Vanda Pharmaceuticals Inc.
Form 10-Q
May 03, 2019
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)
x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2019
or

o 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, D.C.	20037
(Address of principal executive offices)	(Zip Code)

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

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	o
Non-accelerated filer	o	Smaller reporting company	o
		Emerging growth company	o

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 o No x

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	VNDA	The Nasdaq Stock Market LLC (Nasdaq Global Market)

As of April 24, 2019, there were 52,963,676 shares of the registrant's common stock issued and outstanding.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements throughout this report are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. 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 wo 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;
- 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;
- 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;
- limitations on our ability to utilize some or all of our prior net operating losses and orphan drug and research and development credits;
- the cost and effects of litigation;
- our ability to obtain the capital necessary to fund our research and development or commercial activities;
- 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.

We encourage you to read Management’s Discussion and Analysis of our 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

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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.

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

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

(in thousands, except for share and per share amounts)	March 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$34,379	$ 61,005
Marketable securities	233,457	196,355
Accounts receivable, net	26,346	28,780
Inventory	1,112	994
Prepaid expenses and other current assets	11,204	11,998
Total current assets	306,498	299,132
Property and equipment, net	4,294	4,417
Operating lease right-of-use assets	11,994	—
Intangible assets, net	24,162	24,542
Non-current inventory and other	4,218	4,039
Total assets	$351,166	$ 332,130
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$27,423	$ 21,584
Product revenue allowances	31,852	31,231
Milestone obligations under license agreements	—	200
Total current liabilities	59,275	53,015
Operating lease non-current liabilities	13,324	—
Other non-current liabilities	162	3,693
Total liabilities	72,761	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	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized; 52,962,676 and 52,477,593 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	53	52
Additional paid-in capital	615,047	611,587
Accumulated other comprehensive income	135	1
Accumulated deficit	(336,830)	(336,218)
Total stockholders' equity	278,405	275,422
Total liabilities and stockholders' equity	$351,166	$ 332,130

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

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

(in thousands, except for share and per share amounts)	Three Months Ended	
	March 31, 2019	March 31, 2018
Revenues:		
Net product sales	$47,713	$ 43,592
Total revenues	47,713	43,592
Operating expenses:		
Cost of goods sold excluding amortization	5,113	4,560
Research and development	13,278	9,416
Selling, general and administrative	31,029	26,822
Intangible asset amortization	380	352
Total operating expenses	49,800	41,150
Income (loss) from operations	(2,087)	2,442
Other income	1,485	622
Income (loss) before income taxes	(602)	3,064
Provision (benefit) for income taxes	10	(2)
Net income (loss)	$(612)	$ 3,066
Net income (loss) per share:		
Basic	$(0.01)	$ 0.07
Diluted	$(0.01)	$ 0.06
Weighted average shares outstanding:		
Basic	52,752,774	46,336,430
Diluted	52,752,774	48,225,041

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

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

(in thousands)	Three Months Ended March 31, 2019	March 31, 2018
Net income (loss)	$(612)	$ 3,066
Other comprehensive income (loss):		
Net foreign currency translation gain (loss)	(4)	12
Change in net unrealized gain (loss) on marketable securities	138	(6)
Tax provision on other comprehensive income (loss)	—	—
Other comprehensive income, net of tax	134	6
Comprehensive income (loss)	$(478)	$ 3,072

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

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

(in thousands, except for share amounts)	Common Stock Shares	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

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

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

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

(in thousands)	Three Months Ended March 31, 2019	March 31, 2018
Cash flows from operating activities		
Net income (loss)	$(612)	$3,066
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation of property and equipment	332	349
Stock-based compensation	3,282	3,151
Amortization of discounts on marketable securities	(906)	(208)
Intangible asset amortization	380	352
Other non-cash adjustments, net	317	(113)
Changes in operating assets and liabilities:		
Accounts receivable	2,434	(5,713)
Prepaid expenses and other assets	247	(1,263)
Inventory	(44)	63
Accounts payable and other liabilities	3,507	(2,731)
Product revenue allowances	706	4,685
Net cash provided by operating activities	9,643	1,638
Cash flows from investing activities		
Purchases of property and equipment	(393)	(135)
Purchases of marketable securities	(100,803)	(30,433)
Maturities of marketable securities	64,745	46,880
Net cash provided by (used in) investing activities	(36,451)	16,312
Cash flows from financing activities		
Net proceeds from offering of common stock	—	101,068
Proceeds from the exercise of stock options	179	2,666
Net cash provided by financing activities	179	103,734
Effect of exchange rate changes on cash, cash equivalents and restricted cash	2	18
Net change in cash, cash equivalents and restricted cash	(26,627)	121,702
Cash, cash equivalents and restricted cash		
Beginning of period	61,749	34,335
End of period	$35,122	$156,037

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

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VANDA PHARMACEUTICALS INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

1. Business Organization and Presentation

Business organization

Vanda Pharmaceuticals Inc. (the Company) is a global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high unmet medical needs and improve the lives of patients. The Company commenced its operations in 2003 and operates in one reporting segment. The Company's 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 depression 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 for the fiscal year ended December 31, 2018 included in the Company's annual report on Form 10-K. The financial information as of March 31, 2019 and for the three months ended March 31, 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. 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 for a full fiscal year. The financial information included herein should be read in conjunction with the consolidated financial statements and notes in the Company's annual report on Form 10-K for the fiscal year ended December 31, 2018.

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

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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 accounting principles generally accepted in the United States of America 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 Subtopic 842, Leases, effective January 1, 2019, the Company determines if an arrangement is 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 the 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 options 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 in determining the present value of lease payments, including publicly available data for instruments with similar characteristics. 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. 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 months ended March 31, 2019 and 2018 were as follows:

(in thousands)	Three Months Ended March 31, 2019	March 31, 2018
HETLIOZ® product sales, net	$28,957	$ 25,423
Fanapt® product sales, net	18,756	18,169
	$47,713	$ 43,592

Major Customers

HETLIOZ® is available in the U.S. for distribution through a limited number of specialty pharmacies, and is not available in retail pharmacies. Fanapt® is available in the U.S. for distribution through a limited number of wholesalers and is available in retail pharmacies. The Company invoices and records revenue when its customers, specialty pharmacies and wholesalers, receive product from the third-party logistics warehouse which is the point at which control is transferred to the customer. There were five major customers that each accounted for more than 10% of total revenues and, as a group, represented 96% of total revenues for the three months ended March 31, 2019. There were five major customers that each accounted for more than 10% of accounts receivable and, as a group, represented 96% of total accounts receivable at March 31, 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 includes 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

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

(in thousands)	March 31, 2019	March 31, 2018
Cash and cash equivalents	$ 34,379	$ 155,293
Restricted cash included in:		
Prepaid expenses and other current assets	157	—
Non-current inventory and other	586	744
Total cash, cash equivalents and restricted cash	$ 35,122	$ 156,037

Non-Cash Investing and Financing Activities

For the three months ended March 31, 2018, the Company accrued $0.2 million in expense associated with the March 2018 public offering of common stock.

