $10.0 million and $5.0 million for the first approval of a marketing authorization for tradipitant in the U.S. and European Union, respectively, and up to $80.0 million for sales milestones. See *Commitments and Contingencies* footnote to the condensed consolidated financial statements included in Part I of this quarterly report on Form 10-Q for information on our license agreements.

(2) This table does not include potential future milestone obligations under our license agreement with the University of California San Francisco for the exclusive rights to develop and commercialize a portfolio of CFTR activators and inhibitors. As of September 30, 2019, remaining milestone obligations include annual maintenance fees, $12.2 million for pre-NDA approval milestones and $33.0 million for future regulatory approval and sales milestones. Included in the $12.2 million in pre-NDA approval milestone obligations is a $350,000 milestone payment due upon the conclusion of a Phase I study for each licensed product but not to exceed $1.1 million in total for the CFTR portfolio. See *Commitments and Contingencies* footnote to the condensed consolidated financial statements included in Part I of this quarterly report on Form 10-Q for information on our license agreements.

(3) This table does not include liabilities related to uncertain tax positions taken as of September 30, 2019. Due to the uncertainties in the timing of potential tax audits, the timing associated with the resolution of these positions is also uncertain. See *Income Taxes* footnote to the condensed consolidated financial statements included in Part I of this quarterly report on Form 10-Q for information on our income taxes.

(4) 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. See *Leases* footnote to the condensed consolidated financial statements included in Part I of this quarterly report on Form 10-Q for information on our operating leases.

(5) Purchase commitments include noncancellable purchase commitments for agreements longer than one year and primarily relate to commitments for advertising and data services. This table does not include various other long-term agreements entered into for services with other third party vendors due to the cancelable nature of the services. Additionally, this table does not include rebates, chargebacks or discounts recorded as liabilities at the time that product sales are recognized as revenue. See *Commitments and Contingencies* footnote to the condensed consolidated financial statements included in Part I of this quarterly report on Form 10-Q for information on our purchase commitments.

ITEM 3 Quantitative and Qualitative Disclosures about Market Risk

Interest rate risks

Our exposure to market risk is currently confined to our cash and cash equivalents, marketable securities and restricted cash. We currently do not hedge interest rate exposure. We have not used derivative financial instruments for speculation or trading purposes. Because of the short-term maturities of our cash and cash equivalents and marketable securities, we do not believe that an increase in market rates would have any significant impact on the realized value of our investments.

Concentrations of credit risk

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

Revenues and accounts receivable are concentrated with specialty pharmacies and wholesalers. There were five major customers that each accounted for more than 10% of total revenues and, as a group, represented 96% of total revenues for the nine months ended September 30, 2019. 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, 2019. 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, 2019. 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, 2019, 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 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

ITEM 1 Legal Proceedings

Fanapt®. We have been involved in litigation with Roxane Laboratories, Inc. (Roxane) and its affiliates, West-Ward Pharmaceuticals International Limited and West-Ward Pharmaceuticals Corp (West-Ward), since we filed a lawsuit against Roxane in the U.S. District Court for the District of Delaware (Delaware District Court) for patent infringement in June 2014. The lawsuit was filed in response to Roxane's submission to the U.S. Food and Drug Administration (FDA) of an Abbreviated New Drug Application (ANDA) for a generic version of Fanapt® prior to the expiration of certain of our patents covering Fanapt®, including U.S. Patent No. 8,586,610 ('610 Patent). In August 2016, the Delaware District Court ruled in our favor, permanently enjoining Roxane from manufacturing, using, selling, offering to sell, distributing or importing any generic iloperidone product described in Roxane's ANDA until the expiration of the '610 Patent in November 2027, or May 2028 if we obtain pediatric exclusivity. In April 2018, following an appeal by Roxane of the Delaware District Court's decision to the Federal Circuit Court of Appeals (Federal Circuit), the Federal Circuit affirmed the Delaware District Court's ruling. In June 2018, West-Ward, having replaced Roxane as defendants following the acquisition of Roxane by West-Ward's parent company, Hikma Pharmaceuticals PLC, petitioned the Federal Circuit for a rehearing en banc. In August 2018, the Federal Circuit denied West-Ward's petition. In January 2019, West-Ward filed a petition in the U.S. Supreme Court for a writ of certiorari seeking reversal of the Federal Circuit's decision. In March 2019, the U.S. Supreme Court invited the Solicitor General of the U.S. to file a brief in the matter expressing the views of the U.S.

