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

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2016

or

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

For the transition period from _____ to _____

Commission File Number: 001-34186

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

Delaware	**03-0491827**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2200 Pennsylvania Avenue, N.W., Suite 300 E Washington, 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 ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐

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

As of July 21, 2016, there were 43,284,259 shares of the registrant’s common stock issued and outstanding.

Vanda Pharmaceuticals Inc.

Quarterly Report on Form 10-Q
For the Quarter Ended June 30, 2016

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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," and "could," or the negative of these terms and similar expressions or words, identify forward-looking statements. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Important factors that could cause actual results to differ materially from those reflected in our forward-looking statements include, among others:

- the ability of Vanda Pharmaceuticals Inc. (we, our or Vanda) to successfully commercialize HETLIOZ® (tasimelteon) for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in the U.S. and Europe;
- uncertainty as to the market awareness of Non-24 and the market acceptance of HETLIOZ®;
- our ability to generate U.S. sales of Fanapt® (iloperidone) for the treatment of schizophrenia;
- the timing and costs of our establishment of a sales and marketing, supply chain, distribution, pharmacovigilance, compliance and safety infrastructure to promote Fanapt® in the U.S.;
- our dependence on third-party manufacturers to manufacture HETLIOZ® and Fanapt® in sufficient quantities and quality;
- our limited sales and marketing infrastructure;
- the regulatory status of Fanapt® in Europe;
- our ability to successfully commercialize HETLIOZ® and Fanapt® outside of the U.S.;
- our ability to prepare, file, prosecute, defend and enforce any patent claims and other intellectual property rights;
- our ability to obtain the capital necessary to fund our research and development or commercial activities;
- 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 conducted by us and our development partners;
- 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 and liabilities;
- the timing and costs of complying with the remaining post-marketing commitments and post-marketing requirements established in connection with the U.S. Food and Drug Administration approval of Fanapt®;
- 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 of all of our prior net operating losses and orphan drug and research and development credits;
- the cost and effects of litigation;
- 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, 2015, other unknown or unpredictable factors also could affect our results. Therefore, the information in this quarterly report should be read together with other reports and documents that we file with the Securities and Exchange Commission from time to time, including on Form 10-Q and Form 8-K, which may supplement, modify, supersede or update those risk factors. As a result of these factors, we cannot assure you that the forward-looking statements in this report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all.

Part I — FINANCIAL INFORMATION

ITEM 1 Financial Statements (Unaudited)

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

(in thousands, except for share and per share amounts)	June 30, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 23,194	$ 50,843
Marketable securities	112,795	92,337
Accounts receivable, net	14,030	16,331
Inventory	927	1,294
Prepaid expenses and other current assets	9,430	5,742
Total current assets	160,376	166,547
Property and equipment, net	4,246	4,570
Intangible assets, net	32,867	38,752
Non-current inventory and other	4,549	3,181
Total assets	$ 202,038	$ 213,050
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 17,933	$ 15,767
Accrued government and other rebates	33,828	35,550
Total current liabilities	51,761	51,317
Milestone obligation under license agreement	25,000	25,000
Other non-current liabilities	3,663	3,706
Total liabilities	80,424	80,023
Commitments and contingencies (Notes 10 and 11)		
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; 43,282,197 and 42,815,291 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively	43	43
Additional paid-in capital	466,272	460,794
Accumulated other comprehensive income	124	39
Accumulated deficit	(344,825)	(327,849)
Total stockholders' equity	121,614	133,027
Total liabilities and stockholders' equity	$ 202,038	$ 213,050

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

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

(in thousands, except for share and per share amounts)	Three Months Ended		Six Months Ended	
	June 30, 2016	June 30, 2015	June 30, 2016	June 30, 2015
Revenues:				
Net product sales	$ 36,029	$ 27,582	$ 69,291	$ 49,732
Total revenues	36,029	27,582	69,291	49,732
Operating expenses:				
Cost of goods sold	6,494	5,766	12,450	10,781
Research and development	6,700	5,946	14,248	10,424
Selling, general and administrative	24,682	18,386	53,972	37,192
Intangible asset amortization	2,942	2,942	5,885	7,086
Total operating expenses	40,818	33,040	86,555	65,483
Loss from operations	(4,789)	(5,458)	(17,264)	(15,751)
Other income	171	72	288	144
Net loss	$ (4,618)	$ (5,386)	$ (16,976)	$ (15,607)
Basic and diluted net loss per share	$ (0.11)	$ (0.13)	$ (0.39)	$ (0.37)
Weighted average shares outstanding, basic and diluted	43,202,751	41,991,578	43,153,598	41,868,944

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

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

(in thousands)	Three Months Ended		Six Months Ended	
	June 30, 2016	June 30, 2015	June 30, 2016	June 30, 2015
Net loss	$(4,618)	$(5,386)	$(16,976)	$(15,607)
Other comprehensive income:				
Change in net unrealized gain on marketable securities	32	—	85	11
Tax provision on other comprehensive income	—	—	—	—
Other comprehensive income, net of tax	32	—	85	11
Comprehensive loss	$(4,586)	$(5,386)	$(16,891)	$(15,596)

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

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

(in thousands, except for share amounts)	Common Stock Shares	Common Stock Par Value	Additional Paid-in Capital	Other Comprehensive Income	Accumulated Deficit	Total
Balances at December 31, 2015	42,815,291	$ 43	$460,794	$ 39	$ (327,849)	$133,027
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	466,906	—	1,138	—	—	1,138
Stock-based compensation expense	—	—	4,340	—	—	4,340
Net loss	—	—	—	—	(16,976)	(16,976)
Other comprehensive income, net of tax	—	—	—	85	—	85
Balances at June 30, 2016	43,282,197	$ 43	$466,272	$ 124	$ (344,825)	$121,614

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

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

(in thousands)	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015
Cash flows from operating activities		
Net loss	$ (16,976)	$(15,607)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation of property and equipment	435	263
Stock-based compensation	4,340	4,013
Amortization of discounts and premiums on marketable securities	43	426
Intangible asset amortization	5,885	7,086
Other non-cash adjustments	—	314
Changes in operating assets and liabilities:		
Accounts receivable	2,301	(12,164)
Prepaid expenses and other assets	(4,580)	(3,872)
Inventory	(109)	208
Accounts payable and accrued liabilities	2,222	8,746
Accrued government and other rebates	(1,722)	28,243
Net cash provided by (used in) operating activities	(8,161)	17,656
Cash flows from investing activities		
Purchases of property and equipment	(111)	(939)
Purchases of marketable securities	(103,993)	(81,348)
Proceeds from sales of marketable securities	—	999
Maturities of marketable securities	83,577	50,555
Net cash used in investing activities	(20,527)	(30,733)
Cash flows from financing activities		
Obligations paid in connection with settlement of equity awards	—	(282)
Proceeds from exercise of employee stock options	1,039	795
Net cash provided by financing activities	1,039	513
Net decrease in cash and cash equivalents	(27,649)	(12,564)
Cash and cash equivalents		
Beginning of period	50,843	60,901
End of period	$ 23,194	$ 48,337

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

VANDA PHARMACEUTICALS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

1. Business Organization and Presentation

Business Organization

Vanda Pharmaceuticals Inc. (the Company) is a specialty pharmaceutical company focused on the development and commercialization of novel 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), which 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. This authorization is valid in the 28 countries that are members of the European Union, as well as European Economic Area members Iceland, Liechtenstein and Norway. 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 and Smith-Magenis Syndrome (SMS).
- Fanapt® (iloperidone), a product for the treatment of schizophrenia, the oral formulation of which was being marketed and sold in the U.S. by Novartis Pharma AG (Novartis) until December 31, 2014. 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 and Mexico in 2014.
- 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 gastroparesis.
- Trichostatin A, a small molecule histone deacetylase (HDAC) inhibitor.
- AQW051, 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, 2015 included in the Company's annual report on Form 10-K. The financial information as of June 30, 2016 and for the three and six months ended June 30, 2016 and 2015 is unaudited, but in the opinion of management, all adjustments, consisting only of normal recurring accruals, 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, 2015 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, 2015.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates that affect the reported amounts of assets and liabilities at the date of the financial statements, disclosure of contingent assets and liabilities, and the reported amounts of revenue and expenses during the reporting period. The Company has estimated its annual fees for Fanapt® under the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010. Management continually re-evaluates its estimates, judgments and assumptions, and management's evaluation could change. Actual results could differ from those estimates.

Inventory

Inventory, which is recorded at the lower of cost or market, includes the cost of third-party manufacturing and other direct and indirect costs and is valued using the first-in, first-out method. The Company capitalizes inventory costs associated with its 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 is evaluated for impairment by consideration of factors such as lower of cost or market, net realizable value, obsolescence or expiry. Inventory not expected to be consumed within 12 months following the balance sheet date are classified as non-current.

Revenue from Net Product Sales

The Company's revenues consist of net product sales of HETLIOZ® and net product sales of Fanapt®. Net sales by product for the three and six months ended June 30, 2016 and 2015 were as follows:

	Three Months Ended		Six Months Ended	
(in thousands)	June 30, 2016	June 30, 2015	June 30, 2016	June 30, 2015
Revenues:				
HETLIOZ® product sales, net	$17,460	$10,017	$33,661	$17,477
Fanapt® product sales, net	18,569	17,565	35,630	32,255
Total revenues	$36,029	$27,582	$69,291	$49,732

The Company applies the revenue recognition guidance in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Subtopic 605-15, *Revenue Recognition—Products*. The Company recognizes revenue from product sales when there is persuasive evidence that an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collectability is reasonably assured and the Company has no further performance obligations.

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. There were five major customers that each accounted for more than 10% of total revenues and, as a group, represented 86% of total revenues for the six months ended June 30, 2016. There were four major customers that each accounted for more than 10% of accounts receivable and, as a group, represented 76% of total accounts receivable at June 30, 2016.

Product Sales Discounts and Allowances

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. Reserves established for discounts and returns are classified as reductions of accounts receivable if the amount is payable to direct customers, with the exception of service fees. Service fees are classified as a liability. Reserves established for rebates, chargebacks or co-pay assistance are classified as a liability if the amount is payable to a party other than customers. 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 sector benefit providers, such as Medicaid. The allowance for rebates is based on statutory or contracted discount rates and expected utilization. Estimates for the expected utilization of rebates are based on historical activity and, where available, actual and pending prescriptions for which the Company has validated the insurance benefits. Rebates are generally invoiced and paid in arrears, such that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarter's unpaid rebates. If actual future invoicing varies from estimates, the Company may need to adjust accruals, which would affect net revenue in the period of adjustment.

Chargebacks: Chargebacks are discounts that occur when contracted customers purchase directly from specialty pharmacies and wholesalers. Contracted 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. The allowance for chargebacks is based on historical activity and, where available, actual and pending prescriptions for which the Company has validated the insurance benefits.

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. 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. Funding of the coverage gap is generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarter activity. If actual future funding varies from estimates, the Company may need to adjust accruals, which would affect net revenue in the period of adjustment.

Service Fees: The Company also incurs specialty pharmacy and wholesaler fees for services and their data. 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 receives an identifiable and separate benefit for the consideration and it can reasonably estimate the fair value of the benefit received. In which case, service fees 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. The allowance for co-pay assistance is based on actual sales and an estimate for pending sales based on either historical activity or pending sales for which the Company has validated the insurance benefits.

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, inventory levels within the distribution channel, product shelf life, prescription trends and other relevant factors.

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. The Company recognizes the expense over the award's vesting period. The fair value of stock options granted and restricted stock units (RSUs) awarded are amortized using the straight-line method. As stock-based compensation expense recognized in the consolidated statements of operations is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. Forfeitures are required to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates

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 employee and director stock options granted during the six months ended June 30, 2016 and 2015 were as follows:

	Six Months Ended	
	June 30, 2016	June 30, 2015
Expected dividend yield	0%	0%
Weighted average expected volatility	57%	61%
Weighted average expected term (years)	6.08	5.99
Weighted average risk-free rate	1.37%	1.61%
Weighted average fair value per share	$ 4.44	$ 6.15

Stock-based compensation expense recognized for the three and six months ended June 30, 2016 and 2015 was comprised of the following:

	Three Months Ended		Six Months Ended	
(in thousands)	June 30, 2016	June 30, 2015	June 30, 2016	June 30, 2015
Research and development	$ 489	$ 603	$1,013	$1,227
Selling, general and administrative	1,585	1,465	3,327	2,786
	$ 2,074	$ 2,068	$4,340	$4,013

Advertising Expense

The Company expenses the costs of advertising, including branded promotional expenses, as incurred. Branded advertising expenses, recorded in selling, general and administrative expenses, were $0.5 million and $0.9 million for the three months ended June 30, 2016 and 2015, respectively, and $1.1 million and $1.9 million for the six months ended June 30, 2016 and 2015, respectively.

Non-Cash Investing and Financing Activities

For the six months ended June 30, 2015, the Company recorded an intangible asset of $25.0 million relating to HETLIOZ® and recorded the related non-current liability relating to its obligation to make a milestone payment to Bristol-Myers Squibb (BMS) of $25.0 million in the event that cumulative worldwide sales of HETLIOZ® reach $250.0 million. For the six months ended June 30, 2015, the Company recorded purchases of property, plant and equipment and the related current liability in the amount of $0.8 million.

Recent accounting pronouncements

In June 2016, the FASB issued Accounting Standards Update (ASU) 2016-13, *Financial Instruments – Credit Losses*, related to the measurement of credit losses on financial instruments. The standard will require the use of an “expected loss” model for instruments measured at amortized cost. The standard is effective for years beginning after December 15, 2019, and interim periods within annual periods beginning after December 15, 2019. The Company is evaluating this standard to determine if adoption will have a material impact on the Company’s consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, to simplify various aspects related to how share-based payments are accounted for and presented in the financial statements. The ASU provides that all of the tax effects related to share-based payments are recorded as part of the provision for income taxes, allows entities to withhold an amount up to the employees’ maximum individual tax rate in the relevant jurisdiction, allows entities to estimate the effect of forfeitures or recognized forfeitures when they occur, and other improvements to the accounting for share-based awards. The new standard is effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early adoption is permitted. 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 2016-02, *Leases*. 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 Company is evaluating this standard to determine if adoption will have a material impact on the Company’s consolidated financial statements.

In July 2015, the FASB issued ASU 2015-11, *Simplifying the Measurement of Inventory*, dealing with changes to the subsequent measurement of inventory. Currently, an entity is required to measure its inventory at the lower of cost or market, whereby market can be replacement cost, net realizable value, or net realizable value less an approximately normal profit margin. The changes require that inventory be measured at the lower of cost and net realizable value, thereby eliminating the use of the other two market methodologies. Net realizable value is defined as the estimated selling prices in the ordinary course of business less reasonably predictable costs of completion, disposal, and transportation. The new standard is effective for periods beginning after December 15, 2016. The Company adopted this new standard in the second quarter of 2016, and adoption did not have a material impact on the Company’s consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements – Going Concern*. The new standard requires management of public and private companies to evaluate whether there is substantial doubt about the entity’s ability to continue as a

going concern and, if so, disclose that fact. Management will also be required to evaluate and disclose whether its plans alleviate that doubt. The new standard is effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Adoption of this new standard is not expected to have a material impact on the Company's consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers*. This new standard 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, or (ii) retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial adoption. 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 2016-08 *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 2014-09. ASU 2016-08, ASU 2016-10, and ASU 2016-12 follow the same implementation guidelines as ASU 2014-09 and ASU 2015-14. The Company is evaluating this standard to determine if adoption will have a material impact on the Company's consolidated financial statements.

