Vanda Pharmaceuticals Inc.
Form 10-Q
November 07, 2018
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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 September 30, 2018
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

As of October 25, 2018, there were 52,449,880 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. Forward-looking statements may appear throughout this report. Words such as, but not limited to, “believe,” “expect,” “anticipate,” “estimate,” “intend,” “plan,” “project,” “target,” “goal,” “likely,” “will,” “would,” negative of these terms and similar expressions or words, identify forward-looking statements. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Important factors that could cause actual results to differ materially from those reflected in our forward-looking statements include, among others:

- the ability of Vanda Pharmaceuticals Inc. (we, our, the Company or Vanda) to continue to commercialize HETLIOZ® (tasimelteon) for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in the United States (U.S.) and Europe;
- uncertainty as to the ability to increase market awareness of Non-24 and the market acceptance of HETLIOZ®;
- our ability to continue to generate U.S. sales of Fanapt® (iloperidone) for the treatment of schizophrenia;
- our dependence on third-party manufacturers to manufacture HETLIOZ® and Fanapt® in sufficient quantities and quality;
- our level of success in commercializing HETLIOZ® and Fanapt® in new markets;
- our ability to prepare, file, prosecute, defend and enforce any patent claims and other intellectual property rights;
- our ability to complete the clinical development and obtain regulatory approval of tradipitant for the treatment of chronic pruritus in atopic dermatitis and the treatment of gastroparesis;
- 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, 2017, other unknown or unpredictable factors also could affect our results. Therefore, the information in this quarterly report should be read together with other reports and documents that we file with the Securities and Exchange Commission from time to time, including on Form 10-Q and Form 8-K, which may supplement, modify, supersede or update those risk factors. As a result of these factors, we cannot assure you that the

forward-looking statements in this report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all.

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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)	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 60,778	$ 33,627
Marketable securities	179,801	109,786
Accounts receivable, net	25,259	17,601
Inventory	887	840
Prepaid expenses and other current assets	12,082	8,003
Total current assets	278,807	169,857
Property and equipment, net	4,579	5,306
Intangible assets, net	24,922	26,069
Non-current inventory and other	3,629	4,193
Total assets	$ 311,937	$ 205,425
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 19,046	$ 20,335
Product revenue allowances	27,196	23,028
Milestone obligations under license agreements	—	27,000
Total current liabilities	46,242	70,363
Other non-current liabilities	4,278	3,675
Total liabilities	50,520	74,038
Commitments and contingencies (Notes 8 and 14)		
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; 52,400,709 and 44,938,133 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	52	45
Additional paid-in capital	607,873	492,802
Accumulated other comprehensive income (loss)	70	(34)
Accumulated deficit	(346,578)	(361,426)
Total stockholders' equity	261,417	131,387
Total liabilities and stockholders' equity	$ 311,937	$ 205,425

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		Nine Months Ended	
	September 30, 2018	September 30, 2017	September 30, 2018	September 30, 2017
Revenues:				
Net product sales	$49,135	$ 41,336	$140,077	$ 120,807
Total revenues	49,135	41,336	140,077	120,807
Operating expenses:				
Cost of goods sold excluding amortization	5,068	4,525	14,841	13,057
Research and development	11,390	10,178	30,672	28,393
Selling, general and administrative	26,047	31,124	80,829	92,792
Intangible asset amortization	397	432	1,147	1,318
Total operating expenses	42,902	46,259	127,489	135,560
Income (loss) from operations	6,233	(4,923)	12,588	(14,753)
Other income	1,030	396	2,440	1,073
Income (loss) before income taxes	7,263	(4,527)	15,028	(13,680)
Provision for income taxes	92	23	180	49
Net income (loss)	$7,171	$ (4,550)	$14,848	$ (13,729)
Net income (loss) per share:				
Basic	$0.14	$ (0.10)	$0.30	$ (0.31)
Diluted	$0.13	$ (0.10)	$0.28	$ (0.31)
Weighted average shares outstanding:				
Basic	52,389,014	44,885,287	50,321,640	44,669,201
Diluted	54,709,749	44,885,287	52,315,642	44,669,201

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		Nine Months Ended	
	September 30, 2018	September 30, 2017	September 30, 2018	September 30, 2017
Net income (loss)	$7,171	$ (4,550)	$14,848	$ (13,729)
Other comprehensive income (loss):				
Net foreign currency translation gain (loss)	(2)	5	(15)	26
Change in net unrealized gain (loss) on marketable securities	(7)	57	119	(11)
Tax provision on other comprehensive income (loss)	—	—	—	—
Other comprehensive income (loss), net of tax	(9)	62	104	15
Comprehensive income (loss)	$7,162	$ (4,488)	$14,952	$ (13,714)

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	Common Stock Par Value	Additional Paid-in Capital	Other Comprehensive Income	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	100,864	—	—	100,870
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	1,137,576	1	5,463	—	—	5,464
Stock-based compensation expense	—	—	8,744	—	—	8,744
Net income	—	—	—	—	14,848	14,848
Other comprehensive income, net of tax	—	—	—	104	—	104
Balances at September 30, 2018	52,400,709	$ 52	$ 607,873	$ 70	$ (346,578)	$ 261,417

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

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

(in thousands)	Nine Months Ended September 30, 2018	Sep tember 30, 2017
Cash flows from operating activities		
Net income (loss)	$14,848	$ (13,729)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation of property and equipment	1,057	895
Stock-based compensation	8,744	7,683
Amortization of discounts on marketable securities	(1,386)	(274)
Intangible asset amortization	1,147	1,318
Other non-cash adjustments, net	153	399
Changes in operating assets and liabilities:		
Accounts receivable	(7,686)	2,089
Prepaid expenses and other assets	(3,936)	1,023
Inventory	215	(896)
Accounts payable and other liabilities	(3,182)	4,552
Product revenue allowances	4,749	(8,509)
Net cash provided by (used in) operating activities	14,723	(5,449)
Cash flows from investing activities		
Acquisition of intangible asset	(25,000)	—
Purchases of property and equipment	(346)	(1,473)
Purchases of marketable securities	(201,940)	(109,396)
Maturities of marketable securities	133,430	93,277
Net cash used in investing activities	(93,856)	(17,592)
Cash flows from financing activities		
Net proceeds from offering of common stock	100,870	—
Proceeds from the exercise of stock options	5,464	5,170
Net cash provided by financing activities	106,334	5,170
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(14)	34
Net change in cash, cash equivalents and restricted cash	27,187	(17,837)
Cash, cash equivalents and restricted cash		
Beginning of period	34,335	41,256
End of period	$61,522	$ 23,419

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.
- 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 of 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. An assessment of new Fanapt® clinical opportunities 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 and the treatment of gastroparesis.
- 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.
- 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, 2017 included in the Company's annual report on Form 10-K. The financial information as of September 30, 2018 and for the three and nine months ended September 30, 2018 and 2017 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, 2017 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, 2017.