In 2015, we filed six separate patent infringement lawsuits in the Delaware District Court against Roxane, Inventia Healthcare Pvt. Ltd. (Inventia), Lupin Ltd. and Lupin Pharmaceuticals, Inc. (Lupin), Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd. (Taro), and Apotex Inc. and Apotex Corp. (Apotex, and collectively with Roxane, Inventia, Lupin and Taro, the Fanapt® Defendants). These lawsuits were filed in response to the submission to the FDA by each of the Fanapt® Defendants of ANDAs for generic versions of Fanapt® prior to the expiration of the '610 Patent in November 2027 or the U.S. Patent No. 9,138,432 in September 2025. We entered into separate confidential stipulations with each of Inventia and

Lupin regarding any potential launch of their generic versions of Fanapt®. The remaining lawsuits against the other Fanapt® Defendants have been stayed until 14 days after final disposition by the U.S. Supreme Court of the petition for a writ of certiorari filed by West-Ward.

HETLIOZ®. In April and May 2018, we filed three separate patent infringement lawsuits in the Delaware District Court against Teva Pharmaceuticals USA, Inc. (Teva), MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited (MSN) and Apotex (collectively with Teva and MSN, the HETLIOZ® Defendants) after having received Paragraph IV certification notice letters (Paragraph IV Letters) from each of the HETLIOZ® Defendants alleging that certain of our patents covering HETLIOZ® (collectively, the HETLIOZ® Patents) were invalid, unenforceable and/or would not be infringed by the manufacture, use or sale of their generic versions of HETLIOZ®, as described in the ANDAs submitted to the FDA by each of the HETLIOZ® Defendants, prior to the expiration of the latest to expire of the HETLIOZ® Patents in 2034. Each of the HETLIOZ® Patents are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book). In December 2018, we filed amended complaints against each of the HETLIOZ® Defendants following the receipt of additional Paragraph IV Letters from Teva and Apotex concerning our Orange Book listed '977 Patent, which expires in 2035. These lawsuits are scheduled for trial in October 2020.

In March 2019, April 2019, and May 2019, we filed three additional patent infringement lawsuits in the Delaware District Court against the HETLIOZ® Defendants following the receipt of additional Paragraph IV Letters from each concerning our Orange Book listed U.S. Patent No. 10,149,829, which expires in 2033. A trial date has not yet been scheduled for these lawsuits.

In October 2019, we received an additional Paragraph IV certification notice letter from Teva concerning our Orange Book listed U.S. Patent No. 10,376,487 ('487 Patent), which expires in July 2035. In its notice letter, Teva alleges that the ‘487 Patent, which covers a method of treatment using HETLIOZ®, is invalid, unenforceable and/or will not be infringed by Teva’s manufacture, use or sale of its generic version of HETLIOZ® as described in our ANDA. We intend to vigorously pursue a patent infringement lawsuit permanently enjoining Teva from infringing the claims of the ‘487 Patent.

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

On February 5, 2019, we filed a lawsuit against the FDA in the U.S. District Court for the District of Columbia (DC District Court), challenging the FDA’s legal authority to issue the PCH, and seeking an order to set it aside. In February 2019, the FDA filed a Motion for Voluntary Remand to the Agency and for a Stay of the Case. In March 2019, the DC District Court granted the FDA’s request for voluntary remand and returned the matter to the FDA for further consideration. In April 2019, the FDA provided its remand response, in which it indicated that, upon review of scientific literature and tradipitant data, it believes that a partial clinical hold continues to be appropriate until we have adequate safety data from a 9-month non-rodent toxicity study. After reviewing the FDA’s remand response, we continue to believe that additional chronic toxicity studies are unjustified, and that we have provided the FDA with sufficient information regarding the safety of tradipitant to justify the continued study of tradipitant in patients beyond 12 weeks, in accordance with applicable law and FDA regulations. In May 2019, we filed an amended complaint, and in July 2019, we filed a Motion for Summary Judgment. The FDA filed a reply and cross-motion for summary judgment in October 2019. A hearing has been set for December 13, 2019. We intend to continue vigorously pursuing our interests in the matter.

In February 2019, a qui tam action filed against us was unsealed by order of the DC District Court. The qui tam action, which was filed under seal in March 2017, was brought by a former employee of ours on behalf of the U.S., 28 states and the District of Columbia (collectively, the Plaintiff States) and the policyholders of certain insurance companies under the Federal False Claims Act and state law equivalents to the Federal False Claims Act and related state laws. The complaint alleged that we violated these laws through the promotion and marketing of our products Fanapt® and HETLIOZ® and sought, among other things, treble damages, civil penalties for each alleged false claim, and attorneys’ fees and costs. By virtue of the DC District Court having unsealed the original complaint, 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. In August 2019, we filed a motion to dismiss, and in October 2019 the plaintiff filed a reply. According to a filing unsealed in June 2019, the DOJ reaffirmed its decision not to intervene and incorporated its prior filing, indicating that neither the DOJ nor the Plaintiff States were intervening regarding the original complaint. Although the DOJ and the Plaintiff States have elected not to intervene, the plaintiff may litigate this action and the DOJ and the Plaintiff States may later seek to intervene in the action. We intend to vigorously defend ourselves in the case.