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 the first quarter of 2019 to include a reconciliation for the comparative period.

In June 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-13, Financial Instruments – Credit Losses, related to the measurement of credit losses on financial instruments. The standard will require the use of an “expected loss” model for instruments measured at amortized cost. 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 consolidated financial statements.

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 a 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 accounted for under the new standard. The Company elected to exclude short-term leases in the application of the new standard. Accounting for finance leases is substantially unchanged. 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 2019, using a modified retrospective transition, with the cumulative-effect adjustment to the opening balance of retained earnings as of the effective date of January 1, 2019. There was no impact to retained earnings 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

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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 March 31, 2019, which all have contract maturities of less than one year:

March 31, 2019 (in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
U.S. Treasury and government agencies	$112,751	$ 63	$ (4)	$112,810
Corporate debt	104,867	73	(1)	104,939
Asset-backed securities	15,707	3	(2)	15,708
	$233,325	$ 139	$ (7)	$233,457

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
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
	$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 March 31, 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 also is 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 three months ended March 31, 2019 and 2018.

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

		Fair Value Measurement as of March 31, 2019 Using		
(in thousands)	March 31, 2019	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	$112,810	$112,810	$ —	$ —
Corporate debt	109,926	—	109,926	—
Asset-backed securities	15,708	—	15,708	—
	$238,444	$112,810	$ 125,634	$ —

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)	December 31, 2018	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	—
	$ 196,355	$69,270	$ 127,085	$ —

Total assets measured at fair value as of March 31, 2019 includes $5.0 million of cash equivalents.

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

5. Inventory

The Company evaluates expiry risk by evaluating current and future product demand relative to product shelf life. The Company builds demand forecasts by considering factors such as, but not limited to, overall market potential, market share, market acceptance and patient usage. Inventory levels are evaluated for the amount of inventory that would be sold within one year. At certain times, the level of inventory can exceed the forecasted level of cost of goods sold for the next twelve months. The Company classifies the estimate of such inventory as non-current. Inventory consisted of the following as of March 31, 2019 and December 31, 2018:

(in thousands)	March 31, 2019	December 31, 2018
Current assets		
Work-in-process	$ —	$ 48
Finished goods	1,112	946
	$ 1,112	$ 994

Non-Current assets		
Raw materials	$ 86	$ 86
Work-in-process	2,056	2,290
Finished goods	616	516
	$ 2,758	$ 2,892

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6. Leases

The Company's long-term leases primarily include operating leases and subleases for office space in Washington, D.C. and London. 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 March 31, 2019. The Company also has various short-term leases, including office space in Berlin.

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 March 31, 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 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. The Company has the right to renew the lease for five years following its expiration in 2021. As of March 31, 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 March 31, 2019:

(in thousands)	Classification on the Balance Sheet	March 31, 2019
Assets		
Operating lease assets	Operating lease right-of-use assets	$11,994
Liabilities		
Operating lease current liabilities	Accounts payable and accrued liabilities	$2,249
Operating lease non-current liabilities	Operating lease non-current liabilities	13,324
Total lease liabilities		$15,573
Weighted-average remaining lease term		8.7 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 months ended March 31, 2019, the Company recognized operating lease cost of $0.6 million and short-term operating lease cost of $0.1 million. The Company also recognized $0.3 million 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 months ended March 31, 2018, the Company recognized $0.9 million of rent expense, 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 $0.6 million for the three months ended March 31, 2019.

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The table below reconciles the Company's future cash obligations to operating lease liabilities recorded on the balance sheet as of March 31, 2019:

(in thousands)	Operating Leases
2019	$1,903
2020	2,324
2021	2,332
2022	2,355
2023	2,420
Thereafter	10,669
Total minimum lease payments	$22,003
Less: amount of lease payments representing interest	(6,430)
Present value of future minimum lease payments	$15,573
Less: current obligations under leases	(2,249)
Long-term lease obligations	$13,324

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 February 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 February 2035.

The estimated economic useful life of both the $8.0 million and the $25.0 million intangible assets were 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 March 31, 2019:

		March 31, 2019		
(in thousands)	Estimated Useful Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	February 2035	$33,000	$ 8,838	$24,162

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

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		December 31, 2018		
(in thousands)	Estimated Useful Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	May 2034	$33,000	$ 8,458	$24,542

As of March 31, 2019 and December 31, 2018 the Company also had $27.9 of fully amortized intangible assets related to Fanapt®.

Intangible assets are amortized over their estimated useful economic life using the straight-line method. Amortization expense was $0.4 million for each of the three months ended March 31, 2019 and 2018. The following is a summary of the future intangible asset amortization schedule as of March 31, 2019:

(in thousands)	Total	2019	2020	2021	2022	2023	Thereafter
HETLIOZ®	$24,162	$1,138	$1,518	$1,518	$1,518	$1,518	$ 16,952

8. Accounts Payable and Accrued Liabilities

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

(in thousands)	March 31, 2019	December 31, 2018
Research and development expenses	$ 7,857	$ 5,593
Consulting and other professional fees	7,042	2,924
Royalties payable	4,592	5,172
Compensation and employee benefits	3,730	6,363
Operating lease liabilities	2,249	—
Other	1,953	1,532
	$ 27,423	$ 21,584

9. Commitments and Contingencies

The following is a summary of the Company's noncancellable long-term contractual cash obligations as of March 31, 2019. See footnote 6, Leases, for the maturities of the Company's operating lease liabilities as of March 31, 2019.

	Cash Payments Due by Year (1)						
(in thousands)	Total	2019	2020	2021	2022	2023	Thereafter
Purchase commitments	5,266	3,073	847	890	456	—	—

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.

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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 was obligated to make royalty payments to Sanofi S.A. (Sanofi) and Titan Pharmaceuticals Inc. (Titan) at a percentage rate equal to 23% on annual U.S. net sales of Fanapt® up to $200.0 million, and at a percentage rate in the mid-twenties on sales over $200.0 million through November 2016. In February 2016, the Company amended the agreement with Sanofi and Titan to remove Titan as the entity through which royalty payments from the Company are directed to Sanofi following the expiration of the NCE patent for Fanapt® in the U.S. on November 15, 2016. Under the amended agreement, the Company pays directly to Sanofi a fixed royalty of 3% of net sales from November 16, 2016 through December 31, 2019 related to manufacturing know-how. No further royalties on manufacturing know-how are payable by the Company after December 31, 2019. This amended agreement did not alter Titan's obligation under the license agreement to make royalty payments to Sanofi prior to November 16, 2016 or the Company's obligations to pay Sanofi a fixed royalty on Fanapt® net sales equal up 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 are 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 a 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. These milestones include $4.0 million for pre-NDA approval milestones, $10.0 million and $5.0 million for the first approval of a marketing authorization for tradipitant in the U.S. and European Union (E.U.), respectively, and up to $80.0 million for sales milestones. The $4.0 million of pre-NDA approval milestones includes $2.0 million due upon enrollment of the first subject into a Phase III study

for tradipitant and $2.0 million due upon the filing of the first marketing authorization for tradipitant in either the U.S. or the E.U. As a result of enrolling the first subject into a Phase III study for tradipitant in July 2018, the Company made a $2.0 million milestone payment to Lilly in the third quarter of 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,

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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. These milestones include an initial license fee of $1.0 million that was paid by the Company in 2017, annual maintenance fees, $12.4 million for pre-NDA approval milestones and $33.0 million for future regulatory approval and sales milestones. Included in the $12.4 million in 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 fourth quarter of 2018, the Company determined the first pre-NDA approval milestone to be probable and accrued a current liability of $0.2 million as of December 31, 2018. The pre-NDA approval milestone of $0.2 million was paid to UCSF in the first quarter of 2019.