2. Summary of Significant Accounting Policies

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.

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Revenue Recognition

In accordance with Accounting Standards Codification (ASC) Subtopic 606 Revenue from Contracts with Customers (ASC 606), which the Company adopted January 1, 2018, the Company accounts 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. The Company recognizes revenue when control of the product is transferred to the customer in an amount that reflects the consideration the Company expects to be entitled to in exchange for those product sales, which is typically once the product physically arrives at the customer. Sales taxes, value add taxes, and usage-based taxes are excluded from revenues.

The Company's revenues consist of net product sales of HETLIOZ® and net product sales of Fanapt®. Net sales by product for the three and nine months ended September 30, 2018 and 2017 were as follows:

(in thousands)	Three Months Ended		Nine Months Ended	
	September 30, 2018	September 30, 2017	September 30, 2018	September 30, 2017
HETLIOZ® product sales, net	$29,923	$ 22,279	$83,391	$ 64,968
Fanapt® product sales, net	19,212	19,057	56,686	55,839
	$49,135	$ 41,336	$140,077	$ 120,807

Major Customers

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. 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 90% of total revenues for the nine months ended September 30, 2018. There were five major customers that each accounted for more than 10% of accounts receivable and, as a group, represented 95% of total accounts receivable at September 30, 2018. 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.

Reserves for Variable Consideration

The transaction price is determined based upon the consideration to which the Company will be entitled in exchange for transferring product to the customer. The Company's 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. The Company estimates 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 the Company's 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 the Company has 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 included as a component of other non-current liabilities in the condensed consolidated balance sheets. Uncertainties related to variable consideration are generally resolved in the quarter subsequent to period end, with the exception of product returns which are resolved during the product expiry period specified in the customer contract. The Company currently records sales allowances for the following:

Prompt-pay: Specialty pharmacies and wholesalers are offered discounts for prompt payment. The Company expects that the specialty pharmacies and wholesalers will earn prompt payment discounts and, therefore, deducts 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

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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. Vanda accounts for the Medicare Part D coverage gap using a point of sale model. Estimates for expected Medicare Part D coverage gap are based in part on historical activity and, where available, actual and pending prescriptions for which the Company has validated the insurance benefits.

Service Fees: The Company receives sales order management, data and distribution services from certain customers. These fees are based on contracted terms and are known amounts. The Company accrues 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 the Company’s third-party administrator.

Product Returns: Consistent with industry practice, the Company generally offers direct customers a limited right to return as defined within the Company’s returns policy. The Company considers several factors in the estimation process, including historical return activity, expiration dates of product shipped to specialty pharmacies and wholesalers, inventory levels within the distribution channel, product shelf life, prescription trends and other relevant factors. The Company does not expect returned goods to be resalable. There was no right of return asset as of September 30, 2018 or December 31, 2017.

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 will change its presentation of shareholder's equity in the first quarter of 2019.

In November 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-18, Restricted Cash. The new standard requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The standard is effective for annual reporting periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2017. The Company adopted this new standard in the first quarter of 2018 and applied the provisions retrospectively. As a result of the adoption of the new guidance, the Company increased the beginning of year total amount shown on the condensed

consolidated statements of cash flows by $0.7 million for the nine months ended September 30, 2018, equal to the balance of restricted cash included in the condensed consolidated balance sheets as of December 31, 2017. The Company increased the beginning of year and end of year total amounts shown on the consolidated statements of cash flows by $0.8 million for the nine months ended September 30, 2017, equal to the balance of restricted cash included in the condensed consolidated balance sheets as of the period ended September 30, 2017 and December 31, 2016. 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.

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headquarters. As of September 30, 2018, restricted cash of $0.1 million and $0.6 million is included in prepaid and other current assets and other non-current assets, respectively. As of December 31, 2017, restricted cash of $0.7 million is included in other non-current assets.

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows – Classification of Certain Cash Receipts and Cash Payments, to clarify guidance on the classification of certain cash receipts and cash payments in the statement of cash flow. The standard is effective for annual reporting periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2017. The Company's adoption of this standard in the first quarter of 2018 had no impact to the Company's condensed consolidated financial statements.

In June 2016, the FASB issued 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, 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. The new standard requires that lessees will need to recognize a right-of-use asset and a lease liability for virtually all of their leases (other than leases that meet the definition of a short-term lease). The liability will be equal to the present value of lease payments. The asset will be 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 current operating leases) while finance leases will result in a front-loaded expense pattern (similar to current capital leases). The new standard is effective for annual periods ending after December 15, 2018, and interim periods within annual periods beginning after December 15, 2018. Early adoption is permitted. The new standard must be applied using a modified retrospective transition approach to all leases existing as of the date of (i) the beginning of the earliest comparative period presented in the financial statements or (ii) January 1, 2019. The Company has identified existing lease contracts and continues to evaluate the impact of this standard on the Company's consolidated financial statements, including the method of adoption and election of practical expedients. The Company expects that the adoption of the new leasing standard will result in the recognition of material right-of-use asset and liabilities on the condensed consolidated balance sheets for its operating lease commitments.

In May 2014, the FASB issued ASU 2014-9, Revenue from Contracts with Customers. This ASU supersedes the revenue recognition requirements in ASC 605, Revenue Recognition, and creates ASC 606, Revenue from Contracts with Customers. ASC 606 requires companies to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which a company expects to be entitled in exchange for those goods or services. Under the new standard, revenue is recognized when a customer obtains control of a good or service. The standard allows for two transition methods—entities can either apply the new standard (i) retrospectively to each prior reporting period presented (full retrospective), or (ii) retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial adoption (modified retrospective). In July 2015, the FASB issued ASU 2015-14, Revenue from Contracts with Customers, which defers the effective date by one year to December 15, 2017 for fiscal years, and interim periods within those fiscal years, beginning after that date. Early adoption of the standard is permitted, but not before the original effective date of December 15, 2016. In March 2016, the FASB issued ASU 2016-8 Revenue from Contracts with Customers, Principal versus Agent Considerations (Reporting Revenue versus Net), in April 2016, the FASB issued ASU 2016-10, Revenue from Contracts with Customers, identifying Performance Obligations and Licensing, and in May 2016, the FASB issued ASU 2016-12, Revenue from Contracts with Customers, Narrow-Scope Improvements and Practical Expedients, which provide additional clarification on certain topics addressed in ASU 2014-9. ASU 2016-8, ASU 2016-10, and ASU 2016-12 follow the same implementation guidelines as ASU 2014-9 and ASU 2015-14. The Company adopted this new standard in the first quarter of 2018 using the modified retrospective method to those contracts which were not completed as of January 1, 2018. Results for reporting periods beginning after January 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported in accordance with historic

accounting under ASC 605. There was no impact to opening retained earnings as of January 1, 2018 as a result of adoption of the new standard. The impact to the condensed consolidated statements of operations if the Company had applied ASC 605 for the three and nine months ended September 30, 2018 is not material. As a result of adoption, the Company reclassified the provision for product revenue returns of $4.3 million from accounts receivable, net to product revenue allowances and other non-current liabilities in the condensed consolidated balance sheets as of September 30, 2018. The provision for product returns as of December 31, 2017 of $4.1 million is included in accounts receivable in the condensed consolidated balance sheet.