In February 2019, a securities class action, *Gordon v. Vanda Pharmaceuticals Inc.*, was filed in the U.S. District Court for the Eastern District of New York naming us and certain of our officers as defendants. An amended complaint was filed in July 2019. The amended complaint, filed on behalf of a purported stockholder, asserts claims on behalf of a putative class of all persons who purchased our publicly traded securities between November 4, 2015 and February 11, 2019, for alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder. The amended complaint alleges that the defendants made false and misleading statements and/or omissions regarding Fanapt®, HETLIOZ® and our interactions with the FDA regarding tradipitant between November 3, 2015 and February 11, 2019. We believe that we have meritorious defenses and intend to vigorously defend this lawsuit. We do not anticipate that this litigation will have a material adverse effect on our business, results of operations or financial condition. However, this lawsuit is subject to inherent uncertainties, the actual cost may be significant, and we may not prevail. We believe we are entitled to coverage under our relevant insurance policies, subject to a retention, but coverage could be denied or prove to be insufficient.

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

ITEM 1A Risk Factors

We previously disclosed in Part I, Item 1A of our annual report on Form 10-K for the year ended December 31, 2018, filed with the Securities and Exchange Commission on February 19, 2019, important factors which could affect our business, financial condition, results of operations and future operations under the heading *Risk Factors*. Our business, financial condition and operating results can be affected by a number of factors, whether current known or unknown, including but not limited to those described as risk factors, any one or more of which could, directly or indirectly, cause our actual operating results and financial condition to vary materially from past, or anticipated future, operating results and financial condition. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, operating results and the price of our common stock. Except as set forth below, there have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2018.

If the FDA does not accept for filing the NDAs that we may submit for tradipitant for the treatment of chronic pruritus in atopic dermatitis, the treatment of gastroparesis and the treatment of motion sickness, regulatory authorities determine that our clinical trial results for tradipitant for the treatment of chronic pruritus in atopic dermatitis, the treatment of gastroparesis or the treatment of motion sickness do not demonstrate adequate safety and efficacy, or the FDA does not approve an applicable PDUFA-VI date, continued development of tradipitant will be significantly delayed or terminated, our business will be significantly harmed, and the market price of our stock could decline.

We announced the results in September 2017 from a randomized Phase II clinical study of tradipitant as a monotherapy in the treatment of chronic pruritus in patients with atopic dermatitis. Tradipitant was shown to improve the intensity of the worst itch patients experienced, as well as atopic dermatitis disease severity.

We announced results in December 2018 from a randomized clinical study (2301) of tradipitant as a monotherapy in the treatment of gastroparesis. Tradipitant met the primary endpoint of the study of change in nausea score as measured by patient daily diaries and also met the related endpoint of improvement in the number of nausea free days. Tradipitant also showed significant improvement in most of the secondary endpoints studied, including the several key scales reflecting overall

gastroparesis symptoms, specifically Gastroparesis Cardinal Symptom Index (GCSI); Patient Assessment of Gastrointestinal Disorders Symptom Severity Index (PAGI-SYM); Clinical Global Impression Severity (CGI-S); and Patient Global Impression of Change (PGI-C).

We announced the results in July 2019 from a randomized Phase II clinical study of tradipitant as a monotherapy in the treatment of motion sickness, which demonstrated that tradipitant was effective in treating motion sickness. The study had two primary endpoints: percentage of participants vomiting, and Motion Sickness Severity Scale (MSSS) Worst score. In the overall population, a significantly higher percentage of participants experienced vomiting in the placebo arm as compared to the tradipitant arm. The MSSS Worst score endpoint also favored tradipitant, but the difference did not reach statistical significance.

If the results of our ongoing Phase III clinical study of tradipitant for the treatment of chronic pruritus in atopic dermatitis and/or our ongoing Phase III clinical study of tradipitant for the treatment of gastroparesis and/or our planned Phase III clinical study of tradipitant for the treatment of motion sickness are positive, we will likely submit an NDA with the FDA for these indications. Any adverse developments or results or perceived adverse developments or results with respect to our pre-NDA meeting with the FDA, our regulatory submission or the tradipitant clinical programs in either or both indications will significantly harm our business and could cause the market price of our stock to decline. Examples of such adverse developments include, but are not limited to:

- the FDA determining that additional clinical studies are required with respect to the tradipitant for the treatment of chronic pruritus in atopic dermatitis and/or the treatment of gastroparesis and/or motion sickness;
- safety, efficacy or other concerns arising from clinical or non-clinical studies in these programs; or
- the FDA determining that the tradipitant clinical trial programs raise safety concerns or do not demonstrate adequate efficacy.