Purchase Commitments

In the course of its business, the Company regularly enters into agreements with clinical organizations to provide services relating to clinical development and clinical manufacturing activities under fee service arrangements. The Company’s current agreements for clinical and marketing services may be terminated on generally 90 days’ notice without incurring additional charges, other than charges for work completed but not paid for through the effective date of termination and other costs incurred by the Company’s contractors in closing out work in progress as of the effective date of termination. 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) were as follows as of March 31, 2019 and December 31, 2018:

(in thousands)	March 31, 2019	December 31, 2018
Foreign currency translation	$ 3	$ 7
Unrealized gain (loss) on marketable securities	132	(6)
	$ 135	$ 1

There was no tax provision (benefit) included in accumulated other comprehensive income as of March 31, 2019 and December 31, 2018. There were no reclassifications out of accumulated other comprehensive income for either of the three months ended March 31, 2019 or 2018.

12. Stock-Based Compensation

As of March 31, 2019, there were 6,384,857 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 on April 12, 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.

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There are a total of 7,100,000 shares of common stock reserved for issuance under the 2016 Plan, 3,388,804 shares of which remained available for future grant as of March 31, 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 board of directors. Service option awards have 10 years 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 the 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 March 31, 2019, $11.1 million of unrecognized compensation costs related to unvested service option awards are expected to be recognized over a weighted average period of 1.6 years. No option awards are classified as a liability as of March 31, 2019.

A summary of option activity under the Plans for the three months ended March 31, 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	427,500	20.62		
Forfeited	—	—		
Exercised	(17,468)	10.27		143
Outstanding at March 31, 2019	4,779,074	12.00	5.49	31,963
Exercisable at March 31, 2019	3,573,133	10.10	4.34	29,714
Vested and expected to vest at March 31, 2019	4,533,107	11.58	5.27	31,870

The weighted average grant-date fair value of options granted was $11.50 and $10.40 per share for the three months ended March 31, 2019 and 2018, respectively. Proceeds from the exercise of stock options amounted to $0.2 million and $2.7 million for the three months ended March 31, 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 in four equal annual installments provided that the employee remains employed with the Company. Annual service RSUs granted to directors vest on the first anniversary of the grant date.

As of March 31, 2019, $28.3 million of unrecognized compensation costs related to unvested service RSUs are expected to be recognized over a weighted average period of 2.1 years. No RSUs are classified as a liability as of March 31, 2019.

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A summary of RSU activity under the Plans for the three months ended March 31, 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	770,328	20.63
Forfeited	(10,506)	17.18
Vested	(467,615)	14.16
Unvested at March 31, 2019	1,605,783	18.48

The grant date fair value for the 467,615 shares underlying RSUs that vested during the three months ended March 31, 2019 was $6.6 million.

Stock-Based Compensation

Stock-based compensation expense recognized for the three months ended March 31, 2019 and 2018 was comprised of the following:

(in thousands)	Three Months Ended March 31, 2019	March 31, 2018
Research and development	$728	$ 321
Selling, general and administrative	2,554	2,830
	$3,282	$ 3,151

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 three months ended March 31, 2019 and 2018 were as follows:

	Three Months Ended March 31, 2019	March 31, 2018
Expected dividend yield	0 %	0 %
Weighted average expected volatility	58 %	57 %
Weighted average expected term (years)	5.92	5.90
Weighted average risk-free rate	2.51 %	2.64 %

13. Income Taxes

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. Except for 2018 income, the Company has historically generated pretax losses in the U.S., both cumulatively and individually. The losses serve as strong evidence that it is more likely than not that deferred tax assets in the U.S. will not be realized in the future, and as a result of the losses and all other available positive and negative evidence the Company concluded that a full tax valuation allowance was required against all net deferred tax

assets in the U.S. as of March 31, 2019 and December 31, 2018. If the Company begins to regularly generate pretax income, it is reasonably possible that the conclusion about the appropriateness of the valuation allowance could change in a future period. A reduction of the valuation allowance, in whole or in part, would

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result in a non-cash income tax benefit during the period of reduction.The potential timing and amount of any future valuation allowance release has yet to be determined and requires an analysis that is highly dependent upon historical and future projected earnings, among other factors. Any such adjustment could have a material impact on the Company's finance position and results of operations.

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 (loss) before income taxes for three months ended March 31, 2019 and 2018. Taxes have been recorded related to certain U.S. state jurisdictions and non-U.S. income for the three months ended March 31, 2019 and 2018.

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 (IRC), 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. Because the Company maintains a valuation allowance on its U.S. tax attributes, any limitation as a result of application of IRC Section 382 limitation would not have a material impact on the Company's provision for income taxes for the three months ended March 31, 2019.

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 Act 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 (loss) by the weighted average number of shares of common stock outstanding. Diluted EPS is computed by dividing the net income (loss) by the weighted average number of shares of common stock outstanding, plus potential outstanding common stock for the period. Potential outstanding common stock includes stock options and shares underlying RSUs, but only to the extent that their inclusion is dilutive.

The following table presents the calculation of basic and diluted net loss per share of common stock for the three months ended March 31, 2019 and 2018:

(in thousands, except for share and per share amounts)	Three Months Ended March 31, 2019	March 31, 2018
Numerator:		
Net income (loss)	$(612)	$ 3,066
Denominator:		
Weighted average shares outstanding, basic	52,752,774	46,336,430
Effect of dilutive securities	—	1,888,611
Weighted average shares outstanding, diluted	52,752,774	48,225,041
Net income (loss) per share, basic and diluted:		
Basic	$(0.01)	$ 0.07
Diluted	$(0.01)	$ 0.06
Antidilutive securities excluded from calculations of diluted net income (loss) per share	3,068,806	6,057,444

The Company incurred a net loss for the three months ended March 31, 2019 causing inclusion of any potentially dilutive securities to have an anti-dilutive effect, resulting in dilutive loss per share and basic loss per share attributable to common stockholders being equivalent.