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3. Marketable Securities

The following is a summary of the Company's available-for-sale marketable securities as of September 30, 2018, which all have contract maturities of less than one year:

September 30, 2018 (in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
U.S. Treasury and government agencies	$67,449	$ —	$ (37)	$67,412
Corporate debt	91,158	98	(4)	91,252
Asset-backed securities	21,138	1	(2)	21,137
	$179,745	$ 99	$ (43)	$179,801

The following is a summary of the Company's available-for-sale marketable securities as of December 31, 2017, which all have contract maturities of less than one year:

December 31, 2017 (in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
U.S. Treasury and government agencies	$60,681	$ —	$ (63)	$60,618
Corporate debt	49,168	12	(12)	49,168
	$109,849	$ 12	$ (75)	$109,786

4. Fair Value Measurements

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

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

Marketable securities classified in Level 1 and Level 2 as of September 30, 2018 and December 31, 2017 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 nine months ended September 30, 2018 and 2017.

As of September 30, 2018, the Company held certain assets that are required to be measured at fair value on a recurring basis, as follows:

(in thousands)	September 30, 2018	Fair Value Measurement as of September 30, 2018 Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)

U.S. Treasury and government agencies	$ 87,269	$87,269	$ —	$ —
Corporate debt	94,243	—	94,243	—
Asset-backed securities	21,137	—	21,137	—
	$ 202,649	$87,269	$ 115,380	$ —

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As of December 31, 2017, the Company held certain assets that are required to be measured at fair value on a recurring basis, as follows:

(in thousands)	December 31, 2017	Fair Value Measurement as of December 31, 2017 Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
U.S. Treasury and government agencies	$ 60,618	$60,618	$ —	$ —
Corporate debt	53,164	—	53,164	—
	$ 113,782	$60,618	$ 53,164	$ —

Total assets measured at fair value as of September 30, 2018 and December 31, 2017 include $22.8 million and $4.0 million, respectively, 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 September 30, 2018 and December 31, 2017:

(in thousands)	September 30, 2018	December 31, 2017
Current assets		
Work-in-process	$ 108	$ 80
Finished goods	779	760
	$ 887	$ 840
Non-Current assets		
Raw materials	$ 87	$ 87
Work-in-process	2,366	2,821
Finished goods	426	408
	$ 2,879	$ 3,316

6. Intangible Assets

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

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 obligation was recorded as a current liability as of December 31, 2017. 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

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of which expires in February 2035. The estimated economic useful life of the intangible asset was changed from May 2034 to February 2035 based on the February 2035 expiration date of the '977 patent issued by the U.S. Patent and Trademark Office in September 2018.

Fanapt®. In 2009, the Company announced that the FDA had approved the NDA for Fanapt®. As a result of this approval, the Company met a milestone under its original sublicense agreement with Novartis that required the Company to make a license payment of $12.0 million to Novartis. The $12.0 million was amortized on a straight-line basis over the remaining life of the U.S. composition of matter patent for Fanapt® to November 2016.

Pursuant to a settlement agreement entered into in December 2014, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to the Company. As a result, the Company recognized an intangible asset of $15.9 million on December 31, 2014 related to the reacquired rights to Fanapt®, which was fully amortized on a straight-line basis as of November 2016. The useful life estimation for the Fanapt® intangible asset was based on the market participant methodology prescribed by ASC 805, and therefore does not reflect the impact of additional Fanapt® patents solely owned by the Company with varying expiration dates, the latest of which is December 2031.

The following is a summary of the Company's intangible assets as of September 30, 2018:

		September 30, 2018		
(in thousands)	Estimated Useful Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	February 2035	$33,000	$ 8,078	$24,922
Fanapt®	November 2016	27,941	27,941	—
		$60,941	$ 36,019	$24,922

The following is a summary of the Company's intangible assets as of December 31, 2017:

		December 31, 2017		
(in thousands)	Estimated Useful Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	May 2034	$33,000	$ 6,931	$26,069
Fanapt®	November 2016	27,941	27,941	—
		$60,941	$ 34,872	$26,069

Intangible assets are amortized over their estimated useful economic life using the straight-line method. Amortization expense was $0.4 million for each of the three months ended September 30, 2018 and 2017. Amortization expense was $1.1 million and $1.3 million for the nine months ended September 30, 2018 and 2017, respectively. The following is a summary of the future intangible asset amortization schedule as of September 30, 2018:

(in thousands)	Total	2018	2019	2020	2021	2022	Thereafter
HETLIOZ®	$24,922	$380	$1,518	$1,518	$1,518	$1,518	$ 18,470

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7. Accounts Payable and Accrued Liabilities

The following is a summary of the Company's accounts payable and accrued liabilities as of September 30, 2018 and December 31, 2017:

(in thousands)	September 30, 2018	December 31, 2017
Research and development expenses	$ 4,231	$ 4,663
Consulting and other professional fees	3,351	3,961
Compensation and employee benefits	4,787	5,323
Royalties payable	4,752	4,394
Other	1,925	1,994
	$ 19,046	$ 20,335

8. Commitments and Contingencies

The following is a summary of the Company's noncancellable long-term contractual cash obligations as of September 30, 2018:

	Cash Payments Due by Year						
(in thousands)	Total	2018	2019	2020	2021	2022	Thereafter
Operating leases	$23,372	$599	$2,491	$2,501	$2,337	$2,355	$ 13,089
Purchase commitments	8,372	197	5,982	847	890	456	—
	$31,744	$796	$8,473	$3,348	$3,227	$2,811	$ 13,089

Operating leases

Commitments relating to operating leases represent the minimum annual future payments under operating leases and subleases for its Company's headquarters at 2200 Pennsylvania Avenue, N.W. in Washington, D.C., and operating leases for office space in London and Berlin.

In June 2011, the Company entered into an operating lease for its headquarters at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. for 21,400 square feet of office space. The Company subsequently amended the lease in March 2014 and March 2018 to increase the office space under lease to 33,534 square feet and, in March 2018, extended the lease term to July 2028. Subject to the prior rights of other tenants, the Company has the right to renew the lease for five years following its expiration. 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 under which the Company leases 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.

The Company has an operating lease for 2,880 square feet of office space for the Company's European headquarters in London that has a noncancellable lease term ending in 2021, and 1,249 square feet of office space in Berlin under a short-term operating lease.