3. 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 six months ended June 30, 2016 and 2015:

	Three Months Ended		Six Months Ended	
(in thousands, except for share and per share amounts)	June 30, 2016	June 30, 2015	June 30, 2016	June 30, 2015
Numerator:				
Net loss	$ (4,618)	$ (5,386)	$ (16,976)	$ (15,607)
Denominator:				
Weighted average shares outstanding, basic and diluted	43,202,751	41,991,578	43,153,598	41,868,944
Net loss per share, basic and diluted:	$ (0.11)	$ (0.13)	$ (0.39)	$ (0.37)
Antidilutive securities excluded from calculations of diluted net loss per share	5,804,031	5,765,618	6,024,656	5,711,140

The Company incurred net losses for the three and six months ended June 30, 2016 and 2015 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.

4. Marketable Securities

The following is a summary of the Company's available-for-sale marketable securities as of June 30, 2016, which all have contract maturities of less than one year:

June 30, 2016 *(in thousands)*	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Market Value**
U.S. Treasury and government agencies	$ 55,799	$ 42	$ —	$ 55,841
Corporate debt	56,871	83	—	56,954
	$112,670	$ 125	$ —	$112,795

The following is a summary of the Company's available-for-sale marketable securities as of December 31, 2015:

December 31, 2015 *(in thousands)*	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
U.S. Treasury and government agencies	$ 44,059	$ 6	$ (8)	$44,057
Corporate debt	48,239	46	(5)	48,280
	$ 92,298	$ 52	$ (13)	$92,337

5. Fair Value Measurements

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

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

Marketable securities classified in Level 1 and Level 2 as of June 30, 2016 and December 31, 2015 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 and corporate notes that use as their basis readily observable market parameters. The Company did not transfer any assets between Level 2 and Level 1 during the six months ended June 30, 2016 and 2015.

As of June 30, 2016, the Company held certain assets that are required to be measured at fair value on a recurring basis, as follows:

		Fair Value Measurement as of June 30, 2016 Using		
(in thousands)	June 30, 2016	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available-for-sale securities:				
U.S. Treasury and government agencies	$ 55,841	$ 55,841	$ —	$ —
Corporate debt	56,954	—	56,954	
	$112,795	$ 55,841	$ 56,954	$ —

As of December 31, 2015, the Company held certain assets that are required to be measured at fair value on a recurring basis, as follows:

		Fair Value Measurement as of December 31, 2015 Using		
(in thousands)	December 31, 2015	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available-for-sale securities:				
U.S. Treasury and government agencies	$ 44,057	$ 44,057	$ —	$ —
Corporate debt	48,280	—	48,280	
	$ 92,337	$ 44,057	$ 48,280	$ —

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 value of which materially approximate their fair values.

6. Inventory

The Company evaluates expiry risk by evaluating current and future product demand relative to product shelf life. The Company builds demand forecasts by considering factors such as, but not limited to, overall market potential, market share, market acceptance and patient usage. Inventory levels are evaluated for the amount of inventory that would be sold within one year. At certain times, the level of inventory can exceed the forecasted level of cost of goods sold for the next twelve months. The Company classifies the estimate of such inventory as non-current. Inventory consisted of the following as of June 30, 2016 and December 31, 2015:

(in thousands)	June 30, 2016	December 31, 2015
Current assets		
Finished goods	$ 927	$ 1,294
	$ 927	$ 1,294
Non-Current assets		
Raw materials	$ 127	$ 127
Work-in-process	2,241	2,369
Finished goods	604	—
	$ 2,972	$ 2,496

7. Accounts Payable and Accrued Liabilities

The following is a summary of the Company's accounts payable and accrued liabilities as of June 30, 2016 and December 31, 2015:

(in thousands)	June 30, 2016	December 31, 2015
Research and development expenses	$ 3,101	$ 3,199
Consulting and other professional fees	5,058	5,088
Compensation and employee benefits	2,305	468
Royalties payable	6,012	5,328
Other	1,457	1,684
	$ 17,933	$ 15,767

8. Intangible Assets

The following is a summary of the Company's intangible assets as of June 30, 2016:

		June 30, 2016		
(in thousands)	Estimated Useful Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	January 2033	$33,000	$ 4,321	$28,679
Fanapt®	November 2016	27,941	23,753	4,188
		$60,941	$ 28,074	$32,867

The following is a summary of the Company's intangible assets as of December 31, 2015:

		December 31, 2015		
(in thousands)	Estimated Useful Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	January 2033	$33,000	$ 3,460	$29,540
Fanapt®	November 2016	27,941	18,729	9,212
		$60,941	$ 22,189	$38,752

In January 2014, the Company announced that the FDA had approved the NDA for HETLIOZ®. As a result of this approval, the Company met a milestone under its license agreement with 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 remaining life of the U.S. patent for HETLIOZ®,

which prior to June 2014, the Company expected to last until December 2022. In June 2014, the Company received a notice of allowance from the U.S. Patent and Trademark Office for a patent covering the method of use of HETLIOZ®. The patent expires in January 2033, thereby potentially extending the exclusivity protection in the U.S. beyond the composition of matter patent. As a result of the patent allowance, the Company extended the estimated useful life of the U.S. patent for HETLIOZ® from December 2022 to January 2033. The Company is obligated to make a future milestone payment to BMS of $25.0 million in the event that cumulative worldwide sales of HETLIOZ® reach $250.0 million. The likelihood of achieving the milestone and the related milestone obligation was determined to be probable during 2015. As a result, the future obligation of $25.0 million was recorded as a non-current liability along with a capitalized intangible assets relating to HETLIOZ®. The actual payment of the obligation will occur once the $250.0 million in cumulative worldwide sales of HETLIOZ® is realized. Intangible assets relating HETLIOZ® are being amortized on a straight-line basis over the remaining life of the U.S. patent for HETLIOZ®, which is expected to be January 2033.

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. Pursuant to the terms of a settlement agreement with Novartis, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to the Company on December 31, 2014. As a result, the Company recognized an intangible asset of $15.9 million related to the reacquired rights to Fanapt®. Intangible assets relating to Fanapt® are being amortized on a straight-line basis over the remaining life of the U.S. composition of matter patent for Fanapt® through November 2016. The useful life estimation is based on the market participant methodology prescribed by ASC Subtopic 805, *Business Combinations*, 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 intangible assets are being amortized over their estimated useful economic life using the straight-line method. Amortization expense was $2.9 million and $2.9 million for the three months ended June 30, 2016 and 2015, respectively, and $5.9 million and $7.1 million for the six months ended June 30, 2016 and 2015, respectively. The following is a summary of the future intangible asset amortization schedule as of June 30, 2016:

(in thousands)	Total	Remainder of 2016	2017	2018	2019	2020	Thereafter
HETLIOZ®	$28,679	$ 860	$1,721	$1,721	$1,721	$1,721	$ 20,935
Fanapt®	4,188	4,188	—	—	—	—	—
	$32,867	$ 5,048	$1,721	$1,721	$1,721	$1,721	$ 20,935

9. Income Taxes

Deferred tax assets are reduced by a 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 net operating losses (NOLs) serves as strong evidence that it is more likely than not that deferred tax assets will not be realized in the future. Therefore, the Company has a full valuation allowance against all deferred tax assets as of June 30, 2016 and December 31, 2015. As a result of the tax valuation allowance against deferred tax assets, there was no provision for income taxes for the three and six months ended June 30, 2016 and 2015.

Certain tax attributes of the Company, including NOLs and credits, are subject to limitation as a result of any ownership change as defined under Internal Revenue Code of 1986, as amended (IRC), Section 382. A change in ownership could affect the Company's ability to use NOLs and credit carryforward (tax attributes). Ownership changes did occur as of December 31, 2014 and December 31, 2008. However, the Company believes that it had sufficient Built-In-Gain to offset the IRC Section 382 limitation generated by the ownership changes. Any future ownership changes may cause the Company's existing tax attributes to have additional limitations. Additionally, the Company maintains a valuation allowance on its tax attributes and therefore, any IRC Section 382 limitation would not have a material impact on the Company's provision for income taxes as of June 30, 2016.

10. Commitments and Contingencies

Operating leases

Commitments relating to operating leases represent the minimum annual future payments under operating leases for a total of 40,188 square feet of office space for the Company's headquarters at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. that expire in 2026 and the 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. The following is a summary of the minimum annual future payments under operating leases for office space as of June 30, 2016:

	Cash payments due by year						
(in thousands)	Total	Remainder of 2016	2017	2018	2019	2020	Thereafter
Operating leases	$22,562	$ 917	$1,939	$2,236	$2,291	$2,347	$ 12,832

In 2011, the Company entered into an operating lease for its headquarters at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. A lease amendment in 2014 increased the office space under lease to 30,260 square feet, and a lease amendment in June 2016 extended the lease term from April 2023 to September 2026. 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 will lease 9,928 square feet of office space for its headquarters at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. The sublease term begins 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.

Rent expense under operating leases was $0.5 million and $0.5 million for the three months ended June 30, 2016 and 2015, respectively, and $1.0 million and $0.9 million for the six months ended June 30, 2016 and 2015, 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 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®. In partial consideration for the license, the Company paid BMS an initial license fee of $0.5 million. The Company made a milestone payment to BMS of $1.0 million under the license agreement in 2006 relating to the initiation of its first Phase III clinical trial for HETLIOZ®. As a result of the FDA acceptance of the Company's NDA for HETLIOZ® for the treatment of Non-24 in July 2013, the Company incurred a $3.0 million milestone obligation under the license agreement with BMS. As a result of the FDA's approval of the HETLIOZ® NDA in January 2014, the Company incurred an $8.0 million milestone obligation in the first quarter of 2014 under the same license agreement that was capitalized as an intangible asset and is being amortized over the expected HETLIOZ® patent life in the U.S. The Company is obligated to make a future milestone payment to BMS of $25.0 million in the event that cumulative worldwide sales of HETLIOZ® reach $250.0 million. During the first quarter of 2015, the likelihood of achieving the milestone and the related milestone obligation was determined to be probable. As such, the $25.0 million milestone obligation was capitalized as an intangible asset and is being amortized over the expected HETLIOZ® patent life in the U.S. The actual payment of the $25.0 million will occur once the $250.0 million in cumulative worldwide sales of HETLIOZ® is realized. 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 patent in that territory. During the period prior to the expiry of the new chemical entity 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 new chemical entity patent existed or for the remainder of the 10 years after the expiry of the new chemical entity 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®.

The license agreement was amended in April 2013 to add a process that would allow BMS to waive the right to develop and commercialize HETLIOZ® in those countries not covered by a development and commercialization agreement. Subsequent to the execution of the April 2013 amendment, BMS provided the Company with formal written notice that it irrevocably waived the option to exercise the right to reacquire any or all rights to any product (as defined in the license agreement) containing HETLIOZ®, or to develop or commercialize any such product, in the countries not covered by a development and commercialization agreement.

Either party may terminate the HETLIOZ® license agreement under certain circumstances, including a material breach of the agreement by the other. In the event the Company terminates the license, or if BMS terminates the license due to the Company's breach, all rights licensed and developed by the Company under the license agreement will revert or otherwise be licensed back to BMS on an exclusive basis.

Fanapt®. A predecessor company of Sanofi, Hoechst Marion Roussel, Inc. (HMRI) discovered Fanapt® and completed early clinical work on the product. In 1996, following a review of its product portfolio, HMRI licensed its rights to the Fanapt® patents and patent applications to Titan Pharmaceuticals, Inc. (Titan) on an exclusive basis. In 1997, soon after it had acquired its rights, Titan sublicensed its rights to Fanapt® on an exclusive basis to Novartis. In June 2004, the Company acquired exclusive worldwide rights to these patents and patent applications, as well as certain Novartis patents and patent applications to develop and commercialize Fanapt®, through a sublicense agreement with Novartis. In October 2009, subsequent to the FDA's approval of the NDA for Fanapt®, the Company entered into an amended and restated sublicense agreement with Novartis, which amended and restated the June 2004 sublicense agreement. Pursuant to the amended and restated sublicense agreement, Novartis had exclusive commercialization rights to all formulations of Fanapt® in the U.S. and Canada. Novartis began selling Fanapt® in the U.S. during the first quarter of 2010. Novartis was responsible for the further clinical development activities in the U.S. and Canada. The Company also received royalties equal to 10% of net sales of Fanapt® in the U.S. and Canada. The Company retained exclusive rights to Fanapt® outside the U.S. and Canada and was obligated to make royalty payments to Sanofi S.A. (Sanofi) on Fanapt® sales outside the U.S. and Canada.

Pursuant to the terms of the settlement agreement with Novartis, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to the Company on December 31, 2014. The Company is obligated to make royalty payments to Sanofi and 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 new chemical entity (NCE) patent for Fanapt® in the U.S. on November 15, 2016. Under the amended agreement, the Company will pay 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 six months ended June 30, 2016 that applied to this 3% manufacturing know-how royalty and will make additional royalty payments only to the extent that the Company's cumulative royalty obligations during this period exceed the amount of the pre-payment. No further royalties on manufacturing know-how are payable by the Company after December 31, 2019. This amended agreement does not alter Titan's obligation under the license agreement to make royalty payments to Sanofi prior to November 16, 2016 or the Company's obligations under the sublicense agreement to pay Sanofi a fixed royalty on Fanapt® net sales equal up to 6% on Sanofi know-how not related to manufacturing under certain conditions for a period of up to 10 years in markets where the NCE patent has expired or was not issued.

The Company has entered into distribution agreements with Probiomed S.A. de C.V. for the commercialization of Fanapt® in Mexico and Megapharm Ltd. for the commercialization of Fanapt® in Israel.

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 new chemical entity expires in April 2023, except in the U.S., where it expires in June 2024 absent any applicable patent term adjustments.

Pursuant to the license agreement, the Company paid Lilly an initial license fee of $1.0 million and will be responsible for all development costs. The initial license fee was recognized as research and development expense in the consolidated statement of operations for the year ended December 31, 2012. Lilly is also eligible to receive additional 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 and up to $95.0 million for future regulatory approval and sales milestones. The Company is obligated to use its commercially reasonable efforts to develop and commercialize tradipitant.

Either party may terminate the license agreement under certain circumstances, including a material breach of the license agreement by the other. In the event that the Company terminates the license agreement, or if Lilly terminates due to the Company's breach or for certain other reasons set forth in the license agreement, all rights licensed and developed by the Company under the license agreement will revert or otherwise be licensed back to Lilly on an exclusive basis, subject to payment by Lilly to the Company of a royalty on net sales of products that contain tradipitant.

AQW051. In connection with the settlement agreement with Novartis relating to Fanapt®, the Company received an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize AQW051, 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 AQW051 and is responsible for all development costs under the AQW051 license agreement. 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.

Research and Development and Marketing Agreements

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 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.

11. Legal Matters

In June 2014, the Company filed suit against Roxane Laboratories, Inc. (Roxane) in the U.S. District Court for the District of Delaware (the Delaware District Court). The suit seeks an adjudication that Roxane has infringed one or more claims of the Company's U.S. Patent No. 8,586,610 (the '610 Patent) by submitting to the 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 the 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 (the '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 on March 4, 2016. The parties are awaiting the Delaware District Court's decision.