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

On February 5, 2019, we filed a lawsuit against the FDA in the U.S. District Court for the District of Columbia (DC District Court), challenging the FDA's legal authority to issue the PCH, and seeking an order to set it aside. In February 2019, the FDA filed a Motion for Voluntary Remand to the Agency and for a Stay of the Case. In March 2019, the DC District Court granted the FDA's request for voluntary remand and returned the matter to the FDA for further consideration. In April 2019, the FDA provided its remand response, in which it indicated that, upon review of scientific literature and tradipitant data, it believes that a partial clinical hold continues to be appropriate until we have adequate safety data from a 9-month non-rodent toxicity study. After reviewing the FDA's remand response, we continue to believe that additional chronic toxicity studies are unjustified, and that we have provided the FDA with sufficient information regarding the safety of tradipitant to justify the continued study of tradipitant in patients beyond 12 weeks, in accordance with applicable law and FDA regulations. In May 2019, we filed an amended complaint, and in July 2019, we filed a Motion for Summary Judgment. The FDA filed a reply and cross-motion for summary judgment in October 2019. A hearing has been set for December 13, 2019. We intend to continue vigorously pursuing our interests in the matter.

We do not expect the PCH to have any impact on our ongoing clinical studies in atopic dermatitis and gastroparesis, each of which is under 12 weeks in duration, or our planned Phase III study in motion sickness, none of which are subject to the PCH. Nor do we expect the PCH to impact the potential timing of an NDA filing. If the matter has not been fully resolved prior to the date on which we are ready to file the first NDA for tradipitant, then we may choose to file with the safety data we have available at that time. We may pursue additional studies of durations in excess of 12 weeks in countries where the conduct of such studies may be permitted (or we may choose to file for approval of a limited indication). If the FDA determines that our NDA does not contain safety data sufficient for approval, it may not accept the NDA for filing. We will continue to reassess the situation as events unfold.

Even if our lawsuit challenging the FDA's authority to issue the PCH is successful, there can be no assurances that the FDA will not attempt to impose a clinical hold or PCH on other grounds. While we believe we have a strong legal basis, this litigation is subject to uncertainties and we may not prevail. Because the PCH could, however, impede our ability to conduct longer term studies of tradipitant, whether the PCH impacts the timing or approvability of NDA filings with the FDA for any indication will depend on a number of factors, including whether the PCH is resolved through the lawsuit described above, whether we resolve the PCH out of court through discussions with the FDA, and, in addition to the non-clinical animal studies, whether the FDA considers the clinical trials that we conduct to be sufficient. A delay in filing, or FDA delay or denial of approval, of NDA filings for tradipitant for the treatment of chronic pruritus in atopic dermatitis, gastroparesis or motion sickness could materially adversely impact our business.

ITEM 2 Unregistered Sales of Equity Securities and Use of Proceeds

None

ITEM 3 Defaults Upon Senior Securities

None

ITEM 4 Mine Safety Disclosures

Not applicable

ITEM 5 Other Information

None

ITEM 6 Exhibits

Exhibit Number	Description
3.1	Form of Amended and Restated Certificate of Incorporation of the registrant (filed as Exhibit 3.8 to Amendment No. 2 to the registrant's registration statement on Form S-1 (File No. 333-130759) on March 17, 2006 and incorporated herein by reference).
3.2	Fourth Amended and Restated Bylaws of the registrant, as amended and restated on December 17, 2015 (filed as Exhibit 3.1 to the registrant's current report on Form 8-K (File No. 001-34186) on December 21, 2015 and incorporated herein by reference).
10.40	Employment Agreement, dated July 3, 2019, by and between Aranthan "AJ" Jones II and the registrant.
10.41	Employment Agreement, dated August 5, 2019, by and between Joakim Wijkstrom and the registrant.
31.1	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer), as required by Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from this quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2019 formatted in Inline Extensible Business Reporting Language (iXBRL) and filed electronically herewith: (i) Condensed Consolidated Balance Sheets as of September 30, 2019 and December 31, 2018; (ii) Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2019 and 2018; (iii) Condensed Consolidated Statements of Comprehensive Income for the three and nine months ended September 30, 2019 and 2018; (iv) Condensed Consolidated Statements of Changes in Stockholders' Equity for the three and nine months ended September 30, 2019 and 2018; (v) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2019 and 2018; 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 7, 2019 /s/ Mihael H. Polymeropoulos, M.D.

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

November 7, 2019 /s/ James P. Kelly

James P. Kelly
Executive Vice President, Chief Financial Officer and Treasurer
(Principal Financial Officer and Principal Accounting Officer)

VANDA PHARMACEUTICALS INC.
EMPLOYMENT AGREEMENT

This Employment Agreement (this "Agreement") is entered into as of July 3, 2019, by and between **Aranthan "AJ" Jones II** (the "Executive") and **VANDA PHARMACEUTICALS INC.**, a Delaware corporation (the "Company").