Rent expense under operating leases and subleases was $0.9 million and $0.8 million for the three months ended September 30, 2018 and 2017, respectively. Rent expense under operating leases and subleases was $2.7 million and $2.4 million for the nine months ended September 30, 2018 and 2017, respectively.

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

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execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. Since inception, the Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements. The Company also indemnifies its officers and directors for certain events or occurrences, subject to certain conditions.

License Agreements

The Company's rights to develop and commercialize its products are subject to the terms and conditions of licenses granted to the Company by other pharmaceutical companies.

HETLIOZ®. In February 2004, the Company entered into a license agreement with BMS under which it received an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize HETLIOZ®. As a result of the FDA's approval of the HETLIOZ® NDA in January 2014, the Company made an $8.0 million milestone payment to BMS in the first quarter of 2014 under the license agreement that was capitalized as an intangible asset and is being amortized over the estimated economic useful life of the related product patents for HETLIOZ® in the U.S. In April 2018, the Company met another milestone under its license agreement when cumulative worldwide sales of HETLIOZ® reached $250.0 million. As a result of the achievement of this milestone, the Company made a payment to BMS of $25.0 million in the second quarter of 2018. The $25.0 million milestone obligation was capitalized as an intangible asset in the first quarter of 2015 and is being amortized over the estimated economic useful life of the related product patents for HETLIOZ® in the U.S. The Company has no remaining milestone obligations to BMS. Additionally, the Company is obligated to make royalty payments on HETLIOZ® net sales to BMS in any territory where the Company commercializes HETLIOZ® for a period equal to the greater of 10 years following the first commercial sale in the territory or the expiry of the new chemical entity (NCE) patent in that territory. During the period prior to the expiry of the NCE patent in a territory, the Company is obligated to pay a 10% royalty on net sales in that territory. The royalty rate is decreased by half for countries in which no NCE patent existed or for the remainder of the 10 years after the expiry of the NCE patent. The Company is also obligated under the license agreement to pay BMS a percentage of any sublicense fees, upfront payments and milestone and other payments (excluding royalties) that it receives from a third party in connection with any sublicensing arrangement, at a rate which is in the mid-twenties. The Company has agreed with BMS in the license agreement for HETLIOZ® to use its commercially reasonable efforts to develop and commercialize HETLIOZ®.

Fanapt®. Pursuant to the terms of a settlement agreement entered into with Novartis, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to the Company on December 31, 2014. The Company has no remaining milestone obligations related to Fanapt®. 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. The Company made a $2.0 million payment during the year ended December 31, 2016 that applied to this 3% manufacturing know-how royalty. No further royalties on manufacturing know-how are payable by the Company after December 31, 2019. The Company is also obligated 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.

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 the third quarter of 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 three

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months ended September 30, 2017 and a current liability in the condensed consolidated balance sheet as of 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 entered into with Novartis relating to Fanapt®, the Company received an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize VQW-765, a Phase II alpha-7 nicotinic acetylcholine receptor partial agonist. Pursuant to the license agreement, the Company is obligated to use its commercially reasonable efforts to develop and commercialize VQW-765 and is responsible for all development costs. The Company has no milestone obligations; however, Novartis is eligible to receive tiered-royalties on net sales at percentage rates up to the mid-teens.

Portfolio of CFTR activators and inhibitors. In March 2017, the Company entered into a license agreement with the University of California San Francisco (UCSF), under which the Company acquired an exclusive worldwide license to develop and commercialize a portfolio of CFTR activators and inhibitors. Pursuant to the license agreement, the Company will develop and commercialize the CFTR activators and inhibitors and is responsible for all development costs under the license agreement, including current pre-investigational new drug development work. The license agreement provides for an initial license fee of $1.0 million that was paid by the Company in the first quarter of 2017, annual maintenance fees and up to $46.0 million in potential regulatory and sales milestone obligations. UCSF is eligible to receive single-digit tiered royalties on net sales.

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 60 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.

9. 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.

10. Accumulated Other Comprehensive Income (Loss)

The accumulated balances related to each component of other comprehensive income (loss) were as follows as of September 30, 2018 and December 31, 2017:

(in thousands)	September 30, 2018	December 31, 2017
Foreign currency translation	$ 14	$ 29
Unrealized gain (loss) on marketable securities	56	(63)
	$ 70	$ (34)

There was no tax provision (benefit) included in accumulated other comprehensive income (loss) as of September 30, 2018 and December 31, 2017. There were no reclassifications out of accumulated other comprehensive income (loss) for either of the nine months ended September 30, 2018 or 2017.

11. Stock-Based Compensation

As of September 30, 2018, there were 5,759,160 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

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other administrative changes. Both amendments and restatements of the 2016 Plan were approved by the Company's stockholders. There are a total of 7,100,000 shares of common stock reserved for issuance under the 2016 Plan, 4,576,468 shares of which remained available for future grant as of September 30, 2018.

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 new employees 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. Service option awards granted to existing employees vest and become exercisable monthly in equal installments over four years. The initial service option awards granted to directors upon their election vest and become exercisable in equal monthly installments over a period of four years, while the subsequent annual service option awards granted to directors vest and become exercisable in either equal monthly installments over a period of one year or on the first anniversary of the grant date. Certain service option awards to executives and directors provide for accelerated vesting if there is a change in control of the Company. Certain service option awards to employees and executives provide for accelerated vesting if the respective employee’s or executive’s service is terminated by the Company for any reason other than cause or permanent disability.

As of September 30, 2018, $8.2 million of unrecognized compensation costs related to unvested service option awards are expected to be recognized over a weighted average period of 1.4 years. No option awards are classified as a liability as of September 30, 2018.

A summary of option activity under the Plans for the nine months ended September 30, 2018 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, 2017	4,719,784	$ 10.03	5.63	$ 24,421
Granted	567,500	19.22		
Forfeited	(232,527)	13.99		
Exercised	(616,457)	8.86		5,059
Outstanding at September 30, 2018	4,438,300	11.16	5.56	52,343
Exercisable at September 30, 2018	3,419,995	9.92	4.67	44,550
Vested and expected to vest at September 30, 2018	4,290,127	10.93	5.43	51,589

The weighted average grant-date fair value of options granted was $10.66 and $7.81 per share for the nine months ended September 30, 2018 and 2017, respectively. Proceeds from the exercise of stock options amounted to $5.5 million and $5.2 million for the nine months ended September 30, 2018 and 2017, respectively.

Restricted Stock Units

A 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 September 30, 2018, $16.7 million of unrecognized compensation costs related to unvested service RSUs are expected to be recognized over a weighted average period of 1.8 years. No RSUs are classified as a liability as of September 30, 2018.