In 2015, the Company filed six separate patent infringement lawsuits in the Delaware District Court against Roxane, Inventia Healthcare Pvt. Ltd., Lupin Ltd. and Lupin Pharmaceuticals, Inc. (Lupin), Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd., and Apotex Inc. and Apotex Corp., (collectively, 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 (the '432 Patent) by submitting to the FDA and 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 have denied infringement and counterclaimed for declaratory judgment of invalidity and noninfringement of the '610 patent and the '432 Patent. Lupin filed counter claims for declaratory judgment of invalidity and noninfringement of seven of the Company's U.S. method of treatment patents that are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the 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. The Delaware District Court has scheduled a five-day bench trial beginning on May 15, 2017 in which all of these lawsuits regarding infringement of the '610 Patent and the '432 Patent would be tried together and a bench trial on Lupin's counter claims regarding the Method of Treatment Patents for September 18, 2017.

On February 26, 2016, Roxane filed suit against the Company in the U.S. District Court for the Southern District of Ohio. The suit seeks a declaratory judgment of invalidity and noninfringement of the Method of Treatment Patents. The Company has not sued Roxane for infringing the Method of Treatment Patents. The Company filed a motion to dismiss this lawsuit for lack of personal jurisdiction or to transfer the lawsuit to the Delaware District Court. The Company intends to continue to vigorously defend against this lawsuit.

On February 26, 2016, Roxane filed a Petition for *Inter Partes* Review (IPR) of the ‘432 Patent with the Patent Trials and Appeals Board (PTAB) of the United States Patent and Trademark Office. The Company filed a Preliminary Response on June 7, 2016, and the PTAB has until September 7, 2016 in which to institute or deny the IPR proceeding. If the PTAB decides to institute the IPR proceeding, Roxane will have the opportunity to challenge the validity of the ‘432 Patent under certain sections of the Patent Act before the PTAB. The Company intends to continue to vigorously defend the validity of the ‘432 Patent.

12. Stock-Based Compensation

As of June 30, 2016, there were 7,630,211 shares that were subject to outstanding options and RSUs under the 2006 Equity Incentive Plan (2006 Plan) and the 2016 Equity Incentive Plan (2016 Plan) (collectively, the Plans). The 2006 Plan expired by its terms on April 12, 2016. 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. On June 16, 2016, the Company’s stockholders approved the 2016 Plan. There are 2,000,000 shares of common stock reserved for issuance under the 2016 Plan, of which 1,887,000 shares remained available for future grant as of June 30, 2016.

The Company has granted option awards under the Plans with service conditions (service option awards) that are subject to terms and conditions established by the compensation committee of the board of directors. Service option awards have 10-year contractual terms and all service option awards granted prior to December 31, 2006, service option awards granted to new employees, and certain service option awards granted to existing 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. Certain service option awards granted to existing employees after December 31, 2006 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 equal monthly installments over a period of one year. Certain service option awards to executives and directors provide for accelerated vesting if there is a change in control of the Company. Certain service option awards to employees and executives provide for accelerated vesting if the respective employee’s or executive’s service is terminated by the Company for any reason other than cause or permanent disability. As of June 30, 2016, $11.8 million of unrecognized compensation costs related to unvested service option awards are expected to be recognized over a weighted average period of 1.4 years. No option awards are classified as a liability as of June 30, 2016.

A summary of option activity under the Plans for the six months ended June 30, 2016 follows:

Stock Options *(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, 2015	6,252,448	$ 11.87	6.16	$ 7,498
Granted	847,011	8.25		
Forfeited	(317,949)	11.10		
Expired	(122,220)	12.69		
Exercised	(179,240)	6.35		549
Outstanding at June 30, 2016	6,480,050	11.57	6.05	13,219
Exercisable at June 30, 2016	4,362,067	12.12	4.69	10,301
Vested and expected to vest at June 30, 2016	6,300,331	11.62	5.95	12,891

Proceeds from the exercise of stock options amounted to $1.0 million for the six months ended June 30, 2016 and $0.8 million for the six months ended June 30, 2015.

An RSU is a stock award that entitles the holder to receive shares of the Company’s common stock as the award vests. The fair value of each RSU is based on the closing price of the Company’s stock on the date of grant. The Company has granted RSUs under the Plans with service conditions (service RSUs) that vest in four equal annual installments provided that the employee remains employed with the Company. As of June 30, 2016, $9.7 million of unrecognized compensation costs related to unvested service RSUs are expected to be recognized over a weighted average period of 1.9 years. No RSUs are classified as a liability as of June 30, 2016.

A summary of RSU activity under the Plans for the six months ended June 30, 2016 follows:

RSUs	Number of Shares Underlying RSUs	Weighted Average Grant Date Fair Value
Unvested at December 31, 2015	1,022,681	$ 10.90
Granted	593,742	8.03
Forfeited	(178,596)	10.34
Vested	(287,666)	9.65
Unvested at June 30, 2016	1,150,161	9.82

The grant date fair value for the 287,666 shares underlying RSUs that vested during the six months ended June 30, 2016 was $2.8 million.

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

Overview

Vanda Pharmaceuticals Inc. (we, our or Vanda) is a specialty pharmaceutical company focused on the development and commercialization of novel therapies to address high unmet medical needs and improve the lives of patients. We commenced operations in 2003 and our product portfolio includes:

- HETLIOZ® (tasimelteon), a product for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24), was approved by the U.S. Food and Drug Administration (FDA) in January 2014 and launched commercially in the U.S. in April 2014. In July 2015, the European Commission (EC) granted centralized marketing authorization with unified labeling for HETLIOZ® for the treatment of Non-24 in totally blind adults. This authorization is valid in the 28 countries that are members of the European Union, as well as European Economic Area members Iceland, Liechtenstein and Norway. We are preparing to launch HETLIOZ® in Germany in 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 (JLD) and Smith-Magenis Syndrome (SMS).
- Fanapt® (iloperidone), a product for the treatment of schizophrenia, the oral formulation of which was being marketed and sold in the U.S. by Novartis Pharma AG (Novartis) until December 31, 2014. Pursuant to the terms of a settlement agreement with Novartis, Novartis transferred all of the U.S. and Canadian commercial rights to the Fanapt® franchise to us on December 31, 2014. In May 2016, the FDA approved our supplemental New Drug Application (sNDA) for Fanapt®, modifying and expanding the prescribing information to describe the effectiveness of Fanapt® as a maintenance treatment for schizophrenia in adults. In addition, the FDA granted three years of marketing exclusivity for the changes related to this sNDA and added this entry to the Fanapt® Orange Book listing, providing exclusivity until May 26, 2019 based upon three years from the sNDA approval date. In December 2015, the European Medicines Agency (EMA) accepted for review a Marketing Authorization Application (MAA) for Fanaptum® oral. Additionally, our distribution partners launched Fanapt® in Israel and Mexico in 2014.
- 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 gastroparesis.
- Trichostatin A, a small molecule histone deacetylase (HDAC) inhibitor.
- AQW051, a Phase II alpha-7 nicotinic acetylcholine receptor partial agonist.

Operational Highlights

- Total net product sales from HETLIOZ® and Fanapt® were $36.0 million during the second quarter of 2016, an 8% increase compared to $33.3 million in the first quarter of 2016 and a 31% increase compared to $27.6 million in the second quarter of 2015.

HETLIOZ® (tasimelteon)

- HETLIOZ® net product sales grew to $17.5 million in the second quarter of 2016, an 8% increase compared to $16.2 million in the first quarter of 2016 and a 74% increase compared to $10.0 million in the second quarter of 2015.
- A HETLIOZ® product launch in Germany is planned for the third quarter of 2016.
- Enrollment in the SMS open label interventional study is ongoing. An SMS placebo controlled Phase III study is expected to begin in the second half of 2016.
- The Pediatric Non-24 pharmacokinetic study of the HETLIOZ® liquid formulation is enrolling. A Phase III study is expected to begin in 2017.
- The screening of patients for a JLD Phase II proof of concept study began during the second quarter of 2016. Results from the JLD study are expected in the first half 2017.

Fanapt® (iloperidone)

- Fanapt® net product sales were $18.6 million for the second quarter of 2016, a 9% increase compared to $17.1 million in the first quarter of 2016 and a 6% increase compared to $17.6 million in the second quarter of 2015.
- In May 2016, the FDA approved the sNDA for Fanapt®, modifying and expanding the prescribing information for the use of Fanapt® as a maintenance treatment for schizophrenia in adults. The FDA granted three years of marketing exclusivity for the changes related to the approval of the sNDA.
- A review of the Marketing Authorization Application for oral Fanaptum® tablets by the EMA for the treatment of schizophrenia in adults is ongoing. An opinion by the EMA's Committee for Medicinal Products for Human Use (CHMP) is expected in the first quarter of 2017.

Tradipitant

- Enrollment in a tradipitant Phase II proof of concept study for the treatment of chronic pruritus in patients with atopic dermatitis is ongoing. Results are expected in the first half of 2017.
- A tradipitant Phase II proof of concept study for the treatment of gastroparesis is expected to begin enrolling patients in the fourth quarter of 2016. Results are expected in the second half of 2017.

Since we began operations in March 2003, we have devoted substantially all of our resources to the in-licensing, clinical development and commercialization of our products. Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ® and Fanapt® in the U.S. and Europe, on our ability, alone or with others, to complete the development of our products, and to obtain the regulatory approvals for and to manufacture, market and sell our products. The results of our operations will vary significantly from year-to-year and quarter-to-quarter and depend on a number of factors, including risks related to our business, risks related to our industry, and other risks which are detailed in *Risk Factors* reported in Item 1A of Part I of our annual report on Form 10-K for the year ended December 31, 2015.

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 Roxane Laboratories, Inc., Inventia Healthcare Pvt. Ltd., Taro Pharmaceuticals, U.S.A., Inc./Taro Pharmaceuticals Industries, Ltd., Apotex Inc. and Lupin Limited and Lupin Pharmaceuticals, Inc.

Critical Accounting Policies

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

There have been no significant changes in our critical accounting policies including estimates, assumptions and judgments from those described in Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations*, included in our annual report on Form 10-K for the fiscal year ended December 31, 2015. 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, 2015. 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 market, 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 is evaluated for impairment by consideration of factors such as lower of cost or market, net realizable value, obsolescence or expiry.

Net Product Sales

Our net product sales consist of sales of HETLIOZ® and sales of Fanapt®. We apply the revenue recognition guidance in accordance with Financial Accounting Standards Board Accounting Standards Codification (ASC) Subtopic 605-15, *Revenue Recognition—Products*. We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collectability is reasonably assured and we have no further performance obligations.

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 our customers, specialty pharmacies and wholesalers, receive product from the third-party logistics warehouse. Revenues and accounts receivable are concentrated with these customers.

We have entered into distribution agreements with Probiomed S.A. de C.V. (Probiomed) for the commercialization of Fanapt® in Mexico and Megapharm Ltd. for the commercialization of Fanapt® in Israel.

Product Sales Discounts and Allowances. 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. Reserves established for discounts and returns are classified as reductions of accounts receivable if the amount is payable to direct customers, with the exception of service fees. Service fees are classified as a liability. Reserves established for rebates, chargebacks or co-pay assistance are classified as a liability if the amount is payable to a party other than customers. 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 utilization. Estimates for the expected utilization of rebates are based on historical activity and, where available, actual and pending prescriptions for which we have validated the insurance benefits. Rebates are generally invoiced and paid in arrears, such that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarter's unpaid rebates. If actual future invoicing varies from estimates, we may need to adjust accruals, which would affect net revenue in the period of adjustment.

Chargebacks: Chargebacks are discounts that occur when contracted customers purchase directly from specialty pharmacies and wholesalers. Contracted 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. The allowance for chargebacks is based on historical activity and, where available, actual and pending prescriptions for which we have validated the insurance benefits.

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. Estimates for expected Medicare Part D coverage gap are based in part on historical activity and, where available, actual and pending prescriptions for which we have validated the insurance benefits. Funding of the coverage gap is generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarter activity. If actual future funding varies from estimates, we may need to adjust accruals, which would affect net sales in the period of adjustment.

Service Fees: We also incur specialty pharmacy fees and wholesaler for services and their data. 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 receives an identifiable and separate benefit for the consideration and it can reasonably estimate the fair value of the benefit received. In which case, service fees 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. The allowance for co-pay assistance is based on actual sales and an estimate for pending sales based on either historical activity or pending sales for which we have validated the insurance benefits.

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.

The following table summarizes sales discounts and allowance activity for the six months ended June 30, 2016:

(in thousands)	Rebates & Chargebacks	Discounts, Returns and Other	Total
Balance at December 31, 2015	$ 33,423	$ 3,557	$ 36,980
Provision related to current period sales	27,132	9,695	36,827
Adjustments for prior period sales	(1,766)	864	(902)
Credits/payments made	(27,532)	(8,360)	(35,892)
Balance at June 30, 2016	$ 31,257	$ 5,756	$ 37,013

The provision of $27.1 million for rebates and chargebacks for the six months ended June 30, 2016 primarily represents Medicaid rebates and contracted rebate programs applicable to sales of Fanapt®. The provision of $9.7 million for discounts, returns and other for the six months ended June 30, 2016 primarily represents wholesaler distribution fees applicable to sales of Fanapt® and co-pay assistance costs and prompt pay discounts applicable to the sales of both HETLIOZ® and Fanapt®.

Stock-based compensation

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. Stock-based compensation expense is also affected by the expected forfeiture rate for the respective option grants. If our estimates of the fair value of these equity instruments or expected forfeitures are too high or too low, it would have the effect of overstating or understating expenses.

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, 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.

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, marketing and other business activities. Additionally, selling, general and administrative expenses include our estimate for the annual Patient Protection and Affordable Care fee.

Intangible Assets

The following is a summary of our intangible assets as of June 30, 2016:

(in thousands)	Estimated Useful Life (Years)	June 30, 2016 Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	January 2033	$33,000	$ 4,321	$28,679
Fanapt®	November 2016	27,941	23,753	4,188
		$60,941	$ 28,074	$32,867

In January 2014, we announced that the FDA had approved the NDA for HETLIOZ®. As a result of this approval, we met a milestone under our license agreement with Bristol-Myers Squibb (BMS) that required us 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 remaining life of the U.S. patent for HETLIOZ®, which prior to June 2014, we expected to last until December 2022. In June 2014, we received a notice of allowance from the U.S. Patent and Trademark Office for a patent covering the method of use of HETLIOZ®. The patent expires in January 2033, thereby potentially extending the exclusivity protection in the U.S. beyond the composition of matter patent. As a result of the patent allowance, we extended the estimated useful life of the U.S. patent for HETLIOZ® from December 2022 to January 2033. We are obligated to make a future milestone payment to BMS of $25.0 million in the event that cumulative worldwide sales of HETLIOZ® reach $250.0 million. The likelihood of achieving the milestone and the related milestone obligation was determined to be probable during 2015. As a result, the future obligation of $25.0 million was recorded as a non-current liability along with a capitalized intangible assets relating to HETLIOZ®. The actual payment of the obligation will occur once the $250.0 million in cumulative worldwide sales of HETLIOZ® is realized. Intangible assets relating HETLIOZ® are being amortized on a straight-line basis over the remaining life of the U.S. patent for HETLIOZ®, which is expected to be January 2033.