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15. Legal Matters

Fanapt®. In June 2014, the Company filed suit against Roxane Laboratories, Inc. (Roxane) in the U.S. District Court for the District of Delaware (Delaware District Court). The suit sought an adjudication that Roxane has infringed one or more claims of the Company's U.S. Patent No. 8,586,610 (‘610 Patent) by submitting to the U.S. Food and Drug Administration (FDA) an Abbreviated New Drug Application (ANDA) for a generic version of Fanapt® prior to the expiration of the ‘610 Patent in November 2027. In addition, pursuant to a settlement agreement with Novartis Pharma AG (Novartis), the Company assumed Novartis’ patent infringement action against Roxane in the Delaware District Court. That suit alleges that Roxane has infringed one or more claims of U.S. Patent RE39198 (‘198 Patent), which is licensed exclusively to the Company, by filing an ANDA for a generic version of Fanapt® prior to the expiration of the ‘198 Patent in November 2016. These two cases against Roxane were consolidated by agreement of the parties and were tried together in a five-day bench trial that concluded in March 2016. In August 2016, the Delaware District Court ruled that the Company is entitled to a permanent injunction against Roxane enjoining Roxane from infringing the ‘610 Patent, including the manufacture, use, sale, offer to sell, sale, distribution or importation of any generic iloperidone product described in the ‘610 Patent ANDA until the expiration of the ‘610 Patent in November 2027. If the Company obtains pediatric exclusivity, the injunction against Roxane would be extended until May 2028 under the Delaware District Court’s order. In September 2016, Roxane filed a notice of appeal with the Federal Circuit Court of Appeals (Federal Circuit). In July 2017, Roxane, now a subsidiary of Hikma Pharmaceuticals PLC (Hikma), petitioned the Federal Circuit to substitute Roxane with new defendants West-Ward Pharmaceuticals International Limited and West-Ward Pharmaceuticals Corp. (each of which is a subsidiary of Hikma and both of which are referred to collectively herein as West-Ward). In April 2018, the Federal Circuit affirmed the Delaware District Court’s decision that West-Ward infringed the ‘610 Patent. In June 2018, West-Ward filed with the Federal Circuit a petition seeking rehearing en banc. The Federal Circuit invited the Company to respond to West-Ward’s petition; the Company's response was filed in July 2018. In August 2018, the Federal Circuit denied West-Ward's petition for rehearing. In January 2019, West-Ward filed a petition in the United States Supreme Court for a writ of certiorari seeking reversal of the Federal Circuit’s decision. The Company submitted a response to that petition on February 12, 2019. On March 18, 2019, the United States Supreme Court invited the Solicitor General of the United States to file a brief in the matter expressing the views of the United States.

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 Defendants). The lawsuits each seek an adjudication that the respective Defendants infringed one or more claims of the ‘610 Patent and/or the Company's U.S. Patent No. 9,138,432 (‘432 Patent) by submitting to the FDA an ANDA for a generic version of Fanapt® prior to the expiration of the ‘610 Patent in November 2027 or the ‘432 Patent in September 2025. The Defendants denied infringement and counterclaimed for declaratory judgment of invalidity and noninfringement of the ‘610 Patent and the ‘432 Patent. Certain Defendants have since entered into agreements resolving these lawsuits, as discussed below. The remaining matters have been stayed until the later of November 30, 2018 or 14 days after final disposition by the U.S. Supreme Court of any petition for a writ of certiorari filed by West-Ward. The Company entered into a confidential stipulation with each of Inventia and Lupin regarding any potential launch of Inventia’s and Lupin's generic ANDA products.

HETLIOZ®. In March 2018, the Company received a Paragraph IV certification notice letter from Teva Pharmaceuticals USA, Inc. (Teva) notifying the Company that Teva had submitted an ANDA for HETLIOZ® to the FDA requesting approval to market, sell and use a generic version of the 20mg HETLIOZ® capsules for Non-24. In its notice letter, Teva alleges that the Company's U.S. Patent No. RE46,604, U.S. Patent No. 9,060,995, U.S. Patent 9,539,234, U.S. Patent 9,549,913, U.S. Patent 9,730,910 and U.S. Patent 9,885,241 (collectively, the Vanda Patents), each of which is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book), which cover methods of using HETLIOZ®, are invalid, unenforceable and/or will not be infringed by Teva’s manufacture, use or sale of the product described in its ANDA. The Company received similar notice letters in April 2018 from MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited (together, MSN) and Apotex.

In April 2018, the Company filed a patent infringement lawsuit in the Delaware District Court against Teva and in May 2018, the Company filed patent infringement lawsuits in the Delaware District Court against MSN and Apotex. The lawsuits seek an adjudication that Teva, MSN and Apotex have infringed one or more claims of the Vanda Patents by submitting to the FDA an ANDA for a generic version of HETLIOZ® prior to the expiration of the latest to expire of the Vanda Patents in 2034. The relief requested by the Company in the lawsuits includes requests for permanent injunctions preventing Teva, MSN and Apotex from infringing the asserted claims of the Vanda Patents by engaging in the manufacture, use, offer to sell, sale, importation or distribution of generic versions of HETLIOZ® before the last expiration date of the Vanda Patents and for an order that any effective date of FDA approval of Teva, MSN, and Apotex's generic versions of HETLIOZ® be a date not earlier than the expiration of the Vanda Patents. The lawsuits automatically preclude the FDA from approving the submitted ANDAs until the earlier of seven and one-half years after the January 2014 approval of the Company's NCE status application or entry of a

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district court decision finding the Vanda Patents invalid, unenforceable or not infringed. In June 2018, Teva, MSN and Apotex each answered the Company's complaint, and Teva included counterclaims for declarations that the Vanda Patents are invalid. MSN included additional counterclaims for declarations that the Vanda Patents are not infringed. In July 2018, the Company answered Teva and MSN's counterclaims, denying their allegations.

In October 2018, the Company received an additional Paragraph IV certification notice letter from Teva concerning its Orange Book listed U.S. Patent No. 10,071,977, which expires in 2035 (the '977 Patent). In November 2018, the Company received a similar additional Paragraph IV certification notice letter from Apotex concerning the '977 Patent. In December 2018, the Company filed amended complaints against Teva, Apotex, and MSN alleging infringement of one or more claims of the '977 Patent. The amended complaints seek an adjudication that Teva, Apotex, and MSN have infringed one or more claims of the '977 Patent by submitting to FDA an ANDA for a generic version of HETLIOZ® prior to the expiration of the '977 Patent. The relief requested by the Company in the amended complaints includes requests for permanent injunctions preventing Teva, Apotex, and MSN from infringing the asserted claims of the '977 Patent by engaging in the manufacture, use, offer to sell, sale, importation or distribution of generic versions of HETLIOZ® before the expiration date of the '977 Patent and for an order that any effective date of FDA approval of Teva, MSN, and Apotex's generic versions of HETLIOZ® be a date not earlier than the expiration of the '977 Patent. In December 2018, Teva, MSN, and Apotex answered the Company's amended complaints, and Teva and MSN included counterclaims for declarations that the '977 Patent is invalid, and MSN included an additional counterclaim that the '977 Patent is unenforceable for inequitable conduct. In January 2019, the Company answered Teva and MSN's counterclaims. A trial date for these lawsuits has been set for September 2020.