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A summary of RSU activity under the Plans for the nine months ended September 30, 2018 follows:

2006 and 2016 Plans	Number of Shares Underlying RSUs	Weighted Average Grant Date Fair Value
Unvested at December 31, 2017	1,357,838	$ 12.72
Granted	704,086	18.85
Forfeited	(219,945)	15.11
Vested	(521,119)	12.64
Unvested at September 30, 2018	1,320,860	15.63

The grant date fair value for the 521,119 shares underlying RSUs that vested during the nine months ended September 30, 2018 was $6.6 million.

Stock-Based Compensation

Stock-based compensation expense recognized for the three and nine months ended September 30, 2018 and 2017 was comprised of the following:

(in thousands)	Three Months Ended		Nine Months Ended	
	September 30, 2018	September 30, 2017	September 30, 2018	September 30, 2017
Research and development	$326	$ 264	$963	$ 958
Selling, general and administrative	2,546	2,507	7,781	6,725
	$2,872	$ 2,771	$8,744	$ 7,683

The fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton option pricing model that uses the assumptions noted in the following table. Expected volatility rates are based on the historical volatility of the Company's publicly traded common stock and other factors. The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The Company has not paid dividends to its stockholders since its inception (other than a dividend of preferred share purchase rights, which was declared in September 2008) and does not plan to pay dividends in the foreseeable future. Assumptions used in the Black-Scholes-Merton option pricing model for stock options granted during the nine months ended September 30, 2018 and 2017 were as follows:

	Nine Months Ended	
	September 30, 2018	September 30, 2017
Expected dividend yield	0 %	0 %
Weighted average expected volatility	58 %	57 %
Weighted average expected term (years)	5.90	5.89
Weighted average risk-free rate	2.68%	1.97 %

12. Income Taxes

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. The fact that the Company has historically generated pretax losses in the U.S. serves 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. Therefore, the Company had a full tax valuation allowance against all deferred tax assets in the U.S. as of September 30, 2018 and December 31, 2017. 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 and nine months ended September 30, 2018 and 2017. Taxes have been recorded related to certain U.S. state jurisdictions and non-U.S. income for the three and nine months ended September 30, 2018 and 2017.

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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 and nine months ended September 30, 2018.

The Tax Cuts and Jobs Act (TCJA) was enacted in December 2017. The TCJA reduces the U.S. federal corporate tax rate from 35% to 21%, requires companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously deferred and creates new taxes on certain foreign sourced earnings. As of September 30, 2018, the Company has not completed its accounting for the tax effects of the TCJA. Certain U.S. federal deferred tax assets and liabilities were remeasured as of December 31, 2017 based on the rates at which they are expected to reverse in the future, which is generally 21%. However, the Company is still analyzing certain aspects of the U.S. international and executive compensation provisions of the TCJA and refining its calculations, which could potentially affect the measurement of these balances or potentially give rise to new deferred tax amounts. Because the Company has recorded a valuation allowance against deferred tax assets in the U.S., future adjustments recorded as it completes its analysis will not have a material impact to its net deferred tax asset or liability.

13. Earnings per Share

Basic earnings per share (EPS) is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding. Diluted EPS is computed by dividing the net 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 and nine months ended September 30, 2018 and 2017:

(in thousands, except for share and per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Numerator:				
Net income (loss)	$7,171	$ (4,550)	$14,848	$ (13,729)
Denominator:				
Weighted average shares outstanding, basic	52,389,044	42,885,287	50,321,644	41,669,201
Effect of dilutive securities	2,320,737	—	1,994,002	—
Weighted average shares outstanding, diluted	54,709,781	42,885,287	52,315,644	41,669,201
Net income (loss) per share, basic and diluted:				
Basic	$0.14	$ (0.10)	$0.30	$ (0.31)
Diluted	$0.13	$ (0.10)	$0.28	$ (0.31)
Antidilutive securities excluded from calculations of diluted net income (loss) per share	752,194	3,110,823	1,058,058	3,227,011

The Company incurred a net loss for the three and nine months ended September 30, 2017 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.

14. 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 FDA an Abbreviated

New Drug Application

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(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, 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 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. Lupin filed counter claims for declaratory judgment of invalidity and noninfringement of seven of the Company’s method of treatment patents that are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) related to Fanapt® (such seven patents, the Method of Treatment Patents). The Company has not sued Lupin for infringing the Method of Treatment Patents. In October 2016, the Company and Lupin filed a Stipulation of Dismissal in the Delaware District Court pursuant to which Lupin’s counterclaims relating to the Method of Treatment Patents were dismissed without prejudice in recognition of an agreement reached between the parties by which the Company would not assert those patents against Lupin absent certain changes in Lupin’s proposed prescribing information for its iloperidone tablets.

Taro and Apotex each entered into separate License Agreements (together, the License Agreements) resolving these lawsuits in October 2016 and December 2016, respectively. The License Agreements grant Taro and Apotex non-exclusive licenses to manufacture and commercialize a version of Fanapt® in the U.S. effective November 2027, unless prior to that date the Company obtains pediatric exclusivity for Fanapt®, in which case, the license will be effective May 2028. Taro and Apotex each may enter the market earlier under certain limited circumstances. The License Agreements, which are subject to review by the U.S. Federal Trade Commission (FTC) and the U.S. Department of Justice (DOJ), provide for a full settlement and release of all claims that are the subject of the respective litigation with Taro and Apotex.

In February 2016, Roxane filed suit against the Company in the U.S. District Court for the Southern District of Ohio (Ohio District Court). The suit sought a declaratory judgment of invalidity and noninfringement of the Method of

Treatment Patents. In December 2016, the Ohio District Court dismissed Roxane's suit without prejudice for lack of personal jurisdiction.

In February 2016, Roxane filed a Petition for Inter Partes Review (IPR) of the '432 Patent with the Patent Trials and Appeals Board (PTAB) of the U.S. Patent and Trademark Office. In August 2016, the PTAB denied the request by Roxane to institute an IPR of the '432 Patent. In September 2016, Roxane filed a Petition for Rehearing with the PTAB. In November 2016, the PTAB denied Roxane's Petition for Rehearing.

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-Hour-Sleep-Wake Disorder. In its notice

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letter, Teva alleges that the Company's Orange Book listed 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), 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 October 2018, the Company received an additional Paragraph IV certification notice letter from Teva concerning the '977 Patent, which expires in 2035. The composition and use of HETLIOZ® are currently protected by eight patents that are listed in the FDA's Orange Book.

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. 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 application for New Chemical Entity Status or entry of a district court decision finding the Vanda Patents invalid, unenforceable or not infringed. In June 2018, Teva and MSN each answered the Company's complaint, and counterclaimed for declarations that the Vanda Patents are invalid. In July 2018, the Company answered Teva and MSN's counterclaims, denying their allegations. A trial date for these lawsuits has been set for June 2020.