In 2009, we announced that the FDA had approved the NDA for Fanapt®. As a result of this approval, we met a milestone under our original sublicense agreement with Novartis that required us to make a license payment of $12.0 million to Novartis. Pursuant to the terms of the settlement agreement with Novartis, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to us on December 31, 2014. As a result, we recognized an intangible asset of $15.9 million related to the reacquired rights to Fanapt®. Intangible assets relating to Fanapt® are being amortized on a straight-line basis over the remaining life of the U.S. composition of matter patent for Fanapt® to November 2016. The useful life estimation is based on the market participant methodology prescribed by ASC Subtopic 805, *Business Combinations*, and therefore does not reflect the impact of additional Fanapt® patents solely owned by us with varying expiration dates, the latest of which is December 2031.

The following table summarizes our future intangible asset amortization schedule as of June 30, 2016:

(in thousands)	Total	Remainder of 2016	2017	2018	2019	2020	Thereafter
HETLIOZ®	$28,679	$ 860	$1,721	$1,721	$1,721	$1,721	$ 20,935
Fanapt®	4,188	4,188	—	—	—	—	—
	$32,867	$ 5,048	$1,721	$1,721	$1,721	$1,721	$ 20,935

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. Our limited operating history makes predictions of future operations difficult or impossible. Since our inception, we have incurred significant losses resulting in an accumulated deficit of $344.8 million as of June 30, 2016.

Three months ended June 30, 2016 compared to three months ended June 30, 2015

Revenues. Total revenues increased by $8.4 million, or 31%, to $36.0 million for the three months ended June 30, 2016 compared to $27.6 million for the three months ended June 30, 2015. Revenues were as follows:

	Three Months Ended			
(in thousands)	June 30, 2016	June 30, 2015	Net Change	Percent
Revenues:				
HETLIOZ® product sales, net	$17,460	$10,017	$7,443	74%
Fanapt® product sales, net	18,569	17,565	1,004	6%
Total revenues	$36,029	$27,582	$8,447	31%

HETLIOZ® product sales increased by $7.4 million, or 74%, to $17.5 million for the three months ended June 30, 2016 compared to $10.0 million for the three months ended June 30, 2015.

Fanapt® product sales increased by $1.0 million, or 6%, to $18.6 million for the three months ended June 30, 2016 compared to $17.6 million for the three months ended June 30, 2015. We began selling Fanapt® commercially in the U.S. in January 2015.

Cost of goods sold. Cost of goods sold increased by $0.7 million, or 12%, to $6.5 million for the three months ended June 30, 2016 compared to $5.8 million for the three months ended June 30, 2015. 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 U.S. sales of HETLIOZ® and 23% of net U.S. sales of Fanapt®.

HETLIOZ® cost of goods sold as a percentage of HETLIOZ® 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 be less than 2% of our net HETLIOZ® product sales.

Fanapt® work-in-process inventory and finished goods inventory acquired from Novartis as part of the acquisition of the Fanapt® business were recorded at fair value. The fair value of the inventory acquired from Novartis represents a higher cost than if new work-in-process inventory and finished goods inventory was manufactured at this time. We expect that, in the future, total U.S. Fanapt® manufacturing costs included in cost of goods sold will be less than 4% of our net U.S. Fanapt® product sales.

Research and development expenses. Research and development expenses increased by $0.8 million, or 14%, to $6.7 million for the three months ended June 30, 2016 compared to $5.9 million for the three months ended June 30, 2015. The increase is primarily the result of increased clinical trial expenses associated with the HETLIOZ® Jet Lag Disorder and SMS programs and the tradipitant chronic pruritus in atopic dermatitis pruritus program partially offset by a decline in expenses associated with Fanapt® as 2015 results included close out Fanapt® clinical trial expenses transitioned to us as part of the settlement agreement with Novartis. The following table summarizes the costs of our product development initiatives for the three months ended June 30, 2016 and 2015.

	Three Months Ended	
(in thousands)	June 30 2016	June 30 2015
Direct project costs (1)		
HETLIOZ®	$ 2,714	$ 1,763
Fanapt®	584	1,870
Tradipitant	1,643	677
Trichostatin A	614	451
	5,555	4,761
Indirect project costs (1)		
Stock-based compensation	489	603
Other indirect overhead	656	582
	1,145	1,185
Total research and development expense	$ 6,700	$ 5,946

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

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

Selling, general and administrative expenses. Selling, general and administrative expenses increased by $6.3 million, or 34%, to $24.7 million for the three months ended June 30, 2016 compared to $18.4 million for the three months ended June 30, 2015. The increase was primarily the result of marketing and sales efforts around both HETLIOZ® and Fanapt® in the U.S. as well as increased legal fees associated with ongoing litigation.

Intangible asset amortization. Intangible asset amortization was $2.9 million for the three months ended June 30, 2016 and 2015. Intangible asset amortization relating to HETLIOZ® amounted to $0.4 million, and intangible asset amortization relating to Fanapt® amounted to $2.5 million for each of the three-month periods. Pursuant to the terms of the settlement agreement with Novartis, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to us on December 31, 2014 resulting in an increase in capitalized intangible assets of $15.9 million that is being amortized until November 2016.

Six months ended June 30, 2016 compared to six months ended June 30, 2015

Revenues. Total revenues increased by $19.6 million, or 39%, to $69.3 million for the six months ended June 30, 2016 compared to $49.7 million for the six months ended June 30, 2015. Revenues were as follows:

	Six Months Ended			
(in thousands)	June 30, 2016	June 30, 2015	Net Change	Percent
Revenues:				
HETLIOZ® product sales, net	$33,661	$17,477	$16,184	93%
Fanapt® product sales, net	35,630	32,255	3,375	10%
Total revenues	$69,291	$49,732	$19,559	39%

HETLIOZ® product sales increased by $16.2 million, or 93%, to $33.7 million for the six months ended June 30, 2016 compared to $17.5 million for the six months ended June 30, 2015.

Fanapt® product sales increased by $3.4 million, or 10%, to $35.6 million for the six months ended June 30, 2016 compared to $32.2 million for the six months ended June 30, 2015. We began selling Fanapt® commercially in the U.S. in January 2015.

Cost of goods sold. Cost of goods sold increased by $1.7 million, or 16%, to $12.5 million for the six months ended June 30, 2016 compared to $10.8 million for the six months ended June 30, 2015. 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 U.S. sales of HETLIOZ® and 23% of net U.S. sales of Fanapt®.

HETLIOZ® cost of goods sold as a percentage of HETLIOZ® 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 be less than 2% of our net HETLIOZ® product sales.

Fanapt® work-in-process inventory and finished goods inventory acquired from Novartis as part of the acquisition of the Fanapt® business were recorded at fair value. The fair value of the inventory acquired from Novartis represents a higher cost than if new work-in-process inventory and finished goods inventory was manufactured at this time. We expect that, in the future, total U.S. Fanapt® manufacturing costs included in cost of goods sold will be less than 4% of our net U.S. Fanapt® product sales.

Research and development expenses. Research and development expenses increased by $3.8 million, or 37%, to $14.2 million for the six months ended June 30, 2016 compared to $10.4 million for the six months ended June 30, 2015. The increase is primarily the result of increased clinical trial expenses associated with the HETLIOZ® Jet Lag Disorder and SMS programs and the tradipitant chronic pruritus in atopic dermatitis pruritus program partially offset by a decline in expenses associated with Fanapt® as 2015 results included close out Fanapt® clinical trial expenses transitioned to us as part of the settlement agreement with Novartis. The following table summarizes the costs of our product development initiatives for the six months ended June 30, 2016 and 2015.

(in thousands)	Six Months Ended June 30 2016	June 30 2015
Direct project costs (1)		
HETLIOZ®	$ 6,000	$ 3,467
Fanapt®	1,419	2,727
Tradipitant	3,004	1,078
Trichostatin A	1,411	799
	11,834	8,071
Indirect project costs (1)		
Stock-based compensation	1,013	1,227
Other indirect overhead	1,401	1,126
	2,414	2,353
Total research and development expense	$14,248	$10,424

(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 develop our products.

Selling, general and administrative expenses. Selling, general and administrative expenses increased by $16.8 million, or 45%, to $54.0 million for the six months ended June 30, 2016 compared to $37.2 million for the six months ended June 30, 2015. The increase was primarily the result of marketing and sales efforts around both HETLIOZ® and Fanapt® in the U.S., an increase in the number of employees during 2015, including the hiring of new members of the executive management team, as well as increased legal fees associated with ongoing litigation.

Intangible asset amortization. Intangible asset amortization decreased by $1.2 million, or 17%, to $5.9 million for the six months ended June 30, 2016 compared to $7.1 million for the six months ended June 30, 2015. The likelihood of achieving a future milestone obligation that becomes payable to BMS when cumulative sales of HETLIOZ® equal $250.0 million was determined to be probable in the first quarter of 2015 resulting in an increase in capitalized intangible assets of $25.0 million. As a result, intangible asset amortization relating to HETLIOZ® for the six months ended June 30, 2015 had included additional amortization of $1.2 million for a catch-up adjustment to retroactively record cumulative amortization from February 1 to December 31, 2014 relating to the capitalized intangible asset of $25.0 million.

Intangible asset amortization relating to Fanapt® was $5.0 million for the six months ended June 30, 2016 and 2015. Pursuant to the terms of a settlement agreement with Novartis, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to us on December 31, 2014 resulting in an increase in capitalized intangible assets of $15.9 million that is being amortized until November 2016.

Liquidity and Capital Resources

As of June 30, 2016, our total cash and cash equivalents and marketable securities were $136.0 million compared to $143.2 million at December 31, 2015. 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 time deposits, investments in money market funds with commercial banks and financial institutions, and commercial paper of high-quality corporate issuers. Our marketable securities consist of investments in government sponsored enterprises and commercial paper.

Our liquidity resources as of June 30, 2016 and December 31, 2015 are summarized as follows:

(in thousands)	June 30, 2016	December 31, 2015
Cash and cash equivalents	$ 23,194	$ 50,843
Marketable securities:		
U.S. Treasury and government agencies	55,841	44,057
Corporate debt	56,954	48,280
Total marketable securities	112,795	92,337
Total cash and cash equivalents	$135,989	$ 143,180

As of June 30, 2016, we maintained all of our cash and cash equivalents 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 2016 and beyond in connection with our U.S. commercial activities for HETLIOZ® and Fanapt®, including Medicaid rebates, the European commercial launch activities for HETLIOZ® and a probable future milestone payment of $25.0 million to BMS in the event cumulative worldwide sales of HETLIOZ® reach $250.0 million. During this time, we will evaluate the commercial opportunity for Fanapt® in Europe, assuming EMA approval. Additionally, we continue to pursue market approval of HETLIOZ® and Fanapt® in other regions. Because of the uncertainties discussed above, the costs to advance our research and development projects and the U.S. commercial activities for HETLIOZ® and Fanapt® are difficult to estimate and may vary significantly. Additionally, the outcome of the outstanding Fanapt® patent infringement lawsuits could have a material impact on future cash flows. Management believes that our existing funds will be sufficient to meet our operating plans for the foreseeable future. Our future capital requirements and the adequacy of our available funds will depend on many factors, primarily including our ability to generate revenue, the scope and costs of our commercial, manufacturing and process development activities and the magnitude of our discovery, preclinical and clinical development programs.

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

Cash Flow

The following table summarizes our net cash flows from operating, investing and financing activities for the six months ended June 30, 2016 and 2015:

	Six Months Ended		
(in thousands)	June 30, 2016	June 30, 2015	Net Change
Net cash provided by (used in):			
Operating activities:			
Net loss	$(16,976)	$(15,607)	$ (1,369)
Non-cash charges	10,703	12,102	(1,399)
Net change in operating assets and liabilities	(1,888)	21,161	(23,049)
Operating activities	(8,161)	17,656	(25,817)
Investing activities:			
Net purchases of marketable securities	(20,416)	(29,794)	9,378
Other	(111)	(939)	828
Investing activities	(20,527)	(30,733)	10,206
Financing activities	1,039	513	526
Net decrease in cash and cash equivalents	$(27,649)	$(12,564)	$(15,085)

The net decrease in cash and cash equivalents was $27.6 million for the six months ended June 30, 2016 compared to a net decrease of $12.6 million for the six months ended June 30, 2015. The decrease was primarily due to the net change in operating assets and liabilities of $23.0 million resulting primarily from the net impact of accruals for government and other rebates and accounts receivable relating to initial sales of Fanapt® for the six months ended June 30, 2015. The decrease from the net change in operating assets and liabilities was partially offset by a decrease in net purchases of marketable securities of $9.4 million.

Off-Balance Sheet Arrangements

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

Contractual Obligations and Commitments

The following is a summary of our non-cancellable long-term contractual cash obligations as of June 30, 2016:

	Cash payments due by year (1) (2) (3)						
(in thousands)	Total	Remainder of 2016	2017	2018	2019	2020	Thereafter
Operating leases	$22,562	$ 917	$1,939	$2,236	$2,291	$2,347	$ 12,832

(1) This table does not include various agreements that we have entered into for services with third party vendors, including agreements to conduct clinical trials, to manufacture products, and for consulting and other contracted services due to the cancelable nature of the services. We accrued the costs of these agreements based on estimates of work completed to date. Additionally, this table does not include rebates, chargebacks or discounts recorded as liabilities at the time that product sales are recognized as revenue.

(2) This table does not include a probable future milestone obligation under our license agreement with BMS, where we will be obligated to make a future milestone payment of $25.0 million in the event cumulative worldwide sales of HETLIOZ® reach $250.0 million. This probable obligation has been accrued as a non-current liability in our condensed consolidated balance sheet as of June 30, 2016.

(3) This table does not include potential future milestone obligations under our license agreement with Eli Lilly for the exclusive rights to develop and commercialize tradipitant where we could be obligated to make future milestone payments of up to $4.0 million for pre-NDA approval milestones and up to $95.0 million for future regulatory approval and sales milestones.

Operating leases

Commitments relating to operating leases represent the minimum annual future payments under operating leases for a total of 40,188 square feet of office space for our headquarters office at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. that expire in 2026 and the 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.

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 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 86% of total revenues for the six months ended June 30, 2016. There were four major customers that each accounted for more than 10% of accounts receivable and, as a group, represented 76% of total accounts receivable at June 30, 2016. We have not experienced any losses related to receivables from these customers. We mitigate our credit risk relating to accounts receivable from customers by performing ongoing credit evaluations.

Effects of inflation

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

ITEM 4 Controls and Procedures

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (Exchange Act)) as of June 30, 2016. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of June 30, 2016, the end of the period covered by this quarterly report, to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the second quarter of 2016 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

In June 2014, we filed suit against Roxane Laboratories, Inc. (Roxane) in the U.S. District Court for the District of Delaware (the Delaware District Court). The suit seeks an adjudication that Roxane has infringed one or more claims of our U.S. Patent No. 8,586,610 (the '610 Patent) by submitting to the 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 the settlement agreement with 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 (the '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 on March 4, 2016. The parties are awaiting the Delaware District Court's decision.

In 2015, we filed six separate patent infringement lawsuits in the Delaware District Court against Roxane, Inventia Healthcare Pvt. Ltd., Lupin Ltd. and Lupin Pharmaceuticals, Inc. (Lupin), Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd., and Apotex Inc. and Apotex Corp., (collectively, 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 (the '432 Patent) by submitting to the FDA and 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 have denied infringement and counterclaimed for declaratory judgment of invalidity and noninfringement of the ‘610 patent and the ‘432 Patent. Lupin filed counter claims for declaratory judgment of invalidity and noninfringement of seven of the method of treatment patents that are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the 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. The Delaware District Court has scheduled a five-day bench trial beginning on May 15, 2017 in which all of these lawsuits regarding infringement of the ‘610 Patent and the ‘432 Patent would be tried together and a bench trial on Lupin’s counter claims regarding the Method of Treatment Patents for September 18, 2017.