1. **Duties and Scope of Employment.**

(a) **Position**. During his employment under this Agreement ("Employment"), the Company agrees to employ the Executive in the position of Chief Corporate Affairs and Communication Officer. The Executive shall be subject to the supervision of, and shall have such authority as is delegated to him by, the Company's Chief Executive Officer. The Executive hereby accepts such employment, commencing effective as of July 25, 2019 (the "Employment Commencement Date") and agrees to undertake the duties and responsibilities normally inherent in such position and such other duties and responsibilities as the Company's Chief Executive Officer shall from time to time reasonably assign to him.

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

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

2. **Cash and Incentive Compensation.**

(a) **Salary**. The Company shall pay the Executive as compensation for his services a base salary at a gross annual rate of not less than $400,000. Such salary shall be payable in accordance with the Company's standard payroll procedures. The annual compensation specified in this Subsection (a), together with any increases in such compensation that the Company may grant from time to time, is referred to in this Agreement as "Base Compensation."

(b) **Signing Bonus**. On the first pay date of the Company's standard payroll schedule following the Employment Commencement Date, the Company shall pay the Executive a one-time signing bonus of $150,000 (the "Signing Bonus"). The Signing Bonus will be grossed up for state and federal income and payroll taxes and the taxes thereon. In the event that the Executive's employment with the Company is (i) terminated by the Company for Cause or (ii) the Executive voluntarily resigns his Employment, in either case within 2 years after the Employment Commencement Date, the Executive shall repay the Signing Bonus to the Company in its entirety within 30 days of the Executive's last day of Employment.

(c) **Incentive Bonuses**. The Executive shall be eligible for an annual incentive bonus with a target amount equal to 45% of his Base Compensation (the "Annual Target Bonus"). Such bonus (if any) shall be awarded based on objective or subjective criteria established in advance by the Board or the Compensation Committee of the Board (the "Compensation Committee"). Any bonus for the fiscal year in which Executive's employment begins shall not be prorated. Any incentive bonus for a fiscal year shall in no event be paid later than 2½ months after the close of such fiscal year. Except as provided in Section 6, such bonus shall be paid only if the Executive is employed by the Company at the time of payment. The determinations of the Board or the Compensation Committee with respect to such bonus shall be final and binding.

(d) **Stock Options**. On the Employment Commencement Date, the Company shall grant the Executive a nonstatutory stock option to purchase 60,000 shares of the Company's Common Stock (the "Option"). The per-share exercise price of the Option shall be equal to the closing price of one share of the Company's Common Stock on the date of grant as reported on the Nasdaq Global Market. The maximum term of the Option shall be 10 years. The grant of the Option shall be subject to the terms and conditions set forth in the Vanda Pharmaceuticals Inc. Amended and Restated 2016 Equity Incentive Plan (the "Plan") and in the Company's standard form of Stock Option Agreement. The Option will become exercisable with respect to 25% of the shares on the first anniversary of the date of grant and with respect to the remaining 75% of the shares in equal monthly installments over the next 3 years of continuous service thereafter. The Option shall become exercisable in full if (i) the Company is subject to a Change in Control before the Executive's service with the Company terminates and (ii) the Executive is subject to an Involuntary Termination within 24 months after such Change in Control. In addition, Section 6(c) shall apply to the Option. In addition, the Executive will be eligible to receive annual equity awards, if any, subject to the approval of the Board or the Compensation Committee in their sole discretion. The timing and size of the annual equity awards, if any, shall be determined in the sole discretion of the Board or the Compensation Committee based on the Executive's and/or the Company's performance. In the event the Board or the Compensation Committee, in their sole discretion, grants an annual equity award to the Executive relating to performance for the fiscal year ending December 31, 2019, such annual equity award shall not be prorated.

(e) **Restricted Stock Units**. On the Employment Commencement Date, the Company shall award the Executive restricted stock units covering 60,000 shares of the Company's Common Stock (the "RSU Award"). The RSU Award shall be subject to the terms and conditions set forth in the Plan and in the Company's standard form of Restricted Stock Unit Award Agreement. The RSU Award will vest with respect to 25% of the shares on the first anniversary of

the date of grant and an additional 25% of the shares on each of the second, third and fourth anniversaries of the date of grant, provided that Executive remains in continuous service with the Company on each applicable vesting date. The RSU Award shall vest in full if (i) the Company is subject to a Change in Control before the Executive's service with the Company terminates and (ii) the Executive is subject to an Involuntary Termination within 24 months after such Change in Control.