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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 (the FDA) in January 2014 and launched commercially in the U.S. in April 2014. In July 2015, the European Commission (the 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.
- 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 of 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. An assessment of new Fanapt® clinical opportunities 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 and the treatment of gastroparesis.
- 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. 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

- Enrollment in the clinical study of tradipitant in gastroparesis is complete. Results are expected by the end of 2018.
- The Phase III study (EPIONE) of tradipitant in atopic dermatitis is ongoing.

HETLIOZ®

- Enrollment in the clinical study of HETLIOZ® in SMS is complete. Results are expected by the end of 2018.
- Vanda submitted a supplemental New Drug Application (sNDA) to the FDA for HETLIOZ® in jet lag disorder and expects a filing date by the end of 2018.
- In September, a HETLIOZ® driving studying demonstrated no impairment of next day driving performance.

Fanapt®

- A pharmacokinetic study of the long acting injectable (Depot) formulation of Fanapt® enrolled its first patient during October 2018.

VTR-297

- The Phase I study (1101) of VTR-297 in patients with hematologic malignancies randomized its first patient in October 2018.

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

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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, 2017.

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

Critical Accounting Policies

The preparation of our condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements, as well as the reported revenues and expenses during the reported periods. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

With the exception of the revenue recognition as a result of adoption of the new revenue recognition standard on January 1, 2018, 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, 2017. 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, 2017. 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.

Inventory. Inventory, which is recorded at the lower of cost or net realizable value, includes the cost of third-party manufacturing and other direct and indirect costs and is valued using the first-in, first-out method. We capitalize inventory costs associated with our products upon regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed as research and development. Inventory not expected to be sold within 12 months following the balance sheet date are classified as non-current.

Net Product Sales. Our net product sales consist of sales of HETLIOZ® and sales of Fanapt®. In accordance with Accounting Standards Codification (ASC) Subtopic 606 Revenue from Contracts with Customers (ASC 606), 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

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sheet date is classified other non-current liabilities on the condensed consolidated balance sheets. Uncertainties related to variable consideration are generally resolved in the quarter subsequent to period end, with the exception of product returns which are resolved during the product expiry period specified in the customer contract. We currently record sales allowances for the following:

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

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

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

Medicare Part D Coverage Gap: Medicare Part D prescription drug benefit mandates manufacturers to fund approximately 50% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients. Vanda accounts 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 September 30, 2018 or December 31, 2017.

The following table summarizes sales discounts and allowance activity for the nine months ended September 30, 2018:

(in thousands)	Rebates & Chargebacks	Discounts, Returns and Other	Total
Balances at December 31, 2017	$ 20,229	$ 7,357	$27,586
Provision related to current period sales	43,712	17,096	60,808
Adjustments for prior period sales	669	358	1,027
Credits/payments made	(43,969)	(17,168)	(61,137)
Balances at September 30, 2018	$ 20,641	$ 7,643	$28,284

The provision of $43.7 million for rebates and chargebacks for the nine months ended September 30, 2018 primarily represents Medicaid rebates applicable to sales of Fanapt® and HETLIOZ®. The provision of $17.1 million for

discounts, returns and other for the nine months ended September 30, 2018 primarily represents wholesaler distribution fees applicable to sales of Fanapt® and, to a lesser extent, estimated product returns of Fanapt®, as well as co-pay assistance costs and prompt pay discounts applicable to the sales of both HETLIOZ® and 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.

Selling, general and administrative expenses. Selling, general and administrative expenses consist primarily of salaries, other related costs for personnel, including stock-based compensation, related to executive, finance, accounting, information technology, marketing, medical affairs and human resource functions. Other costs include facility costs not otherwise included in research and development expenses and fees for marketing, medical affairs, legal, accounting and other professional services. Selling, general and administrative expenses also include third party expenses incurred to support sales, business development, and other business activities. Additionally, selling, general and administrative expenses included our estimate for the annual Patient Protection and Affordable Care fee.

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. On a periodic basis, we evaluate the realizability of our deferred tax assets and liabilities and will adjust such amounts in light of changing facts and circumstances, including but not limited to future projections of taxable income, the reversal of deferred tax liabilities, tax legislation, rulings by relevant tax authorities and tax planning strategies. Settlement of filing positions that may be challenged by tax authorities could impact our income taxes in the year of resolution.

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In assessing the realizability of deferred tax assets, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period in which those temporary differences becomes deductible or the net operating losses (NOLs) and credit carryforwards can be utilized. When considering the reversal of the valuation allowance, we consider the level of past and future taxable income, the reversal of deferred tax liabilities, the utilization of the carryforwards and other factors. Revisions to the estimated net realizable value of the deferred tax asset could cause our provision for income taxes to vary significantly from period to period.

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 $346.6 million as of September 30, 2018.

Three months ended September 30, 2018 compared to three months ended September 30, 2017

Revenues. Total revenues increased by $7.8 million, or 19%, to $49.1 million for the three months ended September 30, 2018 compared to $41.3 million for the three months ended September 30, 2017. Revenues were as follows:

(in thousands)	Three Months Ended September 30, 2018	September 30, 2017	Net Change	Percent
HETLIOZ® product sales, net	$29,923	$ 22,279	$7,644	34 %
Fanapt® product sales, net	19,212	19,057	155	1 %
	$49,135	$ 41,336	$7,799	19 %

HETLIOZ® product sales, net increased by $7.6 million, or 34%, to $29.9 million for the three months ended September 30, 2018 compared to $22.3 million for the three months ended September 30, 2017. 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 $0.2 million, or 1%, to $19.2 million for the three months ended September 30, 2018 compared to $19.1 million for the three months ended September 30, 2017.

Cost of goods sold. Cost of goods sold increased by $0.5 million, or 12%, to $5.1 million for the three months ended September 30, 2018 compared to $4.5 million for the three months ended September 30, 2017. 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 are 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 4% of our net U.S. Fanapt® product sales.

Research and development expenses. Research and development expenses increased by $1.2 million, or 12%, to $11.4 million for the three months ended September 30, 2018 compared to $10.2 million for the three months ended September 30, 2017. The increase was primarily due to an increase in clinical trial expenses associated with the tradipitant gastroparesis and atopic dermatitis programs and preclinical expenses associated with the CFTR programs, partially offset by a $2.0 million expense accrued during the three months ended September 30, 2017 for a milestone obligation to Eli Lilly (Lilly) for tradipitant. As a result of enrolling the first subject into a Phase III study for tradipitant in July 2018, we paid this $2.0 million milestone

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obligation to Lilly during the three months ended September 30, 2018. The following table summarizes the costs of our product development initiatives for the three months ended September 30, 2018 and 2017:

(in thousands)	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017
Direct project costs (1)		
HETLIOZ®	$2,964	$ 3,171
Fanapt®	462	610
Tradipitant	5,113	4,845
VTR-297	390	389
CFTR	1,465	194
Other	174	141
	10,568	9,350
Indirect project costs (1)		
Stock-based compensation	326	264
Other indirect overhead	496	564
	822	828
Total research and development expense	$11,390	$ 10,178

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

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

Selling, general and administrative expenses. Selling, general and administrative expenses decreased by $5.1 million, or 16%, to $26.0 million for the three months ended September 30, 2018 compared to $31.1 million for the three months ended September 30, 2017. The decrease was primarily the result of lower spend on marketing efforts relating to HETLIOZ® and Fanapt® in the U.S. and sales force employee turnover.