On February 26, 2016, Roxane filed suit against us in the U.S. District Court for the Southern District of Ohio. The suit seeks a declaratory judgment of invalidity and noninfringement of the Method of Treatment Patents. We have not sued Roxane for infringing the Method of Treatment Patents. We filed a motion to dismiss this lawsuit for lack of personal jurisdiction or to transfer the lawsuit to the Delaware District Court. We intend to continue to vigorously defend against this lawsuit.

On February 26, 2016, Roxane filed a Petition for *Inter Partes* Review (IPR) of the ‘432 Patent with the Patent Trials and Appeals Board (PTAB) of the United States Patent and Trademark Office. We filed a Preliminary Response on June 7, 2016, and the PTAB has until September 7, 2016 in which to institute or deny the IPR proceeding. If the PTAB decides to institute the IPR proceeding, Roxane will have the opportunity to challenge the validity of the ‘432 Patent under certain sections of the Patent Act before the PTAB. We intend to continue to vigorously defend the validity of the ‘432 Patent.

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, 2015, filed with the Securities and Exchange Commission on February 12, 2016, 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, 2015.

ITEM 2 Unregistered Sales of Equity Securities and Use of Proceeds

None

ITEM 3 Defaults Upon Senior Securities

None

ITEM 4 Mine Safety Disclosures

Not applicable

ITEM 5 Other Information

None

ITEM 6 Exhibits

Exhibit Number	Description
3.1	Form of Amended and Restated Certificate of Incorporation of the registrant (filed as Exhibit 3.8 to Amendment No. 2 to the registrant's registration statement on Form S-1 (File No. 333-130759) on March 17, 2006 and incorporated herein by reference).
3.2	Form of Certificate of Designation of Series A Junior Participating Preferred Stock (filed as Exhibit 3.10 to the registrant's current report on Form 8-K (File No. 001-34186) on September 25, 2008 and incorporated herein by reference).
3.3	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).
10.42†	Manufacturing Agreement, dated May 6, 2016, by and between Patheon Pharmaceuticals Inc. and the registrant (relating to Fanapt®).
10.43	Second Amendment to Lease Agreement, dated June 20, 2016, by and between Square 54 Office Owner LLC and the registrant.
10.44	Sublease Agreement, dated June 22, 2016, by and between Hunton & Williams LLP 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 June 30, 2016 formatted in XBRL (eXtensible Business Reporting Language) and filed electronically herewith: (i) Condensed Consolidated Balance Sheets as of June 30, 2016 and December 31, 2015; (ii) Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2016 and 2015; (iii) Condensed Consolidated Statement of Comprehensive Loss for the three and six months ended June 30, 2016 and 2015; (iv) Condensed Consolidated Statement of Changes in Stockholders' Equity for the six months ended June 30, 2016; (v) Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2016 and 2015; and (vi) Notes to Condensed Consolidated Financial Statements.

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment. The omitted portions of this exhibit have been filed with the Securities and Exchange Commission.

The certification attached as Exhibit 32.1 that accompanies this quarterly report on Form 10-Q is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Vanda Pharmaceuticals Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this quarterly report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

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.

July 28, 2016 /s/ Mihael H. Polymeropoulos, M.D.

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

July 28, 2016 /s/ James P. Kelly

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

Manufacturing Agreement

May 6, 2016

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MANUFACTURING AGREEMENT

THIS MANUFACTURING AGREEMENT (the "Agreement") made as of the 6th day of May, 2016 ("**Effective Date**")

B E T W E E N:

PATHEON INC.,
a corporation existing under the laws of Canada,

(hereinafter referred to as "**Patheon**"),

- and -

VANDA PHARMACEUTICALS INC.,
a corporation existing under the laws of the State of Delaware in the United States of America,

(hereinafter referred to as the "**Client**").

WHEREAS, Client previously held the rights to the Product in the whole world other than the United States of America ("USA") and Canada; and

WHEREAS, Novartis previously held the rights to the Product for the USA and Canada; and

WHEREAS, Novartis and Client entered into a settlement agreement on December 22, 2014 wherein the rights to the Product for the USA and Canada were transferred to Client (the "Settlement Agreement"); and

WHEREAS, Novartis assigned its manufacturing agreement with Patheon in respect of the Product (the "Novartis MSA") to Client in connection with the Settlement Agreement; and

WHEREAS, Client and Patheon intend that this Agreement shall supersede and replace, as of the Effective Date, the Novartis MSA with respect to the Product;

THIS AGREEMENT WITNESSES THAT in consideration of the rights conferred and the obligations assumed herein, and for other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each party), and intending to be legally bound the parties agree as follows:

ARTICLE 1

INTERPRETATION

1.1 Definitions.

The following terms shall, unless the context otherwise requires, have the respective meanings set out below and grammatical variations of such terms shall have corresponding meanings:

"**Active Materials**" means the materials listed on Schedule D hereto;

"**Active Materials Credit Value**" means the value to be attributed to the Active Materials for certain purposes of this Agreement, as set forth on Schedule D;

"**Affiliate**" means:

(a) a business entity which owns, directly or indirectly, a controlling interest in a party to this Agreement, by stock ownership or otherwise, only for so long as such ownership continues to exist; or

(b) a business entity which is controlled by a party to this Agreement, either directly or indirectly, by stock ownership or otherwise, only for so long as such control continues to exist; or

(c) a business entity, the controlling interest of which is directly or indirectly common to the majority ownership of a party to this Agreement, only for so long as such controlling interest continues to exist;

For the purposes of this definition, "control" means the ownership of shares carrying at least a majority of the votes in respect of the election of the directors of a corporation.

"**Agreement**" has the meaning specified in the preamble;

"Annual Product Review Report" means the annual product review report as described in Title 21 of the United States Code of Federal Regulations, Section 211.180(e);

"**Annual Report"** means the annual report to the FDA prepared by Client as described in Title 21 of the United States Code of Federal Regulations, Section 314.81(b)(2);

"**Annual Volume**" means, if applicable, the minimum volume of Product estimated to be manufactured in any Year of this Agreement as set forth in Schedule B hereto, which shall be prorated for the first Year of this Agreement;

"**Applicable Laws**" means (i) with respect to Patheon, the Laws of the Province of Ontario, being the jurisdiction where the Manufacturing Site is located; and (ii) with respect to Client, the applicable Laws of all jurisdictions where the Products are manufactured, distributed and marketed;

"**Authority**" means any governmental or regulatory authority, department, body or agency or any court, tribunal, bureau, commission or other similar body in the Territory, whether federal, state, provincial, county or municipal;

"**Bill Back Items**" means third party fees and other items listed in Schedule B, excluding Components.

"**Billing Currency**" has the meaning specified in Section 1.2;

"**Breach Notice**" has the meaning specified in Section 8.2(a);

"**Broader Intellectual Property Rights**" has the meaning specified in Section 13.1(c);

"**Business Day**" means a day other than a Saturday, Sunday or a day that is a statutory holiday in the Province of Ontario, Canada (with respect to Patheon only) or a day that is a statutory holiday in Washington, DC, USA (with respect to Client only);

"**cGMPs**" means the rules concerning current and future good manufacturing practices specified by the EU/PIC guidelines (and the corresponding national laws and regulations), the US Code of Federal Regulations, or any other regulatory guidelines made thereunder, as applicable;

"**Change of Control**" shall mean the merger with, transfer to or acquisition of beneficial ownership of more than fifty percent (50%) of the outstanding voting shares of Patheon by a competitor of Client; "competitor" shall mean a pharmaceutical manufacturer which manufactures, markets, or has in its pipeline for development or commercialization, proprietary pharmaceutical and/or proprietary consumer health products within the therapeutic area of the Product.

"**Client Property**" has the meaning specified in Section 8.3(d);

"**CMC**" has the meaning specified in Section 7.8(c);

"**Components**" means Raw Materials, Primary and Secondary Packaging Components and Printed Packaging Components, but for certainty, excludes Active Materials.

"**Confidentiality Agreement**" means the agreement relating to the non-disclosure of confidential information between Patheon and the Client dated February 28, 2006, as amended;

"**Conforming**" with respect to Product, means Product manufactured, packaged and stored by Patheon in accordance with the Specifications, cGMPs, Applicable Laws, the Quality Agreement, other Technical Information and this Agreement.

"**Deficiencies**" has the meaning specified in Section 7.8(d);

"**Deficiency Notice**" shall have the meaning ascribed thereto in Section 6.1(a);

"Delivery Date" has the meaning specified in Section 5.1(b);

"**Disclosure Obligations**" has the meaning set forth in Section 11.1;

"**Effective Date**" has the meaning specified in the preamble;

"EMEA" means the European Medicines Agency**;**

"**FDA**" means the United States government department known as the Food and Drug Administration;

"**Firm Orders**" has the meaning specified in Section 5.1(b);

"**Force Majeure Event**" has the meaning specified in Section 13.7;

"**Health Canada**" means the section of the Canadian Government known as Health Canada and includes, among other departments, the Therapeutic Products Directorate and the Health Products and Food Branch Inspectorate;

"**Initial Set Exchange Rate**" means 1.374 (3 digits) as of the Effective Date of the Agreement being the initial exchange rate to convert one unit of the Billing Currency into Patheon's Manufacturing Site local currency;

"**Initial Term**" has the meaning specified in Section 8.1;

"**Intellectual Property**" includes, without limitation, rights in patents, patent applications, formulae, trade-marks, trade-mark applications, trade-names, Inventions, copyright and industrial designs and all other intellectual and industrial property rights of any sort throughout the world now known or hereafter recognized;

"**Invention**" means any idea, concept, innovation, improvement, development, discovery, technology, computer program, device, trade secret, work of authorship, formula, compound, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable, that is conceived or reduced to practice by one or more person(s) in the course of the performance of this Agreement;

"JAMS" means Judicial Arbitration and Mediation Services, Inc.;

"**Late Delivery**" has the meaning specified in Section 5.5;

"**Laws**" means all laws, statutes, ordinances, regulations, rules, by-laws, judgments, decrees or orders of any Authority;

"**Manufacture or Manufacturing**" means any one of more of the manufacturing, quality control, quality assurance and stability testing, packaging and related services, as contemplated in this Agreement, required to produce Products from Active Materials, Raw Materials, Primary and Secondary Packaging Components and Printed Packaging Components;

"**Manufacturing License**" has the meaning specified in Section 5.5(c);

"**Manufacturing Site**" means the facility owned and operated by Patheon that is located at 2100 Syntex Court, Mississauga, Ontario, Canada;

****

"**Minimum Order Quantity**" or "**Run Quantity**" means the minimum number of units of a Product to be Manufactured (if applicable) in order to obtain the Price as set forth in Schedule B hereto.

"**Order Countries**" means, collectively, all countries in the Territory for which Vanda places Orders hereunder;

"**PPI**" has the meaning specified in Section 4.2(a);

"**Primary and Secondary Packaging Components**" means, collectively, all packaging components required to be used in order to produce the Products in accordance with the Specifications, other than the Printed Packaging Components;

"**Printed Packaging Components**" means labels, inserts or other printed materials affixed to or accompanying Product(s) as required by the Specifications;

Product(s)" means the products listed on Schedule A hereto;

"**Product Claims**" has the meaning specified in Section 6.3(c);

"**Quality Agreement**" means the agreement between the parties hereto setting out the quality assurance standards to be applicable to the Manufacturing performed by Patheon, which agreement shall be finalized and entered into by the parties within thirty (30) days after the Effective Date and may be amended from time to time by mutual written agreement of the parties;

"**Raw Materials**" means all excipients or other starting materials used to manufacture a batch of bulk, unpackaged Product(s), excluding the Active Materials;

“Recall” has the meaning specified in Section 6.2(a);

“**Regulatory Authority**” means the FDA, EMEA and Health Canada and any other foreign regulatory agencies competent to grant marketing approvals for pharmaceutical products including the Products in the Territory;

“**Remediation Period**” has the meaning specified in Section 8.2(a);

“**Reset Date**” means, with reference to any particular (and applicable) Year, the date on which Patheon is to provide Client with updated pricing for the Product for the next Year; which date will be not less than one month prior to the beginning of that Year;

“**SEC**” has the meaning set forth in Section 11.1;

“**Set Exchange Rate**” means the exchange rate to convert one unit of the Billing Currency into Patheon’s Manufacturing Site local currency for each applicable Year, calculated as the average daily interbank exchange rate for conversion of one unit of the billing currency into Patheon’s Manufacturing Site local currency during the one year period immediately preceding the Reset Date by one month as published by OANDA.com “The Currency Site” under the heading “FxHistory: historical currency exchange rates” at www.OANDA.com/convert/fxhistory;

“**Specifications**” means the file, for each Product, which is provided by the Client to Patheon in accordance with the procedures listed in Schedule A hereto and which contains documents relating to such Product, including, without limitation:

(a) specifications for Active Materials, Raw Materials, Primary and Secondary Packaging Components and Printed Packaging Components;

(b) Manufacturing specifications, directions and processes;

(c) storage requirements;

(d) all environmental, health and safety information relating to the Product including material safety data sheets; and

(e) the finished Product specifications, packaging specifications and shipping requirements for each Product;

all as updated, amended and revised from time to time by the Client in accordance with the terms of this Agreement;

“Surplus New Product” has the meaning specified in Section 5.3;

“**Technical Dispute**” has the meaning specified in Section 12.2;

"**Technical Information**" means all documents and materials generated by the Client and Patheon, as the case may be, as well as all written amendments thereto, including without limitation, manufacturing and quality control instructions or requirements under any quality control agreements between the parties (including the Quality Agreement), and specifications necessary to manufacture, label, package, store, handle, stability test, quality control test and release of the Product, all in accordance with this Agreement.

"Territory" means in the geographic area of the United States of America, Canada, European Union, Israel, Singapore, South Korea, Mexico and Australia and any other geographic areas as may be added to this definition from time-to-time by Client (in its sole discretion) by written notice to Patheon;

"**Third Party Rights**" means the Intellectual Property of any third party;

"**Wind-Down Period**" has the meaning specified in Section 8.3(d);

"**Year**" means in the first year of this Agreement the period from the Effective Date up to and including December 31 of the same calendar year, and thereafter shall mean a calendar year.

1.2 Currency.

Unless otherwise indicated, all monetary amounts are expressed in this Agreement in the lawful currency of the United States of America.

1.3 Sections and Headings.

The division of this Agreement into Articles, sections, subsections and Schedules and the insertion of headings are for convenience of reference only and shall not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to a Section or Schedule refers to the specified Section or Schedule to this Agreement. In this Agreement, the terms "**this Agreement**", "**hereof**", "**herein**", "**hereunder**" and similar expressions refer to this Agreement and not to any particular part, Section, Schedule or the provision hereof, and unless the context of this Agreement otherwise requires, "**include**", "**includes**" and "**including**" are not limiting.

1.4 Singular Terms.

Except as otherwise expressly provided herein or unless the context otherwise requires, all references to the singular shall include the plural and vice versa.