3. **Vacation and Employee Benefits.** During his Employment, the Executive shall be eligible for 20 paid vacation days each year. Vacation days shall accrue, and may be taken, in accordance with the Company's standard policy for similarly situated employees, as it may be amended from time to time. During his Employment, the Executive shall be eligible to participate in any employee benefit plans maintained by the Company for similarly situated employees, subject in each case to the generally applicable terms and conditions of the plan in question and to the determinations of any person or committee administering such plan.

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

5. **Term of Employment.**

(a) **Employment at Will**. The Executive's Employment with the Company shall be "at will," meaning that either the Executive or the Company may terminate the Executive's Employment at any time and for any reason, with or without Cause. Any contrary representations which may have been made to the Executive shall be superseded by this Agreement. This Agreement shall constitute the full and complete agreement between the Executive and the Company on the "at will" nature of the Executive's Employment, which may only be changed in an express written agreement signed by the Executive and a duly authorized officer of the Company (other than the Executive). The termination of Executive's Employment shall not limit or otherwise affect his obligations under Section 7 below.

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

(c) **Rights Upon Termination**. Except as expressly provided in Section 6, upon the termination of the Executive's Employment pursuant to this Section 5, the Executive shall only be entitled to accrued and unpaid compensation, benefits and expense

reimbursements described in Sections 2, 3 and 4 for the period preceding the effective date of the termination. The payments under this Agreement shall fully discharge all responsibilities of the Company to the Executive.

6. **Termination Benefits.**

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

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

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

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

(i) **Base Compensation**. The Company shall continue to pay Executive his Base Compensation for a period of 12 months following the Separation (the "Continuation Period"). Such severance payments shall be paid at the Base Compensation rate in effect at the time of the Separation and in accordance with the Company's standard payroll procedures. The severance payments shall commence within 60 days after the Executive's Separation and, once they commence (the "Payment Commencement"), shall include any unpaid amounts accrued from the date of the Employee's Separation. However, if the 60-day period described in the preceding sentence spans two calendar years, then the Payment Commencement shall in any event begin on the first payroll period following expiration of any applicable revocation period in the second calendar year.

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

(c) **Options**. If, during the term of this Agreement, Executive is subject

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

(d) **Termination Prior to Employment Commencement Date**. The Company may terminate this Agreement without Cause prior to the Employment Commencement Date by providing the Executive with written notice of such termination. Upon delivery of the written notice, the Company shall provide the Executive with Termination Benefits in accordance with Sections 6(a) and (b) and this Agreement shall thereafter be deemed terminated except with respect to the Company's continuing obligations under Sections 6(a) and (b). For the avoidance of doubt, the Executive shall not be entitled to any stock options or restricted stock units under Sections 2(d) or (e).

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

8. **Successors.**

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

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

9. **Definitions.** For all purposes under this Agreement:

"**Cause**" shall mean:

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

(b) A material breach by the Executive of any agreement between the Executive and the Company;

(c) A material failure by the Executive to comply with the Company's written policies or rules;

(d) The Executive's conviction of, or plea of "guilty" or "no contest" to, a felony under the laws of the United States or any State thereof;

(e) The Executive's gross negligence or willful misconduct;

(f) A continuing failure by the Executive to perform assigned duties after receiving written notification of such failure from the Board; or

(g) A failure by the Executive to cooperate in good faith with a governmental or internal investigation of the Company or its directors, officers or employees, if the Company has requested the Executive's cooperation.

"**Change in Control**" shall mean:

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

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

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

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

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

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

Sections 13(d) and 14(d) of the Exchange Act but shall exclude (i) a trustee or other fiduciary holding securities under an employee benefit plan of the Company or of a parent or subsidiary of the Company and (ii) a corporation owned directly or indirectly by the stockholders of the Company in substantially the same proportions as their ownership of the Common Stock of the Company.

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

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

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

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

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

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

10. **Miscellaneous Provisions.**

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

(b) **Modifications and Waivers**. No provision of this Agreement shall be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by the Executive and by an authorized officer of the Company (other than the Executive). No waiver by either party of any breach of, or of compliance with, any condition or

provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

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

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

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

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

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

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

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

(g) **No Assignment**. This Agreement and all rights and obligations of the Executive hereunder are personal to the Executive and may not be transferred or assigned by the Executive at any time. The Company may assign its rights under this Agreement to any entity

that assumes the Company's obligations hereunder in connection with any sale or transfer of all or a substantial portion of the Company's assets to such entity.

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

[REMAINDER OF PAGE LEFT BLANK INTENTIONALLY]

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

/s/ Aranthan "AJ" Jones II
Aranthan "AJ" Jones II

VANDA PHARMACEUTICALS INC.