In February 2019, the Company received additional Paragraph IV certification notice letters separately from Teva and Apotex concerning Vanda's Orange Book listed U.S. Patent No. 10,149,829, which expires in 2033 (the '829 Patent). In their notice letters, Teva and Apotex allege that the '829 Patent, which covers methods of using HETLIOZ®, is invalid, unenforceable and will not be infringed by Teva's and Apotex's respective manufacture, use or sale of the product described in their respective ANDAs. In March 2019 and April 2019, Vanda filed separate patent infringement lawsuits in the Delaware District Court against Teva and Apotex, respectively. The lawsuits seek adjudications that Teva and Apotex have infringed one or more claims of the '829 Patent by submitting to the FDA an ANDA for a generic version of HETLIOZ® prior to the expiration of the '829 Patent. The relief requested by the Company includes permanent injunctions preventing Teva and Apotex from infringing the asserted claims of the '829 Patent by engaging in the manufacture, use, offer to sell, sale, importation or distribution of generic versions of HETLIOZ® before the expiration of the '829 Patent, and includes orders that any effective date of FDA approval of Teva and Apotex's generic versions of HETLIOZ® be a date not earlier than the expiration of the '829 Patent. In April 2019, Teva answered the Company's complaint, in which Teva included a counterclaim for a declaration that the '829 Patent is invalid. The Company's response to Teva's counterclaim is due May 3, 2019.

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, no patients were ever enrolled in any study beyond 12 weeks. On December 19, 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 United States 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. On February 14, 2019, the FDA filed a Motion for Voluntary Remand to the Agency and for a Stay of the Case. On March 14, 2019, the DC District Court granted the FDA's request for voluntary remand and returned the matter to the FDA for further consideration. On April 26, 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 Vanda 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 the Company 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. On April 29, 2019, the Company and the FDA filed a Joint Motion for Extension of Time to Propose a Scheduling Order for this matter. On April 30, 2019, the DC District Court granted the motion, thereby extending the deadline until May 3, 2019 for the FDA and the Company to file proposals regarding a scheduling order. The Company intends to continue vigorously pursuing its interests in the matter.

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In February 2019, a qui tam action filed against the Company was unsealed by order of the DC District Court. The qui tam action, United States ex rel. Richard Gardner v. Vanda Pharmaceuticals Inc., 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 alleges that the Company violated these laws through the promotion and marketing of its products Fanapt® and HETLIOZ®. The complaint seeks, among other things, treble damages, civil penalties for each alleged false claim, and attorneys' fees and costs.

By virtue of the court having unsealed the case, it learned that in January 2019, the U.S., as well as the Plaintiff States, filed notice of their election not to intervene in the qui tam action at this time. The U.S.' and the Plaintiff States' election not to intervene does not prevent the plaintiff/relator from litigating this action and the U.S. and the Plaintiff States may later seek to intervene in the action. The deadline for the Company to be served with the qui tam complaint was May 1, 2019, and the Company has not been served.

In February 2019, a securities class action, Gordon v. Vanda Pharmaceuticals Inc., Case No. 1:19-cv-01108-ARR-LB, 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. The complaint, filed on behalf of a purported stockholder of the Company, asserts claims on behalf of a putative class of all persons who purchased the Company's publicly traded securities between November 4, 2015 through 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 complaint alleges that the defendants made false and misleading statements and/or omissions regarding Fanapt® and HETLIOZ® between November 3, 2015 and February 11, 2019. The Company believes that its 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. The Company has not yet responded to the complaint.

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ITEM 2 Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview

Vanda Pharmaceuticals Inc. (we, our or Vanda) is a global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high unmet medical needs and improve the lives of patients. 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 depression 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 gastrointestinal disorders, including cholera.
- VQW-765, a Phase II alpha-7 nicotinic acetylcholine receptor partial agonist.

Operational Highlights

Tradipitant - Clinical Development

- We plan to meet with the FDA in the second quarter of 2019 to further define and confirm the path towards approval of tradipitant in the treatment of patients with gastroparesis.
- We plan to initiate a Phase III clinical study of tradipitant in gastroparesis in the second quarter of 2019.
- Enrollment in the Phase III clinical study (EPIONE) of tradipitant in atopic dermatitis is ongoing. Results are expected in the first half of 2020. A second Phase III clinical study is expected to begin in the first quarter of 2020.
- In January 2019, we initiated a Phase II clinical study of tradipitant in motion sickness. Study results are expected in the third quarter of 2019.

HETLIOZ®

- The HETLIOZ® supplemental New Drug Application (sNDA) for the treatment of jet lag disorder is under review by the FDA with a Prescription Drug User Fee Act target action date of August 16, 2019.
- We expect to meet with the FDA in the third quarter of 2019 to confirm the regulatory path forward for HETLIOZ® in the treatment of patients with SMS and expect to file an sNDA in the third quarter of 2019.
- We plan in the third quarter of 2019 to initiate a Phase II clinical study of HETLIOZ® in DSPD in patients who have a mutation in the CRY1 gene, which is believed to be causative in a subset of patients with DSPD.

Fanapt®

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

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VTR-297

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

Tradipitant - Partial Clinical Hold and FDA Dispute

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, no patients were ever enrolled in any study beyond 12 weeks. On December 19, 2018, the FDA imposed a partial clinical hold (PCH) on two of our proposed clinical studies of tradipitant, 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 United States 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. On February 14, 2019, the FDA filed a Motion for Voluntary Remand to the Agency and for a Stay of the Case. On March 14, 2019, the DC District Court granted the FDA's request for voluntary remand and returned the matter to the FDA for further consideration. On April 26, 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. On April 29, 2019, we and the FDA filed a Joint Motion for Extension of Time to Propose a Scheduling Order for this matter. On April 30, 2019, the DC District Court granted the motion, thereby extending the deadline until May 3, 2019 for the FDA and us to file proposals regarding a scheduling order. We intend to continue vigorously pursuing our interest in the matter.

We do not expect the PCH to have any impact on our ongoing clinical studies in atopic dermatitis and motion sickness, each of which is under 12 weeks in duration, or our planned 12-week Phase III study in gastroparesis, 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.

Since we began operations in March 2003, 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

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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) Subtopic 842, Leases, effective January 1, 2019, we determine if an arrangement is a lease at inception. Right-of-use (ROU) assets represent the our right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the 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 options 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. 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 add, and usage-based taxes are excluded from revenues.

HETLIOZ® is only 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 updates its 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 the condensed consolidated balance sheets, with the exception of prompt-pay discounts which are classified as reductions of accounts receivable. The reserve for product returns for which the product may not be returned for a period of greater than one year from the balance sheet date is classified other non-current liabilities on the condensed consolidated balance sheets. Uncertainties related to

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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 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 March 31, 2019 or December 31, 2018.