Intangible asset amortization. Intangible asset amortization was $0.4 million for each of the three months ended September 30, 2018 and 2017.

Other income. Other income was $1.0 million for the three months ended September 30, 2018 compared to $0.4 million for the three months ended September 30, 2017. 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.

Provision for income taxes. As a result of the tax valuation allowance against deferred tax assets in the U.S., there was no expense (benefit) for income taxes associated with the income (loss) before income taxes for three months ended September 30, 2018 and 2017. Taxes have been recorded related to certain U.S. state jurisdictions and non-U.S. income for the three months ended September 30, 2018 and 2017.

Nine months ended September 30, 2018 compared to nine months ended September 30, 2017

Revenues. Total revenues increased by $19.3 million, or 16%, to $140.1 million for the nine months ended September 30, 2018 compared to $120.8 million for the nine months ended September 30, 2017. Revenues were as follows:

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(in thousands)	Nine Months Ended September 30, 2018	September 30, 2017	Net Change	Percent
HETLIOZ® product sales, net	$83,391	$ 64,968	$18,423	28 %
Fanapt® product sales, net	56,686	55,839	847	2 %
	$140,077	$ 120,807	$19,270	16 %

HETLIOZ® product sales, net increased by $18.4 million, or 28%, to $83.4 million for the nine months ended September 30, 2018 compared to $65.0 million for the nine months ended September 30, 2017. 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 $0.8 million, or 2%, to $56.7 million for the nine months ended September 30, 2018 compared to $55.8 million for the nine months ended September 30, 2017.

Cost of goods sold. Cost of goods sold increased by $1.8 million, or 14%, to $14.8 million for the nine months ended September 30, 2018 compared to $13.1 million for the nine months ended September 30, 2017. 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 are 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 4% of our net U.S. Fanapt® product sales.

Research and development expenses. Research and development expenses increased by $2.3 million, or 8%, to $30.7 million for the nine months ended September 30, 2018 compared to $28.4 million for the nine months ended September 30, 2017. The increase was primarily due to an increase in clinical trial expenses associated with the tradipitant gastroparesis program and preclinical expenses associated with the CFTR programs, partially offset by a decrease in expenses associated with the HETLIOZ® jet lag disorder program and a $2.0 million expense accrued during the nine months ended September 30, 2017 for a milestone obligation payable to Lilly for tradipitant. As a result of enrolling the first subject into a Phase III study for tradipitant in July 2018, we paid this $2.0 million milestone obligation to Lilly during the three months ended September 30, 2018. The following table summarizes the costs of our product development initiatives for the nine months ended September 30, 2018 and 2017:

(in thousands)	Nine Months Ended September 30, 2018	September 30, 2017
Direct project costs (1)		
HETLIOZ®	$9,009	$ 10,863
Fanapt®	2,018	1,599
Tradipitant	11,762	9,642
VTR-297	1,682	1,692
CFTR	2,764	1,521
Other	527	288
	27,762	25,605
Indirect project costs (1)		
Stock-based compensation	963	958
Other indirect overhead	1,947	1,830
	2,910	2,788
Total research and development expense	$30,672	$ 28,393

(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

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

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

Selling, general and administrative expenses. Selling, general and administrative expenses decreased by $12.0 million, or 13%, to $80.8 million for the nine months ended September 30, 2018 compared to $92.8 million for the nine months ended September 30, 2017. The decrease was primarily the result of lower spend on marketing efforts relating to HETLIOZ® and Fanapt® in the U.S.

Intangible asset amortization. Intangible asset amortization was $1.1 million for the nine months ended September 30, 2018 compared to $1.3 million for the nine months ended September 30, 2017.

Other income. Other income was $2.4 million for the nine months ended September 30, 2018 compared to $1.1 million for the nine months ended September 30, 2017. 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.

Provision for income taxes. As a result of the tax valuation allowance against deferred tax assets in the U.S., there was no expense (benefit) for income taxes associated with the income (loss) before income taxes for the nine months ended September 30, 2018 and 2017. Taxes have been recorded related to certain U.S. state jurisdictions and non-U.S. income for the nine months ended September 30, 2018 and 2017.

Liquidity and Capital Resources

As of September 30, 2018, our total cash and cash equivalents and marketable securities (Cash) were $240.6 million compared to $143.4 million at December 31, 2017. The increase in Cash of $97.2 million includes $100.9 million net cash proceeds from the public offering of our common stock completed in March 2018, after deducting the underwriting discounts and commissions and offering expenses. Our cash and cash equivalents are deposits in operating accounts and highly liquid investments with an original maturity of 90 days or less at date of purchase and consist of investments in money market funds with commercial banks and financial institutions, government agencies and commercial paper of high-quality corporate issuers. Our marketable securities consist of investments in government sponsored and corporate enterprises, commercial paper and asset-backed securities.

Our liquidity resources as of September 30, 2018 and December 31, 2017 are summarized as follows:

(in thousands)	September 30, 2018	December 31, 2017
Cash and cash equivalents	$ 60,778	$ 33,627
Marketable securities:		
U.S. Treasury and government agencies	67,412	60,618
Corporate debt	91,252	49,168
Asset-backed securities	21,137	—
Total marketable securities	179,801	109,786
Total cash, cash equivalents and marketable securities	$ 240,579	$ 143,413

As of September 30, 2018, 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 2018 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 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,

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primarily including our ability to generate revenue, the scope and costs of our commercial, manufacturing and process development activities, the magnitude of our discovery, preclinical and clinical development programs, and potential costs to acquire or license the rights to additional products.

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

Cash Flow

The following table summarizes our net cash flows from operating, investing and financing activities for the nine months ended September 30, 2018 and 2017:

(in thousands)	Nine Months Ended September 30, 2018	September 30, 2017	Net Change
Net cash provided by (used in):			
Operating activities:			
Net income (loss)	$14,848	$(13,729)	$28,577
Non-cash charges	9,715	10,021	(306)
Net change in operating assets and liabilities	(9,840)	(1,741)	(8,099)
Operating activities	14,723	(5,449)	20,172
Investing activities:			
Acquisition of intangible asset	(25,000)	—	(25,000)
Purchases of property and equipment	(346)	(1,473)	1,127
Net purchases of marketable securities	(68,510)	(16,119)	(52,391)
Investing activities	(93,856)	(17,592)	(76,264)
Financing activities:			
Net proceeds from offering of common stock	100,870	—	100,870
Proceeds from the exercise of stock options	5,464	5,170	294
Financing activities	106,334	5,170	101,164
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(14)	34	(48)
Net change in cash, cash equivalents and restricted cash	$27,187	$(17,837)	$45,024

The increase of $20.2 million in net cash provided by operating activities reflects an increase of $28.6 million in net income, partially offset by a decrease of $8.1 million from the net change in operating assets and liabilities. The decrease of $8.1 million from the net change in operating assets and liabilities primarily relates to an increase in accounts receivable attributable to the timing of shipments and payments and a decrease in accounts payable and other liabilities attributable to the timing of activities and payments and the payment of a $2.0 million milestone obligation during the nine months ended September 30, 2018.