By /s/ Mihael H. Polymeropoulos

Title: Chief Executive Officer

VANDA PHARMACEUTICALS INC.
EMPLOYMENT AGREEMENT

This Employment Agreement (this "Agreement") is entered into as of August 5, 2019, by and between **Joakim Wijkstrom** (the "Executive") and **VANDA PHARMACEUTICALS INC.**, a Delaware corporation (the "Company").

1. **Duties and Scope of Employment.**

(a) **Position**. During his employment under this Agreement ("Employment"), the Company agrees to employ the Executive in the position of SVP, Chief Marketing Officer. The Executive shall be subject to the supervision of, and shall have such authority as is delegated to him by, the Company's Chief Executive Officer. The Executive hereby accepts such employment, commencing effective as of August 19, 2019 (the "Employment Commencement Date") and agrees to undertake the duties and responsibilities normally inherent in such position and such other duties and responsibilities as the Company's Chief Executive Officer shall from time to time reasonably assign to him.

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

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

2. **Cash and Incentive Compensation.**

(a) **Salary**. The Company shall pay the Executive as compensation for his services a base salary at a gross annual rate of not less than $500,000. Such salary shall be payable in accordance with the Company's standard payroll procedures. The annual compensation specified in this Subsection (a), together with any increases in such compensation that the Company may grant from time to time, is referred to in this Agreement as "Base Compensation."

(b) **Incentive Bonuses**. The Executive shall be eligible for an annual incentive bonus with a target amount equal to 45% of his Base Compensation (the "Annual Target Bonus"). Such bonus (if any) shall be awarded based on objective or subjective criteria established in advance by the Board or the Compensation Committee of the Board (the "Compensation Committee"). Any bonus for the fiscal year in which Executive's employment begins shall be prorated. Any incentive bonus for a fiscal year shall in no event be paid later than 2½ months after the close of such fiscal year. Except as provided in Section 6, such bonus shall be paid only if the Executive is employed by the Company at the time of payment. The determinations of the Board or the Compensation Committee with respect to such bonus shall be final and binding.

(c) **Stock Options**. On the Employment Commencement Date, the Company shall grant the Executive a nonstatutory stock option to purchase 90,000 shares of the Company's Common Stock (the "Option"). The per-share exercise price of the Option shall be equal to the closing price of one share of the Company's Common Stock on the date of grant as reported on the Nasdaq Global Market. The maximum term of the Option shall be 10 years. The grant of the Option shall be subject to the terms and conditions set forth in the Vanda Pharmaceuticals Inc. Amended and Restated 2016 Equity Incentive Plan (the "Plan") and in the Company's standard form of Stock Option Agreement. The Option will become exercisable with respect to 25% of the shares on the first anniversary of the date of grant and with respect to the remaining 75% of the shares in equal monthly installments over the next 3 years of continuous service thereafter. The Option shall become exercisable in full if (i) the Company is subject to a Change in Control before the Executive's service with the Company terminates and (ii) the Executive is subject to an Involuntary Termination within 24 months after such Change in Control. In addition, Section 6(c) shall apply to the Option. In addition, the Executive will be eligible to receive annual equity awards, if any, subject to the approval of the Board or the Compensation Committee in their sole discretion. The timing and size of the annual equity awards, if any, shall be determined in the sole discretion of the Board or the Compensation Committee based on the Executive's and/or the Company's performance.

(d) **Restricted Stock Units**. On the Employment Commencement Date, the Company shall award the Executive restricted stock units covering 30,000 shares of the Company's Common Stock (the "RSU Award"). The RSU Award shall be subject to the terms and conditions set forth in the Plan and in the Company's standard form of Restricted Stock Unit Award Agreement. The RSU Award will vest with respect to 25% of the shares on the first anniversary of the date of grant and an additional 25% of the shares on each of the second, third and fourth anniversaries of the date of grant, provided that Executive remains in continuous service with the Company on each applicable vesting date. The RSU Award shall vest in full if (i) the Company is subject to a Change in Control before the Executive's service with the Company terminates and (ii) the Executive is subject to an Involuntary Termination within 24 months after such Change in Control.

3. **Vacation, Employee Benefits and Relocation Benefit.**

(a) During his Employment, the Executive shall be eligible for 20 paid vacation days each year. Vacation days shall accrue, and may be taken, in accordance with the

Company's standard policy for similarly situated employees, as it may be amended from time to time.

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

(c) The Company shall reimburse the Executive for up to $50,000 of reasonable expenses incurred by him in connection with his relocation to the Washington, DC metropolitan area, upon presentation of an itemized account and appropriate supporting documentation, all in accordance with the Company's generally applicable policies (the "Relocation Expenses"). Such reimbursement shall be paid promptly, but not later than 30 days following the presentation to the Company of such itemized account and supporting documentation. In the event that the Executive's employment is terminated other than in connection with an Involuntary Termination within 24 months of the Employment Commencement Date, then Executive shall repay 100% of the Relocation Expenses to the Company within 30 days of the Executive's last day of Employment.