1.5 Schedules.

The following Schedules are attached to, incorporated in and form part of this Agreement:

Schedule A -Product List
Schedule B -Commercial Pricing
Schedule C -Stability Testing
Schedule D -Active Materials, Active Materials Credit Value & ****
Schedule E -Batch Numbering & Expiration Dates
Schedule F -Technical Dispute Resolution
Schedule G -Intentionally Omitted
Schedule H -Quarterly Active Materials Inventory Report
Schedule I -Report of Annual Active Materials Inventory Reconciliation and Calculation of Actual Annual Yield
**** - ****
Schedule K -Intentionally Omitted
Schedule L -Example of Price Adjustments under Section 4.2

ARTICLE 2

PATHEON'S MANUFACTURING

2.1 Manufacturing.

In accordance with Client's Firm Orders, Patheon shall perform Manufacturing for the Territory at the Manufacturing Site for the fees specified in Schedules B and C in order to produce Products for the Client. Patheon may change the Manufacturing Site for the Products ****. If Manufacturing has not commenced within **** months after the date of execution of this Agreement, Patheon reserves the right, in good faith, to amend the fees set out in Schedules B and C provided that the delay in the commencement of the Manufacturing does not arise or result from the acts or omissions of Patheon. In providing the Manufacturing, Patheon and the Client agree that:

(a) Conversion of Active Materials and Components. Patheon shall convert Active Materials and Components into Products.

(b) Quality Control and Quality Assurance. Patheon shall perform the quality control and quality assurance testing specified in the Quality Agreement. Batch review and release to the Client shall be the responsibility of Patheon's quality assurance group. Patheon shall perform its batch review and release responsibilities in accordance with Patheon's standard operating procedures. Upon the Client's request, Client may review Patheon's standard operating procedures at Patheon's facility. Each time Patheon ships Products to the Client, it shall provide the Client, in English, a certificate of analysis and certificate of compliance including a statement that the batch has been manufactured and tested in accordance with Specifications and cGMPs. The Client will have sole responsibility for the release of Products to the market.

(c) Components. Patheon shall purchase and test all Components (with the exception of those that are supplied by the Client), in accordance with the Specifications. The parties shall agree upon a list of key components and shall work together to identify a list of critical vendors of such key components. Patheon shall, with the reasonable assistance of the Client where applicable, use commercially reasonable efforts to ****. The cost of Components is included in the Price quoted in Schedule B.

(d) Stability Testing. If applicable, Patheon shall conduct stability testing on the Products in accordance with the protocols set out in Schedule C for the separate fees specified in Schedule C. Patheon shall not make any changes to these testing protocols without prior written approval from the Client. In the event of a confirmed stability test failure, Patheon will notify the Client within ****, after which Patheon and the Client shall jointly determine the proceedings and methods to be undertaken to investigate the causes of such failure, including which party shall bear the cost of such investigation****. Patheon will promptly provide any and all data and results relating to the stability testing upon request by the Client.

(e) Packaging. Patheon shall package the Products as set out in the Specifications. The Client shall be responsible for the cost of artwork development for the Printed Packaging Components. Patheon will be responsible for obtaining the Components. Patheon shall make arrangements for and implement the imprinting of batch numbers and expiration dates for each Product shipped. Such batch numbers and expiration dates shall be affixed on the Products and on the shipping carton of each Product as outlined in the Specifications and as required by cGMPs. The system used by Patheon for batch numbering and expiration dates is detailed in Schedule E hereto. The Client may, in its sole discretion, make changes to labels, product inserts and other packaging for the Products, which changes shall be submitted by the Client to all applicable governmental agencies and other third parties responsible for the approval of the Products. The Client shall be responsible for the cost of labelling obsolescence when changes occur, as contemplated in Section 4.4. Patheon's name shall not appear on the label or anywhere else on the Products unless: (i) required by any applicable Laws; or (ii) Patheon expressly consents to such use of its name in writing.

(f) Active Materials. The Client will deliver all Active Materials as mutually agreed upon by the parties to Patheon DDP (Incoterms 2010).

(g) Bill Back Items. The expenses in respect of all third party supplier fees for the purchase of those items specifically identified in Schedule B as Bill Back Items that are necessary for Patheon to perform the Manufacturing shall be charged to the Client ****. Any invoices for such items shall include reasonable documentation of the costs of such items. Any and all orders in excess of **** for any such items require the prior written approval of the Client. For certainty, the cost of Components is included in the Price quoted in Schedule B, and therefore, Components are not included in Bill Back Items.

(h) Requirements. Client hereby agrees to order at least **** of its total Yearly requirement in the Territory for new units of Products **** (the "Patheon Requirement") from Patheon. However, Client may order any part or all of the Patheon Requirement from a third party supplier in the event that Patheon ****. In addition, ****. Notwithstanding the foregoing, Patheon acknowledges and agrees **** shall not be counted in determining Client's "total Yearly requirement in the Territory for new units of Products" (i.e., Client may order Product from other suppliers at any time during the term of this Agreement as reasonably necessary to validate such suppliers, and Client may use, market, sell, distribute or transfer such Product, without breach of this Section 2.1(h)). For the sake of clarity, during those Years in which Client orders Product from a third party supplier in accordance with the terms in this subsection, then in no event shall Client be deemed to be in breach of this Section 2.1(h) if it does not purchase at least **** of its total Yearly requirement for new units of Products from Patheon.

2.2 Active Material Yield.

(a) Reporting. Patheon shall provide the Client with a quarterly inventory report of the Active Materials supplied by Client (if applicable) and held by Patheon in accordance with the inventory report form annexed hereto as Schedule H, which shall contain the following information for such quarter:

Quantity Received: The total quantity of Active Materials that complies with the Specifications and is received at the Manufacturing Site during the applicable period.

Quantity Dispensed: The total quantity of Active Materials dispensed at the Manufacturing Site during the applicable period. The Quantity Dispensed is calculated by adding the Quantity Received to the inventory of Active Materials that complies with the Specifications and is held at the beginning of the applicable period, less the inventory of Active Materials that complies with the Specifications and is held at the end of such period. The Quantity Dispensed shall only include Active Materials received and dispensed in connection with commercial manufacturing of any Products and, for certainty, shall not include any (i) Active Materials that must be retained by Patheon as samples, (ii) Active Materials contained in any Product that must be retained as samples, (iii) Active Materials used in connection with testing (if applicable) and (iv) Active Materials received or dispensed in connection with technical transfer activities or development activities during the applicable period, including, without limitation, any regulatory, stability, validation or test batches manufactured during the applicable period.

Quantity Converted: The total amount of Active Materials contained in the Products produced with the Quantity Dispensed (including any additional Products produced in accordance with Section 6.1 or 6.2 or 6.3), delivered by Patheon, and not rejected, recalled or returned in accordance with Section 6.1 or 6.2 as a result of a failure by Patheon to provide Manufacturing in accordance with Specifications, cGMPs, Applicable Laws, the Quality Agreement, any other Technical Information or this Agreement.

Quantity Held: The total quantity of Active Materials that is at the Manufacturing Site on the last day of such quarter.

Patheon will target within ****, but within no more than **** after the **** of each ****, Patheon shall prepare an annual reconciliation of Active Materials in accordance with the reconciliation report form annexed hereto as Schedule I including the calculation of the "**Actual Annual Yield**" or "**AAY**" for the Products (including all strengths**)** at the Manufacturing Site during the Year. AAY is the percentage of the Quantity Dispensed that was converted to Products and is calculated as follows:

$$\frac{\text{Quantity Converted during the Year}}{\text{Quantity Dispensed during the Year}} \times 100\%$$

Patheon shall use its commercially reasonable efforts to obtain maximum yield of the Products from Active Materials provided by the Client in connection with its Manufacturing services provided hereunder. The target yield in respect of the Products at the Manufacturing Site is **** ("**Target Yield**"). The parties will meet annually to

review the acceptable Target Yield and adjust it as appropriate in order to achieve the parties' objective to move towards an improved target yield. Patheon shall strive to maintain Actual Annual Yield levels for the Products equal to or above the current Target Yield. For the sake of clarity, the AAY and the Target Yield are each calculated for all of the Products as a whole, and not on a strength-by-strength or packaging-by-packaging basis.

(b) Shortfall Calculation. If the Actual Annual Yield falls more than **** below the respective Target Yield in a Year, then the shortfall for such Year (the "**Shortfall**") shall be determined based on the following calculation:

Shortfall = ****

The Shortfall shall be disclosed by Patheon on the reconciliation report prepared in the form annexed hereto as Schedule I.

(c) Credit. If there is a Shortfall for the Products in a Year, then Patheon shall credit the Client's account for the value of any such Shortfall, as determined using the following formula, not later than **** after the end of each Year.

****

Patheon acknowledges that such credit is a liquidated damage reflecting a reasonable measure of actual damages and is not a penalty. Each credit under this Section 2.2 shall be summarized on the reconciliation report prepared in the form annexed hereto as Schedule I and shall be made not later than **** after the end of each Year. Upon expiration or termination of this Agreement any remaining credit amount owing under this Section 2.2 (or other Section under this Agreement) shall be reimbursed to the Client by payment thereof to the Client.

(d) ****. Notwithstanding the foregoing provisions of this Section 2.2, Patheon's liability for Active Materials calculated in accordance with Section 2.2(c) for the Products in a Year ****.

(e) No Material Breach. It shall not constitute a material breach of this Agreement by Patheon, for the purposes of Section 8.2(a), if the ****.

(f) Use of Active Materials. Patheon shall always use the first-expiry, first-out (FEFO) method of material usage.

ARTICLE 3

CLIENT'S OBLIGATIONS

3.1 Payment.

Pursuant to the terms of this Agreement, the Client shall pay Patheon for the provision of the Manufacturing according to the fees specified in Schedules B and C hereto (such fees being subject to adjustment in accordance with the terms hereof).

3.2 Supply of Active Materials.

Client shall, at its sole cost and expense, deliver the Active Materials to Patheon (in accordance with Section 2.1(f)) in sufficient quantities and at such times as mutually agreed upon by the parties to facilitate the provision of the Manufacturing by Patheon. The Active Materials shall be held and stored by Patheon on behalf of the Client on the terms and subject to the conditions herein contained, the Specifications, cGMPs and any written instructions provided by the Client to Patheon from time to time. Title to the Active Materials shall at all times belong to and remain the property of the Client. Any Active Materials received by Patheon shall only be used by Patheon to provide the Manufacturing. Patheon will not chemically or biologically modify the Active Materials except in accordance with the Specifications. Patheon's liability with respect to any lost or damaged Active Materials shall be as set forth in Section 10.2(a). Patheon will store Active Materials in a secure manner and in accordance with the Specifications.

ARTICLE 4

CONVERSION FEES AND COMPONENT COSTS

4.1 First Period Pricing.

The fees for the Manufacturing through **** are listed in Schedules B and C and are subject to the adjustments set forth in Section 4.3.

4.2 Price Adjustments - Subsequent Years' Pricing.

The fees for the Manufacturing during any period following the date set forth in Section 4.1 of this Agreement shall be determined in accordance with the following:

(a) Manufacturing and Component Costs. On each **** of this Agreement after **** (i.e., on **** and each **** thereafter during the term of this Agreement), Patheon and the Client shall be entitled to an adjustment to the fees (i) for Manufacturing in respect of the Products to reflect inflation, which adjustment shall be solely based on ****

****, unless the parties otherwise agree in writing and (ii) for Component costs ****.

(b) Annual Quantity.

The Client acknowledges that the fee for Manufacturing in respect of a Product in any Year is quoted based upon the Annual Volume and Minimum Order Quantity per Product specified in Schedule B (if applicable) and is subject to change following good faith discussions by the parties if the specified Annual Volume or Minimum Order Quantity (if and as applicable) increases or decreases. For greater certainty, if Patheon and the Client agree that the Annual Volume or Minimum Order Quantity (if and as applicable) in respect of a Product shall be reduced beyond the range of such values provided in the tables in Schedule B, and, as a result of such reduction, Patheon's costs for services relating to such Product increase on a per unit basis, then Patheon shall be entitled to an increase in the fee for Manufacturing in respect of such Product. In addition, for greater certainty, if Patheon and the Client agree that the Annual Volume or Minimum Order Quantity (if and as applicable) in respect of a Product shall be increased beyond the range of such values provided in the tables in Schedule B, and, as a result of such increase, Patheon's costs for services relating to such Product decrease on a per unit basis, then the Client shall be entitled to a decrease in the fee for Manufacturing in respect of such Product.

(c) Adjustments Due to Currency Fluctuations. On each **** following the date set forth in Section 4.1 of this Agreement (i.e., on **** and each **** thereafter during the term of this Agreement), ****. The adjustment will be calculated after all other fee adjustments under this Section 4.2 have been made. The adjustment will proportionately reflect the increase or decrease, if any, in the Set Exchange Rate compared to the Set Exchange Rate established for the prior Year or the Initial Set Exchange Rate, as the case may be. An example of the calculation of the price adjustment is set forth in Schedule K.

In connection with all fee adjustments requests pursuant to this Section 4.2, Patheon shall deliver to the Client by not later than **** of each **** a revised Schedule B in draft form and such budgetary pricing information or other documentation reasonably sufficient to demonstrate that an increase or decrease in the fee adjustment is justified (and/or upon the reasonable request of Client, such budgetary pricing information or other documentation reasonably sufficient to demonstrate to Client that a decrease in the fee adjustment is not justified), provided that to the extent such documents are subject to obligations of confidentiality between Patheon and its suppliers, Patheon shall make such

documents available, subject to the confidentiality obligations provided in this Agreement, to a third party designated by Client and approved by Patheon (such approval not to be unreasonably withheld or delayed) at Patheon's facility for the purpose of allowing such third party to confirm that the fee adjustments proposed by Patheon are justified. Upon delivery of such a fee adjustment request pursuant to this Section, each of the Client and Patheon shall forthwith use reasonable efforts to agree on a revised fee for the Manufacturing in respect of each affected Product, if any, and Schedule B shall be amended accordingly. If the parties are unable to agree on a revised fee for the Manufacturing in respect of each affected Product within **** after receipt by Client of Patheon's fee adjustment request, then ****. The revised fee shall be effective with respect to any Product ordered after the end of the then current **** or the date set forth in Section 4.1 of this Agreement, as applicable. For the sake of clarity, the revised fee shall not affect any Product ordered before the end of the then current **** or the date set forth in Section 4.1 of this Agreement, as applicable, even if such Product has not yet been delivered by the date of the fee change. An example of price adjustments under this Section 4.2 is shown in Schedule L.

4.3 Price Adjustments – Current Year Pricing.

During any Year of this Agreement, the fees set out in Schedule B shall be subject to adjustment in accordance with the following:

(a) Minimum Order Quantity. Subject to and without limiting Section 5.3, if at any time and from time to time Patheon or Client determines, acting reasonably and based on the forecasts and Firm Orders received from the Client, that the current Minimum Order Quantity (if applicable) listed in Schedule B for each specific Product strength will either not be met or will be exceeded (i.e., the actual Minimum Order Quantity and the costs of such variations, exceed the range of such value(s) provided in the tables in Schedule B), then Patheon or Client shall be entitled to request an adjustment to the fee for Manufacturing in respect of that Product to reflect the increased or decreased costs that Patheon will incur as a result of the increased or reduced volumes beyond the range of such values provided in the tables in Schedule B. To the extent that the fee for Manufacturing in respect of a Product has been previously adjusted pursuant to this clause (a) to reflect reduced volumes or increased volumes, the adjustment provided in this clause (a) shall operate based on the fees attributed to such Product at the time the last of such adjustments were made.