The following table summarizes sales discounts and allowance activity for the three months ended March 31, 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	15,027	5,985	21,012
Adjustments for prior period sales	426	4	430
Credits/payments made	(14,443)	(6,361)	(20,804)
Balances at March 31, 2019	$ 23,144	$ 9,328	$32,472

The provision of $15.0 million for rebates and chargebacks for the three months ended March 31, 2019 primarily represents Medicaid rebates applicable to sales of Fanapt® and HETLIOZ®. The provision of $6.0 million for

discounts, returns and other for the three months ended March 31, 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®.

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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-estimates 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 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. Except for 2018 income, we have historically generated pretax losses in the U.S., both cumulatively

and individually. The losses serve as strong evidence that it is more likely than not that deferred tax assets in the U.S. will not be realized in the future, and as a result of the losses and all other available positive and negative evidence we concluded that a full tax valuation allowance was required against all net deferred tax assets in the U.S. as of March 31, 2019 and December 31, 2018. If we begin to regularly generate pretax income, it is reasonably possible that the conclusion about the appropriateness of the valuation allowance could change in a future period. A reduction of the valuation allowance, in whole or in part, would result in a non-cash income tax benefit during the period of reduction. The potential timing and amount of any future valuation allowance release has yet to be determined and requires an analysis that is highly dependent upon historical and future projected earnings, among other factors. Any such adjustment could have a material impact on our finance position and results of operations.

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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 $336.8 million as of March 31, 2019. Our total stockholders' equity was $278.4 million as of March 31, 2019.

Three months ended March 31, 2019 compared to three months ended March 31, 2018

Revenues. Total revenues increased by $4.1 million, or 9%, to $47.7 million for the three months ended March 31, 2019 compared to $43.6 million for the three months ended March 31, 2018. Revenues were as follows:

(in thousands)	Three Months Ended March 31, 2019	March 31, 2018	Net Change	Percent
HETLIOZ® product sales, net	$28,957	$25,423	$3,534	14 %
Fanapt® product sales, net	18,756	18,169	587	3 %
	$47,713	$43,592	$4,121	9 %

HETLIOZ® product sales, net increased by $3.5 million, or 14%, to $29.0 million for the three months ended March 31, 2019 compared to $25.4 million for the three months ended March 31, 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 $0.6 million, or 3%, to $18.8 million for the three months ended March 31, 2019 compared to $18.2 million for the three months ended March 31, 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 $0.6 million, or 12%, to $5.1 million for the three months ended March 31, 2019 compared to $4.6 million for the three months ended March 31, 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% of net sales of HETLIOZ® in the U.S. and 9% of net sales of Fanapt®.

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

Research and development expenses. Research and development expenses increased by $3.9 million, or 41%, to $13.3 million for the three months ended March 31, 2019 compared to $9.4 million for the three months ended March 31, 2018. The increase was primarily due to an increase in clinical trial expenses associated with the tradipitant atopic dermatitis and motion sickness programs and expenses associated with the CFTR programs partially offset by a decrease in expenses associated with our HETLIOZ® jet lag disorder program. The following table summarizes the costs of our product development initiatives for the three months ended March 31, 2019 and 2018:

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(in thousands)	Three Months Ended March 31, 2019	March 31, 2018
Direct project costs (1)		
HETLIOZ®	$2,097	$ 4,058
Fanapt®	1,081	662
Tradipitant	6,652	2,277
VTR-297	390	664
CFTR	1,367	509
Other	105	169
	11,692	8,339
Indirect project costs (1)		
Stock-based compensation	728	322
Other indirect overhead	858	755
	1,586	1,077
Total research and development expense	$13,278	$ 9,416

(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 $31.0 million for the three months ended March 31, 2019 compared to $26.8 million for the three months ended March 31, 2018. The increase was primarily the result of higher spend on Non-24 direct to consumer advertising and increased legal fees associated with ongoing litigation.

Intangible asset amortization. Intangible asset amortization was $0.4 million for each of the three months ended March 31, 2019 and 2018.

Other income. Other income was $1.5 million for the three months ended March 31, 2019 compared to $0.6 million for the three months ended March 31, 2018. The increase was primarily the result of an increase in investment income due to an increase in our balance of marketable securities from the proceeds of the public offering of our common stock completed in March 2018 and a higher yield on investments.

Liquidity and Capital Resources

As of March 31, 2019, our total cash and cash equivalents and marketable securities (Cash) were $267.8 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.

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

(in thousands)	March 31, 2019	December 31, 2018
Cash and cash equivalents	$34,379	$ 61,005
Marketable securities:		
U.S. Treasury and government agencies	112,810	69,270
Corporate debt	104,939	105,910
Asset-backed securities	15,708	21,175
Total marketable securities	233,457	196,355
Total cash, cash equivalents and marketable securities	$267,836	$ 257,360

As of March 31, 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 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® are difficult to estimate and may vary significantly. Management believes 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.

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Cash Flow

The following table summarizes our net cash flows from operating, investing and financing activities for the three months ended March 31, 2019 and 2018:

(in thousands)	Three Months Ended March 31, 2019	March 31, 2018	Net Change
Net cash provided by (used in):			
Operating activities:			
Net income (loss)	$(612)	$3,066	$(3,678)
Non-cash charges	3,405	3,531	(126)
Net change in operating assets and liabilities	6,850	(4,959)	11,809
Operating activities	9,643	1,638	8,005
Investing activities:			
Purchases of property and equipment	(393)	(135)	(258)
Net purchases of marketable securities	(36,058)	16,447	(52,505)
Investing activities	(36,451)	16,312	(52,763)
Financing activities:			
Net proceeds from offering of common stock	—	101,068	(101,068)
Proceeds from the exercise of stock options	179	2,666	(2,487)
Financing activities	179	103,734	(103,555)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	2	18	(16)
Net change in cash, cash equivalents and restricted cash	$(26,627)	$121,702	$(148,329)

The increase of $8.0 million in net cash provided by operating activities reflects an increase of $11.8 million from the net change in operating assets and liabilities, partially offset by a decrease of $3.7 million in net income and $0.1 million in non-cash charges. The increase of $11.8 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.

Off-Balance Sheet Arrangements

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

Contractual Obligations and Commitments

The following is a summary of our noncancellable long-term contractual cash obligations as of March 31, 2019:

	Cash Payments Due by Year (1)(2)						
(in thousands)	Total	2019	2020	2021	2022	2023	Thereafter
Operating leases(3)	$22,003	$1,903	$2,324	$2,332	$2,355	$2,420	$ 10,669
Purchase commitments(4)	5,266	3,073	847	890	456	—	—
	$27,269	$4,976	$3,171	$3,222	$2,811	$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 of $97.0 million, which consist of $2.0 million due upon the filing of the first marketing authorization for tradipitant in either the U.S. or the E.U., $10.0 million and $5.0 million for the first approval of a marketing authorization for tradipitant in the U.S. and the E.U., respectively, and up to $80.0 million for future 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.