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

5. **Term of Employment.**

(a) **Employment at Will**. The Executive's Employment with the Company shall be "at will," meaning that either the Executive or the Company may terminate the Executive's Employment at any time and for any reason, with or without Cause. Any contrary representations which may have been made to the Executive shall be superseded by this Agreement. This Agreement shall constitute the full and complete agreement between the Executive and the Company on the "at will" nature of the Executive's Employment, which may only be changed in an express written agreement signed by the Executive and a duly authorized officer of the Company (other than the Executive). The termination of Executive's Employment shall not limit or otherwise affect his obligations under Section 7 below.

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

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

6. **Termination Benefits.**

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

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

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

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

(i) **Base Compensation**. The Company shall continue to pay Executive his Base Compensation for a period of 12 months following the Separation (the "Continuation Period"). Such severance payments shall be paid at the Base Compensation rate in effect at the time of the Separation and in accordance with the Company's standard payroll procedures. The severance payments shall commence within 60 days after the Executive's Separation and, once they commence (the "Payment Commencement"), shall include any unpaid amounts accrued from the date of the Employee's Separation. However, if the 60-day period described in the preceding sentence spans two calendar years, then the Payment Commencement shall in any event begin on the first payroll period following expiration of any applicable revocation period in the second calendar year.

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

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

(d) **Termination Prior to Employment Commencement Date**. The Company may terminate this Agreement without Cause prior to the Employment Commencement Date by providing the Executive with written notice of such termination. Upon delivery of the written notice, the Company shall provide the Executive with Termination Benefits in accordance with Sections 6(a) and (b) and this Agreement shall thereafter be deemed terminated except with respect to the Company's continuing obligations under Sections 6(a) and (b). For the avoidance of doubt, the Executive shall not be entitled to any stock options or restricted stock units under Sections 2(d) or (e).

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

8. **Successors.**

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

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

9. **Definitions.** For all purposes under this Agreement:

"**Cause**" shall mean:

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

(b) A material breach by the Executive of any agreement between the Executive and the Company;

(c) A material failure by the Executive to comply with the Company's written policies or rules;

(d) The Executive's conviction of, or plea of "guilty" or "no contest" to, a felony under the laws of the United States or any State thereof;

(e) The Executive's gross negligence or willful misconduct;

(f) A continuing failure by the Executive to perform assigned duties after receiving written notification of such failure from the Board; or

(g) A failure by the Executive to cooperate in good faith with a governmental or internal investigation of the Company or its directors, officers or employees, if the Company has requested the Executive's cooperation.

"**Change in Control**" shall mean:

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

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

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

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

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

(d) Any transaction as a result of which any person is the "beneficial owner" (as defined in Rule 13d-3 under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), directly or indirectly, of securities of the Company representing at least 50% of the total voting power represented by the Company's then outstanding voting securities. For purposes of this Subsection (d), the term "person" shall have the same meaning as when used in Sections 13(d) and 14(d) of the Exchange Act but shall exclude (i) a trustee or other fiduciary holding securities under an employee benefit plan of the Company or of a parent or subsidiary of the Company

and (ii) a corporation owned directly or indirectly by the stockholders of the Company in substantially the same proportions as their ownership of the Common Stock of the Company.

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

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

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

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

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

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

10. **Miscellaneous Provisions.**

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

(b) **Modifications and Waivers**. No provision of this Agreement shall be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by the Executive and by an authorized officer of the Company (other than the Executive). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

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

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

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

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

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

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

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

(g) **No Assignment**. This Agreement and all rights and obligations of the Executive hereunder are personal to the Executive and may not be transferred or assigned by the Executive at any time. The Company may assign its rights under this Agreement to any entity that assumes the Company's obligations hereunder in connection with any sale or transfer of all or a substantial portion of the Company's assets to such entity.

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

[REMAINDER OF PAGE LEFT BLANK INTENTIONALLY]

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

/s/ Joakim Wijkstrom
Joakim Wijkstrom

VANDA PHARMACEUTICALS INC.

By /s/ James Kelly

Title: Chief Financial Officer

EXHIBIT 31.1

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

I, Mihael H. Polymeropoulos, certify that:

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

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

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

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

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

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

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

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

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

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

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

November 7, 2019

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

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

EXHIBIT 31.2

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

I, James P. Kelly, 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 7, 2019

/s/ James P. Kelly

James P. Kelly
Executive Vice President, Chief Financial Officer and Treasurer
(Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER

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

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

The Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 (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 7, 2019 /s/ Mihael H. Polymeropoulos, M.D.

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

November 7, 2019 /s/ James P. Kelly

James P. Kelly
Executive 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.