Extraordinary Increase or Decrease in Component Costs. If at any time market conditions result in Patheon's Components costs being *** than normal forecasted increases or decreases, then Patheon or Client shall be entitled

to an adjustment to the fee for Manufacturing in respect of any affected Product solely to compensate it for such increased or decreased Components costs that may be justified by reasonable documentation, provided that to the extent such documents are subject to obligations of confidentiality between Patheon and its suppliers, Patheon shall make such documents available, subject to the confidentiality obligations provided in this Agreement, to a third party designated by Client and approved by Patheon (such approval not to be unreasonably withheld or delayed) at Patheon's facility for the purpose of allowing such third party to confirm that the fee adjustments proposed by Patheon are justified. For the purposes of this clause (b), changes materially greater than normal forecasted increases or decreases shall be considered to have occurred only if: (i) ****; or (ii) ****. To the extent that Component costs have been previously adjusted pursuant to clause (a) of Section 4.2 or this clause (b) to reflect an increase or decrease in the cost of one or more Components, the adjustments provided for in (i) and (ii) above shall operate based on the costs attributed to such Components at the time the last of such adjustments were made.

In connection with a fee adjustment request pursuant to this Section 4.3, Patheon shall deliver to the Client a revised Schedule B and such budgetary pricing information or other documentation reasonably sufficient to demonstrate that an increase or decrease in fee adjustment is justified (and/or upon the reasonable request of Client, such budgetary pricing information or other documentation reasonably sufficient to demonstrate to Client that a decrease in the fee adjustment is not justified), provided that to the extent such documents are subject to obligations of confidentiality between Patheon and its suppliers, Patheon shall make such documents available, subject to the confidentiality obligations provided in this Agreement, to a third party designated by Client and approved by Patheon (such approval not to be unreasonably withheld or delayed) at Patheon's facility for the purpose of allowing such third party to confirm that the fee adjustments proposed by Patheon are justified. Upon delivery of such a request, each of the Client and Patheon shall forthwith use all reasonable efforts to agree on a revised fee for the Manufacturing in respect of each affected Product and Schedule B shall be amended accordingly. If the parties are unable to agree on a revised fee for the Manufacturing in respect of each affected Product within **** after receipt by Client of Patheon's fee adjustment request, then ****.

Patheon will use commercially reasonable efforts to ensure that the increases in cost of Components and Bill Back Items will not be materially greater than normal forecasted increases.

4.4 Adjustments Due to Technical Changes.

Amendments to the Specifications or the Quality Agreement requested by the Client will only be implemented following a good faith technical and cost review by Patheon and are subject to the Client and Patheon reaching agreement in writing as to revisions, if any, to the fees specified in Schedules B or C necessitated by any such amendment. Amendments to the Specifications, the Quality Agreement or the Manufacturing Site or any material deviations from the assumptions specified in Schedule B requested by Patheon will only be implemented following the written approval of Client, such approval not to be unreasonably withheld. If the Client accepts the proposed fee change (if any), the proposed change in the Specifications or the Quality Agreement requested by Client shall be implemented, and the fee change shall become effective only with respect to those orders of Products that are manufactured in accordance with the revised Specifications or Quality Agreement. In addition, the Client agrees ****. If the parties are unable to agree on what costs incurred by Patheon are reasonable, then the parties shall resolve such issue in accordance with Section 12.1 Open purchase orders for Components and Bill Back Items no longer required under any revised Specifications or Quality Agreement that were placed by Patheon with suppliers in order to fill Firm Orders or in accordance with Section 5.2 shall be cancelled or used in connection with other Patheon services where possible, and where such orders are not subject to cancellation without penalty or cannot be used in connection with other Patheon services, Client shall pay to Patheon ****.

4.5 Multi-Country Packaging Requirements.

Prices in Schedule B are for bulk or packaged (with Primary and Secondary Packaging Components and/or Printed Packaging Components, as applicable) Product(s). Should Client wish to have Patheon provide Manufacturing in respect of the Product in

additional packaging formats, Patheon shall, in good faith, prepare a quotation for consideration by the Client of the additional Primary and Secondary Packaging Component costs and Printed Packaging Components costs, if any, and the change over fees for the Product. The agreed additional packaging requirements and related packaging costs and change over fees shall be set out in a written amendment to this Agreement mutually agreed upon by the parties.

4.6 Improvement of Manufacturing Efficiency.

EACH OF PATHEON AND THE CLIENT SHALL USE ITS REASONABLE EFFORTS TO IMPROVE PRODUCT MANUFACTURING EFFICIENCY, WHEN AND WHERE POSSIBLE, DURING THE TERM OF THIS AGREEMENT. ANY COST SAVINGS RESULTING IN WHOLE OR IN PART FROM CONTRIBUTIONS BY THE CLIENT SHALL BE **.**

ARTICLE 5

ORDERS, SHIPMENT, INVOICING, PAYMENT

5.1 Orders and Forecasts.

(a) Rolling Forecasts. Concurrent with the execution of this Agreement, the Client shall provide Patheon with a written **** forecast of the volume of each Product that the Client then anticipates will be required to be produced and delivered to the Client during ***. Such forecast will be updated by the Client **** on or before the **** of **** on a ****, and the Client shall use commercially reasonable efforts to update such forecast forthwith if the Client determines that the volumes contemplated in the most recent of such forecasts for the next **** has changed by more than ****. The most recent **** forecast shall prevail.

(b) Firm Orders. On or before the **** of each ****, the Client shall issue a firm written order ("**Firm Order**") for Manufacturing in respect of the Products to be produced and released to the Client on one (1) or more dates not less than **** from the first day of the calendar month immediately following the date that the Firm Order is submitted (each, a **"Delivery Date"**). For clarity, Products will be placed at Client's disposal for collection by Client's carrier on the date of release by Patheon Quality Control. Such date of Patheon Quality Control release shall be deemed to be the Delivery Date. Such Firm Orders submitted to Patheon shall specify the Client's Manufacturing purchase order number, quantities by Product type, monthly delivery schedule, shipment location and any other elements necessary to ensure the timely production and shipment of the Products. The quantities of Products ordered in such Firm Orders shall be ****. In the event that Client cancels

any or part of a Firm Order, Client shall be responsible for **** of such cancelled part of a Firm Order, provided that if Client informs Patheon at any time during the **** of this Agreement, at **** prior to the commencement of dispensing, that it would like to cancel any or part of such Firm Order, then ****. Patheon shall indicate its acceptance of Firm Orders for the Product by promptly acknowledging acceptance of each Firm Order in writing within **** of its receipt; each such acceptance shall include, subject to Client confirmation, the Delivery Date for the Product ordered. The agreed upon Delivery Date may be amended from time to time by written agreement of the parties, with the newly agreed upon date becoming the new Delivery Date. For the avoidance of doubt, Patheon will accept all Firm Orders submitted by the Client for Product so long as ****. All Firm Orders will be deemed to incorporate all of the terms and conditions in this Agreement.

(c)**** Forecast. On or before the **** of **** of ****, the Client shall provide Patheon with a written **** forecast (broken down by ****) of the volume of each Product the Client then anticipates will be required to be produced and delivered to the Client during the ****.

5.2 Reliance by Patheon.

(a) The Client understands and acknowledges that Patheon will rely on the Firm Orders and rolling forecasts submitted pursuant to Sections 5.1(a) and (b) in ordering the Components required to meet such Firm Orders. In addition, the Client understands that to ensure an orderly supply of such Components and/or to achieve economies of scale in costs, it may be necessary for Patheon to purchase such Components in sufficient volumes to meet the production requirements for Products during part of the forecasted periods referred to in Section 5.1(a) or to meet the production requirements of any longer period agreed to in writing by Patheon and the Client. Accordingly, the Client authorizes Patheon to purchase Components in order to satisfy the Manufacturing requirements for Products for the **** contemplated in the most recent forecast provided by the Client pursuant to Section 5.1(a)

or in order to satisfy the vendor's minimum order quantity for such Components, whichever is greater, and agrees that Patheon may make such other purchases of Components to meet Manufacturing requirements during such longer periods as may be agreed to in writing from time to time by the Client at the request of Patheon or the Client. If Components ordered by Patheon pursuant to Firm Orders or this Section 5.2 are not included in finished Products manufactured for the Client within **** after the forecasted month in respect of which such purchases have been made (or such longer period as the parties may agree) or if such Components have expired during such period, then the Client shall pay to Patheon ****. If the parties are unable to agree on what costs incurred by Patheon are reasonable, then the parties shall resolve such issue in accordance with Section 12.1 Patheon shall use commercially reasonable efforts to use such Components in connection with third party clients. Patheon shall be responsible for obtaining material safety data sheets (**"MSDS"**) and certificates of analysis or compliance of all Raw Materials purchased by Patheon pursuant to this Agreement. The MSDS and certificates of analysis or compliance will be used to establish conformance of the Raw Materials to the Specifications and to advise Patheon as to any safety or special handling requirements related to the Raw Materials.

(b) Patheon shall provide Client, initially upon execution of this Agreement and thereafter on an annual basis, with a listing of all components which are unique to the Client, which Patheon anticipates purchasing pursuant to the terms of this Agreement (in accordance with rolling forecasts and Firm Orders as per Section 5.2(a)) (the "**Exclusive Component Purchasing Summary**"). The Exclusive Component Purchasing Summary shall indicate which components have a limited shelf-life and that are subject to minimum order quantities as specified by the supplier.

5.3 Minimum Orders.

Patheon will only Manufacture Products in multiples of the Minimum Order Quantities as set out in Schedule B. Notwithstanding the foregoing, the parties acknowledge and agree that ****

****. With respect to Product supplied, after the **** following release by Patheon of the respective batch from which the Product has been supplied (such release date to be notified by Patheon to the Client promptly following the release), the Client shall pay Patheon **** per pallet per month thereafter for the time that Patheon is required to store any Surplus New Product on behalf of the Client. If Surplus New Product requires refrigeration, then the applicable storage fee will be **** per pallet per month for the time that Patheon is required to store such Surplus New Product on behalf of the Client. Storage fees are subject to a ****. Patheon shall provide the Client with an annual invoice setting forth the cumulative storage fees associated with any Surplus New Product.

Subject to the paragraph immediately below, the Client shall use commercially reasonable efforts to place Firm Orders with Patheon in a timely manner to ensure that Surplus New Product can be packaged or shipped in compliance with the required levels of remaining shelf life as indicated in this Agreement. In the event that the Client does not place Firm Orders in a timely manner with the direct result that Surplus New Product cannot be supplied in accordance with the shelf life, and in the event that the Client will not accept the Product with less than the required remaining shelf life, then the Client ****.

Without prejudice to any other rights and obligations that Patheon may have under the Agreement, Patheon will use commercially reasonable efforts to manage its inventory so that such Surplus New Product can be supplied in accordance with the terms of the Agreement for future Firm Orders placed by the Client and to manage its inventory of Surplus New Product to comply with the requirements regarding shelf life mentioned above. In the event that the Client places a purchase order with Patheon and the difference between the amount of new Product ordered and the amount of Surplus New Product that Patheon has on stock is more or less than ****, then Patheon shall immediately inform the Client and provide the Client with an opportunity to modify such purchase order.

5.4 Shipments.

Shipments of Products shall be made ****, unless otherwise mutually agreed in writing. Risk of loss or of damage to Products shall remain with **** at which time risk of loss or damage (and title to such Products) shall transfer to ****. **** shall, in accordance with ****, (i) arrange for shipping to be paid by the Client and (ii) at **** risk and expense, obtain any export license or other official authorization necessary to export the Products. **** shall arrange for insurance and shall select the freight carrier to be used by **** to ship Products and may

monitor **** shipping and freight practices as they pertain to this Agreement. Products shall be packaged for transport and transported in accordance with the Specifications, and temperature monitors (as mutually agreed upon by the parties) will be included with each shipment of Products. The residual shelf life of the Product must be at least **** following release of the Product by Patheon.

5.5 <u>On Time Delivery</u>

(a) Patheon shall ****. Patheon and the Client understand that there may be uncertainties and necessary adjustments associated with any initial manufacturing period and the parties agree that they will work together closely to expedite deliveries and manage the scheduling of the initial Product launch.

(b) If subsequent to the creation of a delivery plan, Patheon is unable to supply the Client with the quantity of Product ordered pursuant to the Firm Order within **** following the Delivery Date and ****, then that inability to supply will constitute a late delivery of Product (**"Late Delivery"**), and the Client ****. If the parties mutually agree in writing to change the Delivery Date for any reason then that new date becomes the Delivery Date.

**** In no event shall the Late Delivery ****. Patheon acknowledges that ****.

No credit for Late Delivery will occur in the event the Late Delivery is caused by a Force Majeure Event (as defined below) or by other events outside of Patheon's reasonable control, including, but not limited to, delays in: ****. Additionally, on time delivery credits provided for in this Section are only available to Client if ****.

(c) Upon the written request of Client, Patheon shall agree to assist, at Client's cost, in ****

****. Patheon shall ensure that it has enforceable written agreements with its approved subcontractors ****. Upon Client's request, Patheon shall immediately co-operate with Client to ****.

Notwithstanding the foregoing, ****.

Client shall not be liable to pay the direct costs incurred by Patheon and/or any approved subcontractor in assisting and/or supporting the respective ****. All such reasonable costs shall be borne by Patheon and/or its approved subcontractors.

5.6 Invoices and Payment.

Invoices shall be sent by fax or email to such fax number or email address as may be provided by the Client in writing from time to time. Such invoices for Products may only be sent **** (with respect to which such invoices apply) in accordance with the Quality Agreement, and such invoices shall reflect any outstanding credit amounts owed under this Agreement by Patheon to Client. Patheon shall also submit to the Client, with each shipment of Products, a duplicate copy of the invoice covering such shipment. Patheon shall also provide the Client with an invoice covering any Component which has been purchased by Patheon pursuant to the terms of this Agreement and which has not been used in accordance with the terms of this Agreement. Patheon will include sufficient details in all such invoices to enable identification of such Component. Each such invoice shall, to the extent applicable, identify the Client's Manufacturing purchase order number, Product numbers, names and quantities, unit price, freight charges and the total amount to be remitted by the Client (after taking into account any outstanding credit amounts owed under this Agreement by Patheon to Client). The Client shall pay all undisputed amounts in such invoices within **** of the date thereof provided, however, that payment will only be for ****.

5.7 Inventory Reports.

Patheon hereby agrees to provide to the Client a monthly inventory statement at the end of each calendar month of this Agreement setting out as a minimum the amount of Active Materials and Product (in bulk and finished form) that Patheon is holding in stock at the Manufacturing Site.

ARTICLE 6

PRODUCT CLAIMS AND RECALLS

6.1 Product Claims.

(a) Product Claims. The Client has the right to reject any portion of any shipment of Products that deviates from the **** any remainder of such shipment. The Client shall inspect the Products manufactured by Patheon upon receipt thereof and shall give Patheon written notice (a "**Deficiency Notice**") of all claims for Products that deviate from the **** within **** after the Client's receipt thereof (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, within **** after discovery thereof by the Client, but in no event after the expiration date of the Product). Should the Client fail to provide Patheon with the Deficiency Notice within the applicable period, then the delivery shall be deemed to have been accepted by the Client on the **** after delivery or **** after discovery, as applicable. Except as otherwise provided in this Agreement, Patheon shall have no liability for any deviations for which it has not received notice within the applicable period. For the sake of clarity, if the Client does not provide a Deficiency Notice within **** after Client's receipt of the applicable Product, but instead provides a Deficiency Notice within **** after discovery of a defect not reasonably susceptible to discovery upon receipt of the Product, then Client retains its rights and remedies with respect to the defective Product.