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(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 under which we could be obligated to make potential future milestone payments of up to $45.2 million, which includes $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 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. 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) 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.

(4) 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 three months ended March 31, 2019. There were five major customers that each accounted for more than 10% of accounts receivable and, as a group, represented 96% of total accounts receivable at March 31, 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.

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ITEM 4 Controls and Procedures

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (Exchange Act)) as of March 31, 2019. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of March 31, 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 first quarter of 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. We implemented internal controls to ensure we properly assessed the impact of the new accounting standards related to leases on our financial statements to facilitate their adoption on January 1, 2019. There were no significant changes to our internal control over financial reporting due to the adoption of the new standard.

PART II — OTHER INFORMATION

ITEM 1 Legal Proceedings

Fanapt®. In June 2014, we filed suit against Roxane Laboratories, Inc. (Roxane) in the U.S. District Court for the District of Delaware (Delaware District Court). The suit sought an adjudication that Roxane has infringed one or more claims of our U.S. Patent No. 8,586,610 ('610 Patent) by submitting to the U.S. Food and Drug Administration (FDA) an Abbreviated New Drug Application (ANDA) for a generic version of Fanapt® prior to the expiration of the '610 Patent in November 2027. In addition, pursuant to a settlement agreement with Novartis Pharma AG (Novartis), we assumed Novartis' patent infringement action against Roxane in the Delaware District Court. That suit alleges that Roxane has infringed one or more claims of U.S. Patent RE39198 ('198 Patent), which is licensed exclusively to us, by filing an ANDA for a generic version of Fanapt® prior to the expiration of the '198 Patent in November 2016. These two cases against Roxane were consolidated by agreement of the parties and were tried together in a five-day bench trial that concluded in March 2016. In August 2016, the Delaware District Court ruled that we are entitled to a permanent injunction against Roxane enjoining Roxane from infringing the '610 Patent, including the manufacture, use, sale, offer to sell, sale, distribution or importation of any generic iloperidone product described in the '610 Patent ANDA until the expiration of the '610 Patent in November 2027. If we obtain pediatric exclusivity, the injunction against Roxane would be extended until May 2028 under the Delaware District Court's order. In September 2016, Roxane filed a notice of appeal with the Federal Circuit Court of Appeals (Federal Circuit). In July 2017, Roxane, now a subsidiary of Hikma Pharmaceuticals PLC (Hikma), petitioned the Federal Circuit to substitute Roxane with new defendants West-Ward Pharmaceuticals International Limited and West-Ward Pharmaceuticals Corp. (each of which is a subsidiary of Hikma and both of which are referred to collectively herein as West-Ward). In April 2018, the Federal Circuit affirmed the Delaware District Court's decision that West-Ward infringed the '610 Patent. In June 2018, West-Ward filed with the Federal Circuit a petition seeking rehearing en banc. The Federal Circuit invited us to respond to West-Ward's petition; our response was filed in July 2018. In August 2018, the Federal Circuit denied West-Ward's petition for rehearing. In January 2019, West-Ward filed a petition in the United States Supreme Court for a writ of certiorari seeking reversal of the Federal Circuit's decision. We submitted a response to that petition on February 12, 2019. On March 18, 2019, the United States Supreme Court invited the Solicitor General of the United States to file a brief in the matter expressing the views of the United States.

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 Defendants). The lawsuits each seek an adjudication that the respective Defendants infringed one or more claims of the ‘610 Patent and/or our U.S. Patent No. 9,138,432 (‘432 Patent) by submitting to the FDA an ANDA for a generic version of Fanapt® prior to the expiration of the ‘610 Patent in November 2027 or the ‘432 Patent in September 2025. The Defendants denied infringement and counterclaimed for declaratory judgment of invalidity and noninfringement of the ‘610 Patent and the ‘432 Patent. Certain Defendants have since entered into agreements resolving these lawsuits, as discussed below.

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The remaining matters have been stayed until the later of November 30, 2018 or 14 days after final disposition by the U.S. Supreme Court of any petition for a writ of certiorari filed by West-Ward. We entered into a confidential stipulation with each of Inventia and Lupin regarding any potential launch of Inventia's and Lupin's generic ANDA products.

HETLIOZ®. In March 2018, we received a Paragraph IV certification notice letter from Teva Pharmaceuticals USA, Inc. (Teva) notifying us that Teva had submitted an ANDA for HETLIOZ® to the FDA requesting approval to market, sell and use a generic version of the 20mg HETLIOZ® capsules for Non-24. In its notice letter, Teva alleges that our U.S. Patent No. RE46,604, U.S. Patent No. 9,060,995, U.S. Patent 9,539,234, U.S. Patent 9,549,913, U.S. Patent 9,730,910 and U.S. Patent 9,885,241 (collectively, the Vanda Patents), each of which is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book), which cover methods of using HETLIOZ®, are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of the product described in its ANDA. We received similar notice letters in April 2018 from MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited (together, MSN) and Apotex.

In April 2018, we filed a patent infringement lawsuit in the Delaware District Court against Teva and in May 2018, we filed patent infringement lawsuits in the Delaware District Court against MSN and Apotex. The lawsuits seek an adjudication that Teva, MSN and Apotex have infringed one or more claims of the Vanda Patents by submitting to the FDA an ANDA for a generic version of HETLIOZ® prior to the expiration of the latest to expire of the Vanda Patents in 2034. The relief requested by us in the lawsuits includes requests for permanent injunctions preventing Teva, MSN and Apotex from infringing the asserted claims of the Vanda Patents by engaging in the manufacture, use, offer to sell, sale, importation or distribution of generic versions of HETLIOZ® before the last expiration date of the Vanda Patents and for an order that any effective date of FDA approval of Teva, MSN, and Apotex's generic versions of HETLIOZ® be a date not earlier than the expiration of the Vanda Patents. The lawsuits automatically preclude the FDA from approving the submitted ANDAs until the earlier of seven and one-half years after the January 2014 approval of our NCE status application or entry of a district court decision finding the Vanda Patents invalid, unenforceable or not infringed. In June 2018, Teva, MSN and Apotex each answered our complaint, and Teva included counterclaims for declarations that the Vanda Patents are invalid. MSN included additional counterclaims for declarations that the Vanda Patents are not infringed. In July 2018, we answered Teva and MSN's counterclaims, denying their allegations.