Off-Balance Sheet Arrangements

We currently do not have any, and during the periods presented, did not have any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission.

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Contractual Obligations and Commitments

The following is a summary of our noncancellable long-term contractual cash obligations as of September 30, 2018:

	Cash Payments Due by Year (1)(2)						
(in thousands)	Total	2018	2019	2020	2021	2022	Thereafter
Operating leases (3)	$23,372	$599	$2,491	$2,501	$2,337	$2,355	$ 13,089
Purchase commitments (4)	8,372	197	5,982	847	890	456	—
	$31,744	$796	$8,473	$3,348	$3,227	$2,811	$ 13,089

(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.

(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 $46.0 million upon the achievement of regulatory and sales milestones.

(3) This table includes minimum annual future payments under operating leases and subleases for a total of 43,462 square feet of office space for our headquarters office at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. that generally expire in 2028, an operating lease for 2,880 square feet of office space for our European headquarters in London that has a noncancellable lease term ending in 2021, and 1,249 square feet of office space in Berlin under a short-term operating lease.

(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.

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 90% of total revenues for the nine months ended September 30, 2018. There were five major customers that each accounted for more than 10% of accounts receivable and, as a group, represented 95% of total accounts receivable at September 30, 2018. We mitigate our credit risk relating to accounts receivable from customers by performing ongoing credit evaluations.

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Foreign currency risk

We are exposed to risks related to changes in foreign currency exchange rates relating to our foreign operations. The functional currency of our international subsidiaries is the local currency. We are exposed to foreign currency risk to the extent that we enter into transactions denominated in currencies other than our subsidiaries' respective functional currencies. We are also exposed to unfavorable fluctuations of the U.S. dollar, which is our reporting currency, against the currencies of our operating subsidiaries when their respective financial statements are translated into U.S. dollars for inclusion in our condensed consolidated financial statements. We do not currently hedge our foreign currency exchange rate risk. Foreign currency has not had a material impact on our results of operations.

Effects of inflation

Inflation has not had a material impact on our results of operations.

ITEM 4 Controls and Procedures

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (Exchange Act)) as of September 30, 2018. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of September 30, 2018, the end of the period covered by this quarterly report, to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the third quarter of 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

ITEM 1 Legal Proceedings

Fanapt®. In 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

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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 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. 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.

Lupin filed counter claims for declaratory judgment of invalidity and noninfringement of seven of our method of treatment patents that are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) related to Fanapt® (such seven patents, the Method of Treatment Patents). We have not sued Lupin for infringing the Method of Treatment Patents. In October 2016, we, along with Lupin, filed a Stipulation of Dismissal in the Delaware District Court pursuant to which Lupin's counterclaims relating to the Method of Treatment Patents were dismissed without prejudice in recognition of an agreement reached between the parties by which we would not assert those patents against Lupin absent certain changes in Lupin's proposed prescribing information for its iloperidone tablets.

Taro and Apotex each entered into separate License Agreements (together, the License Agreements) resolving these lawsuits in October 2016 and December 2016, respectively. The License Agreements grant Taro and Apotex non-exclusive licenses to manufacture and commercialize a version of Fanapt® in the U.S. effective November 2027, unless prior to that date we obtain pediatric exclusivity for Fanapt®, in which case, the license will be effective May 2028. Taro and Apotex each may enter the market earlier under certain limited circumstances. The License Agreements, which are subject to review by the U.S. Federal Trade Commission (FTC) and the U.S. Department of Justice (DOJ), provide for a full settlement and release of all claims that are the subject of the respective litigation with Taro and Apotex.

In February 2016, Roxane filed suit against us in the U.S. District Court for the Southern District of Ohio (Ohio District Court). The suit sought a declaratory judgment of invalidity and noninfringement of the Method of Treatment Patents. In December 2016, the Ohio District Court dismissed Roxane's suit without prejudice for lack of personal jurisdiction.

In February 2016, Roxane filed a Petition for Inter Partes Review (IPR) of the '432 Patent with the Patent Trials and Appeals Board (PTAB) of the U.S. Patent and Trademark Office. In August 2016, the PTAB denied the request by Roxane to institute an IPR of the '432 Patent. In September 2016, Roxane filed a Petition for Rehearing with the PTAB. In November 2016, the PTAB denied Roxane's Petition for Rehearing.

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-Hour-Sleep-Wake Disorder. In its notice letter, Teva alleges that our Orange Book listed 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), 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 October 2018, we received an additional Paragraph IV certification notice letter from Teva concerning our Orange Book listed U.S. Patent No. 10,071,977, which expires in 2035 (the '977 Patent). The composition and use of HETLIOZ® are currently protected by eight patents that are listed in the FDA's Orange Book.

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. 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

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application for New Chemical Entity Status or entry of a district court decision finding the Vanda Patents invalid, unenforceable or not infringed. In June 2018, Teva and MSN each answered our complaint, and counterclaimed for declarations that the Vanda Patents are invalid. In July 2018, we answered Teva and MSN's counterclaims, denying their allegations. A trial date for these lawsuits has been set for June 2020.

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, 2017, filed with the Securities and Exchange Commission on February 15, 2018, important factors which could affect our business, financial condition, results of operations and future operations under the heading Risk Factors. Our business, financial condition and operating results can be affected by a number of factors, whether current known or unknown, including but not limited to those described as risk factors, any one or more of which could, directly or indirectly, cause our actual operating results and financial condition to vary materially from past, or anticipated future, operating results and financial condition. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, operating results and the price of our common stock. There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2017.

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).
10.41	Employment Agreement, dated August 13, 2018, by and between Timothy Williams and the registrant.
31.1	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer), as required by Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from this quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2018 formatted in XBRL (eXtensible Business Reporting Language) and filed electronically herewith: (i) Condensed Consolidated Balance Sheets as of September 30, 2018 and December 31, 2017; (ii) Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2018 and 2017; (iii) Condensed Consolidated Statement of Comprehensive Loss for the three and nine months ended September 30, 2018 and 2017; (iv) Condensed Consolidated Statement of Changes in Stockholders' Equity for the nine months ended September 30, 2018; (v) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2018 and 2017; 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.

November 7, 2018

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

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

November 7, 2018

/s/ James P. Kelly

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