In October 2018, we received an additional Paragraph IV certification notice letter from Teva concerning its Orange Book listed U.S. Patent No. 10,071,977, which expires in 2035 (the '977 Patent). In November 2018, we received a similar additional Paragraph IV certification notice letter from Apotex concerning the '977 Patent. In December 2018, we filed amended complaints against Teva, Apotex, and MSN alleging infringement of one or more claims of the '977 Patent. The amended complaints seek an adjudication that Teva, Apotex, and MSN have infringed one or more claims of the '977 Patent by submitting to FDA an ANDA for a generic version of HETLIOZ® prior to the expiration of the '977 Patent. The relief requested by us in the amended complaints includes requests for permanent injunctions preventing Teva, Apotex, and MSN from infringing the asserted claims of the '977 Patent by engaging in the manufacture, use, offer to sell, sale, importation or distribution of generic versions of HETLIOZ® before the expiration date of the '977 Patent and for an order that any effective date of FDA approval of Teva, MSN, and Apotex's generic versions of HETLIOZ® be a date not earlier than the expiration of the '977 Patent. In December 2018, Teva, MSN, and Apotex answered our amended complaints, and Teva and MSN included counterclaims for declarations that the '977 Patent is invalid, and MSN included an additional counterclaim that the '977 Patent is unenforceable for inequitable conduct. In January 2019, we answered Teva and MSN's counterclaims. A trial date for these lawsuits has been set for September 2020.

In February 2019, we received additional Paragraph IV certification notice letters separately from Teva and Apotex concerning our Orange Book listed U.S. Patent No. 10,149,829, which expires in 2033 (the '829 Patent). In their notice letters, Teva and Apotex allege that the '829 Patent, which covers methods of using HETLIOZ®, is invalid, unenforceable and will not be infringed by Teva's and Apotex's respective manufacture, use or sale of the product described in their respective ANDAs. In March 2019 and April 2019, we filed separate patent infringement lawsuits in the Delaware District Court against Teva and Apotex, respectively. The lawsuits seek adjudications that Teva and

Apotex have infringed one or more claims of the ’829 Patent by submitting to the FDA an ANDA for a generic version of HETLIOZ® prior to the expiration of the ’829 Patent. The relief requested by us includes permanent injunctions preventing Teva and Apotex from infringing the asserted claims of the ’829 Patent by engaging in the manufacture, use, offer to sell, sale, importation or distribution of generic versions of HETLIOZ® before the expiration of the ’829 Patent, and includes orders that any effective date of FDA approval of Teva and Apotex’s generic versions of HETLIOZ® be a date not earlier than the expiration of the ’829 Patent. In April 2019, Teva answered our complaint, in which Teva included a counterclaim for a declaration that the ’829 Patent is invalid. Our response to Teva’s counterclaim is due May 3, 2019.

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

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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, no patients were ever enrolled in any study beyond 12 weeks. On December 19, 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 United States 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. On February 14, 2019, the FDA filed a Motion for Voluntary Remand to the Agency and for a Stay of the Case. On March 14, 2019, the DC District Court granted the FDA's request for voluntary remand and returned the matter to the FDA for further consideration. On April 26, 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. On April 29, 2019, we and the FDA filed a Joint Motion for Extension of Time to Propose a Scheduling Order for this matter. On April 30, 2019, the DC District Court granted the motion, thereby extending the deadline until May 3, 2019 for the FDA and us to file proposals regarding a scheduling order. 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, United States ex rel. Richard Gardner v. Vanda Pharmaceuticals Inc., 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 alleges that we violated these laws through the promotion and marketing of our products Fanapt® and HETLIOZ®. The complaint seeks, among other things, treble damages, civil penalties for each alleged false claim, and attorneys' fees and costs. By virtue of the court having unsealed the case, we learned that in January 2019, the U.S., as well as the Plaintiff States, filed notice of their election not to intervene in the qui tam action at this time. The U.S.' and the Plaintiff States' election not to intervene does not prevent the plaintiff/relator from litigating this action and the U.S. and the Plaintiff States may later seek to intervene in the action. The deadline for us to be served with the qui tam complaint was May 1, 2019, and we have not been served.

In February 2019, a securities class action, Gordon v. Vanda Pharmaceuticals Inc., Case No. 1:19-cv-01108-ARR-LB, was filed in the U.S. District Court for the Eastern District of New York naming Vanda and certain of our officers as defendants. The complaint, filed on behalf of a purported stockholder of ours, asserts claims on behalf of a putative class of all persons who purchased our publicly traded securities between November 4, 2015 through 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 complaint alleges that the defendants made false and misleading statements and/or omissions regarding Fanapt® and HETLIOZ® 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. We have not yet responded to the complaint.

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.

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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 GCSI; PAGI-SYM; CGI-S; PGI-C.

In January 2019, we initiated a Phase II clinical study of tradipitant in motion sickness.

If the results of our ongoing Phase III clinical study of tradipitant for the treatment of chronic pruritus in atopic dermatitis and/or our planned Phase III clinical study of tradipitant for the treatment of gastroparesis and/or a future 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, no patients were ever enrolled in any study beyond 12 weeks. On December 19, 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 United States District Court for the District of Columbia, challenging the FDA's legal authority to issue the PCH, and seeking an order to set it aside. On February 14, 2019, the FDA filed a Motion for Voluntary Remand to the Agency and for a Stay of the Case. On March 14, 2019, the DC District Court granted the FDA's request for voluntary remand and returned the matter to the FDA for further consideration. On April 26, 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. On April 29, 2019, we and the FDA filed a Joint Motion for Extension of Time to Propose a Scheduling Order for this matter. On April 30, 2019, the

DC District Court granted the motion, thereby extending the deadline until May 3, 2019 for the FDA and us to file proposals regarding a scheduling order. We intend to continue vigorously pursuing our interest in the matter.

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We do not expect the PCH to have any impact on our ongoing clinical studies in atopic dermatitis and motion sickness, each of which is under 12 weeks in duration, or our planned 12-week Phase III study in gastroparesis, 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

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ITEM 6 Exhibits

Exhibit Number	Description
3.1	Form of Amended and Restated Certificate of Incorporation of the registrant (filed as Exhibit 3.8 to Amendment No. 2 to the registrant's registration statement on Form S-1 (File No. 333-130759) on March 17, 2006 and incorporated herein by reference).
3.2	Fourth Amended and Restated Bylaws of the registrant, as amended and restated on December 17, 2015 (filed as Exhibit 3.1 to the registrant's current report on Form 8-K (File No. 001-34186) on December 21, 2015 and incorporated herein by reference).
31.1	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer), as required by Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from this quarterly report on Form 10-Q for the fiscal quarter ended March 31, 2019 formatted in XBRL (eXtensible Business Reporting Language) and filed electronically herewith: (i) Condensed Consolidated Balance Sheets as of March 31, 2019 and December 31, 2018; (ii) Condensed Consolidated Statements of Operations for the three months ended March 31, 2019 and 2018; (iii) Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2019 and 2018; (iv) Condensed Consolidated Statements of Changes in Stockholders' Equity for the three months ended March 31, 2019 and 2018; (v) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2019 and 2018; and (vi) Notes to Condensed Consolidated Financial Statements.

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SIGNATURES

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

Vanda Pharmaceuticals Inc.

May 3, 2019

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

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

May 3, 2019

/s/ James P. Kelly

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