(b) Determination of Deficiency. Upon receipt of a Deficiency Notice, Patheon shall have **** to advise the Client by notice in writing that it disagrees with the contents of such Deficiency Notice. If the Client and Patheon fail, after good faith discussions, to agree within **** after Patheon's notice to the Client as to whether any Products identified in the Deficiency Notice deviate from the Specifications or cGMPs, then the parties shall mutually select an independent laboratory to evaluate if the Products deviate from ****. Such evaluation shall be binding on the parties, and if such evaluation certifies that any Products deviate from ****, the Client may reject those Products in the manner contemplated in this Section 6.1. If such evaluation does not so certify in respect of any such Products, then the Client shall be deemed to have accepted delivery of such Products on the **** after delivery (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, on the ****

after discovery thereof by the Client, but in no event after the expiration date of the Product). The decision of the laboratory shall be binding on the parties, and the party that the decision disfavours shall bear the costs charged by such laboratory in connection with its decision.

(c) Shortages. Claims for shortages in the amount of Products shipped by Patheon shall be dealt with as may reasonably be agreed to by the parties.

6.2 Product Recalls and Returns.

(a) Records and Notice. **** shall each maintain such records as may be necessary to permit a Recall (as defined below) of any Products delivered to the Client or customers of the Client. **** shall promptly notify **** by telephone (to be confirmed in writing) of any information which is reasonably likely to adversely affect the marketability, safety or effectiveness of the Products in a material manner and/or which might result in the Recall or seizure of the Products. Upon receiving any such notice or upon any such discovery, **** shall cease and desist from further shipments of such Products in its possession or control until a decision has been made whether a Recall or some other corrective action is necessary. The decision to initiate a Recall or to take some other corrective action, if any, shall be made and implemented by ****. "**Recall**" shall mean any action (i) by the Client to recover title to or possession of quantities of the Products sold or shipped to third parties (including, without limitation, the voluntary withdrawal of Products from the market); or (ii) by any regulatory authorities to detain or destroy any of the Products. Recall shall also include any action by either party to refrain from selling or shipping quantities of the Products to third parties which would have been subject to a Recall if sold or shipped.

(b) Recalls. In the event (i) any governmental or regulatory authority issues a directive, order or, following the issuance of a safety warning or alert with respect to a Product, a written request that any Product be Recalled, (ii) a court of competent jurisdiction orders such a Recall, or (iii) **** determines that any Product should be Recalled or that a "dear doctor" letter is required relating to the restrictions on the use of any Product, Patheon will co-operate as reasonably required by the Client, having regard to all applicable laws and regulations.

(c) Product Returns. **** shall have the responsibility for handling customer returns of the Products. **** shall provide **** with such assistance as **** may reasonably require to handle such returns.

6.3 Patheon's Responsibility for Defective and Recalled Products.

(a) Defective Product. In the event the Client rejects Products in accordance with Section 6.1 and the deviation is determined to have arisen from Patheon's failure to provide the Manufacturing in accordance with ****, Patheon shall promptly, ****

****. For greater certainty, Patheon's responsibility for ****.

(b) Recalled Product. To the extent that a Recall results from, or arises out of, a failure by Patheon to provide the Manufacturing in accordance with ****, Patheon shall be responsible for ****. For greater certainty, Patheon's responsibility for ****. In the event that Patheon is unable to replace the Recalled Products, then the Client may request Patheon to ****. In all other circumstances, Recalls shall be made at the Client's cost and expense. Notwithstanding anything to the contrary in this Agreement, PATHEON shall only be required to ****. The quantity of Active Materials contained in Product described above shall be included in the Quantity Dispensed but not in the Quantity Converted for purposes of determining the Shortfall.

(c) Patheon shall have no obligation for any deficiencies in, or other liabilities associated with, any Product manufactured by it (collectively, **"Product Claims"**) to the extent such Product Claim ****

****.

6.4 Disposition of Defective or Recalled Products.

The Client shall not dispose of any damaged, defective, returned or Recalled Products in relation to which it intends to assert a claim against Patheon without Patheon's prior written authorization to do so. Alternatively, Patheon may instruct the Client to return such Products to Patheon. Patheon shall bear the cost of disposition with respect to any damaged, defective, returned or Recalled Products in relation to which it bears responsibility under Section 6.3 hereof. In all other circumstances, the Client shall bear the cost of disposition, including all applicable fees for Manufacturing, with respect to any damaged, defective, returned or Recalled Products.

6.5 Customer Questions and Complaints.

The Client shall have the sole responsibility for responding to questions and complaints from the Client's customers. Questions or complaints received by Patheon from the Client's customers shall be promptly referred to the Client. Patheon shall cooperate as reasonably required to allow the Client to determine the cause of and resolve any customer questions and complaints. Such assistance shall include follow-up investigations, including testing. In addition, Patheon shall promptly provide the Client with all mutually agreed upon information that will enable the Client to respond properly to questions or complaints relating to the Products as provided in the Quality Agreement. Unless it is determined that the cause of any customer complaint resulted from a failure by Patheon to provide the Manufacturing in accordance with ****.

6.6 ****.

****.

ARTICLE 7

CO-OPERATION

7.1 Quarterly Review.

Each party shall forthwith upon execution of this Agreement appoint one of its employees to be a relationship manager responsible for liaison between the parties. The relationship managers shall meet not less than **** to review the current status of the

business relationship and manage any issues that have arisen. Each party may replace its relationship manager at any time and will fill a vacancy for its relationship manager as soon as reasonably practicable. Each party shall promptly notify the other party of any substitution of another person as its relationship manager. Each party's relationship manager shall be available throughout the term of this Agreement to answer any reasonable questions from the other party's relationship manager.

7.2 Governmental Agencies.

Client may communicate with any governmental agency, including but not limited to governmental agencies responsible for granting regulatory approval for the Products, regarding Product specific issues. Subject to Section 7.8, Patheon may communicate with any governmental agency, including but not limited to governmental agencies responsible for granting regulatory approval for the Products, regarding Product specific issues, if ****.

7.3 Records and Accounting by Patheon.

Patheon shall keep records of the Manufacture, testing and shipping of the Products, and retain samples of such Products as are necessary to comply with manufacturing regulatory requirements applicable to Patheon, as well as to assist with resolving Product complaints and other similar investigations. Copies of such records and samples shall be retained for a period of **** following the date of Product expiry, or longer if required by law, at which time the Client will be contacted in writing concerning the delivery and destruction of such documents and/or Products, ****. The Client is responsible for retaining samples of the Products necessary to comply with the legal/regulatory requirements applicable to the Client.

7.4 Inspection.

During the term of this Agreement and for **** thereafter, or alternatively the period of time less than **** in which Patheon is required to keep reports and records pursuant to Section 7.3, the Client may inspect Patheon reports and records relating to this Agreement, including without limitation relating to the invoices issued hereunder, during normal business hours and with reasonable advance notice, provided a Patheon representative is present during any such inspection.

7.5 Access.

Patheon shall provide the Client with reasonable access at mutually agreeable times (as discussed in good faith) to the areas of the Manufacturing Site in which the

Products are manufactured, stored, handled or shipped in order to permit the Client's verification of the performance of the Manufacturing in accordance with the Specifications, cGMPs, Applicable Laws, the Quality Agreement and other Technical Information and this Agreement. For greater certainty, the right of access provided in this Section 7.5 shall not include a right to access or inspect Patheon's financial records.

7.6 Notification of Regulatory Inspections.

In accordance with applicable laws and regulations governing regulatory inspections, and without waiving any rights and protections afforded Patheon under such laws and regulations, Patheon shall permit authorized representatives of relevant regulatory authorities, including the FDA, to inspect any plant and production facilities (including the Manufacturing Site) relating to or used in connection with the Manufacturing and/or the Product. Patheon shall notify the Client within **** of any inspections by any governmental agency that may bear directly on the Products. ****.

7.7 Reports.

Patheon will supply on an annual basis or as requested by Client at any other time all Product data in its control, including release test results, complaint test results, and all investigations (in manufacturing, testing and storage), that the Client reasonably requires in order to complete any filing under any applicable regulatory regime, including any Annual Report that the Client is required to file with the FDA. All rights, title and interest in any and all data related to Product that is generated or derived by Patheon in the course of performing the Manufacturing shall be the exclusive property of Client (and the confidential information of ****). **** hereby makes, and agrees to make, any and all assignments necessary to effect, exclusively and throughout the world, the ownership by **** of such data. **** shall, and shall cause its employees and contractors to, fully cooperate with and sign any documents reasonably requested by **** to evidence, perfect or take any other action with respect to such assignments or to obtain protection, maintain or take any other action regarding such assigned data.

7.8 FDA Filings

(a) Regulatory Authority. The Client shall have the sole responsibility for filing all documents with all Regulatory Authorities and taking any other actions that may be required for the receipt and/or maintenance of Regulatory Authority approval for the commercial Manufacture of the Products. Patheon shall assist the Client, as is reasonable, to obtain Regulatory Authority approval for the commercial Manufacture of all Products as quickly as reasonably possible.

(b) Verification of Data. At least **** prior to filing any documents with any Regulatory Authority that incorporate data generated by Patheon, the Client shall ****.

(c) Verification of CMC. At least **** prior to filing with any Regulatory Authority any documentation which is or is equivalent to the FDA's Chemistry and Manufacturing Controls ("CMC") related to any Marketing Authorization, such as a New Drug Application or Abbreviated New Drug Application, the Client shall ****.

(d) Deficiencies. If in Patheon's sole discretion, acting reasonably, Patheon determines that any of the information provided by the Client in accordance with paragraphs (b) and (c) above is inaccurate or deficient in any manner whatsoever, and Patheon reasonably believes that Patheon's standing with regulatory authorities may be jeopardized thereby (the "**Deficiencies**"), Patheon shall notify the Client in writing of such Deficiencies promptly but in no event less than **** prior to Client's applicable scheduled filing with the Regulatory Authority. The parties shall work together in good faith to have such Deficiencies resolved prior to any pre-approval inspection.

ARTICLE 8

TERM AND TERMINATION

8.1 Initial Term.

This Agreement shall become effective as of the Effective Date and shall continue for five (5) years following the Effective Date (the "**Initial Term**"), unless terminated earlier by one of the parties in accordance herewith. This Agreement shall automatically continue after the Initial Term for successive terms of one (1) year each unless either party gives written notice to the other party of its intention to terminate this Agreement at least twelve (12) months prior to the end of the then current term.

8.2 Termination.

(a) Either party at its sole option may terminate this Agreement as a whole or on a country-by-country basis upon written notice in circumstances where the other party has failed to remedy a material breach of any of its representations, warranties or other

obligations under this Agreement within **** following receipt of a written notice (the "**Remediation Period**") of said breach that expressly states that it is a notice under this Section 8.2(a) (a "**Breach Notice**").

(b) Either party at its sole option may immediately terminate this Agreement upon written notice, but without prior advance notice, to the other party in the event that: (i) the other party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by such other party; or (iii) this Agreement is assigned by such other party for the benefit of creditors.

(c) The Client may terminate this Agreement as to any Product or on a country-by-country basis upon **** prior written notice in the event that any governmental agency takes any action, or raises any objection, that prevents the Client from importing, exporting, purchasing or selling such Product.

(d) Patheon may terminate this Agreement upon **** prior written notice if the Client assigns pursuant to Section 13.6 any of its rights under this Agreement to an assignee that, in the opinion of Patheon acting reasonably, is: (i) not a credit worthy substitute for the Client; or (ii) a competitor of Patheon, where a "competitor of Patheon" means a corporation which (a) specializes in the business of manufacturing pharmaceutical products for third parties and (b) does not directly or indirectly own or market pharmaceutical products in its own name.

(e) A party may terminate this Agreement when permitted pursuant to Section 13.7.

(f) The Client may terminate this Agreement as a whole or on a country-by-country basis due to Client's discontinuation of the development of Product manufactured at the Manufacturing Site, upon written notice delivered at least **** prior to such discontinuation.

(g) The Client may, upon the completion of **** of this Agreement, terminate this Agreement as a whole or with respect to a particular countr(ies) at any time, for any or no reason, upon **** notice to Patheon, provided ****. The Client may, upon the completion of **** of this Agreement, terminate this Agreement as a whole or with respect to a particular country(ies) at any time, for any or no reason, upon ****.

8.3 Obligations on Termination.

If this Agreement expires or is terminated in whole for any reason, then following the expiration or termination of this Agreement, or the end of the Wind-Down Period, if applicable (in addition to any other remedies either party may have in the event of default by the other party):

(a) the Client shall take delivery of and pay for (in accordance with Section 5.6) all undelivered Products that are manufactured and/or packaged pursuant to a Firm Order, at the price in effect at the time the Firm Order was placed.

(b) the Client shall purchase, at Patheon's cost ****, the remaining Components which were purchased by Patheon in contemplation of filling Firm Orders or in accordance with Section 5.2 prior to notice of termination being given to the extent that such Components cannot be returned or used to produce product for another client; and (ii) all remaining work-in-process produced by Patheon in contemplation of filling Firm Orders prior to notice of termination being given. If the parties are unable to agree on what costs incurred by Patheon are reasonable, then the parties shall resolve such issue in accordance with Section 12.1

(c) the Client acknowledges that no competitor of Patheon (as defined in Section 8.2(d)) shall be permitted access to the Manufacturing Site.

(d) Client will make commercially reasonable efforts, at its own expense but with Patheon's reasonable cooperation, to remove from Patheon site(s), within ****, all of Client's Components, Active Materials and supplies, undelivered Product and works-in-progress, chattels, equipment or other moveable property owned by Client, related to the Agreement and located at a Patheon site or that is otherwise under Patheon's care and control (**"Client Property"**). If Client fails to remove the Client Property within **** following the termination or expiration of the Agreement (or following the end of the Wind-Down Period, if applicable), Client will pay Patheon **** per pallet, per month, one pallet minimum (**** per pallet, per month, one pallet minimum, for any of the Client Property that contains controlled substances or requires refrigeration) thereafter for storing the Client Property and will assume any third party storage charges invoiced to Patheon regarding the Client Property. Patheon will invoice Client for the storage charges as set forth in Section 5.6 of this Agreement.

If this Agreement expires or is terminated in whole for any reason, then (in addition to any other remedies the Client may have in the event of default by Patheon), Patheon shall

return to the Client all Client Property (with shipping and related expenses, if any, to be borne by the Client), following such expiration or termination or the end of the Wind-Down Period, if applicable.

In addition, for a period of **** after the termination or expiration of this Agreement (the "Wind-Down Period"), Client may continue to order Manufacturing, and Patheon shall continue to provide Manufacturing in accordance with such orders from Client (if any), in each case subject to the terms and conditions of this Agreement. In the event of termination by Patheon pursuant to Section 8.2(a) due to Client's failure to pay undisputed amounts, Patheon may require that Client pay such amounts before filling any Firm Orders and may require that Client pre-pay for any Manufacturing provided during the Wind-Down Period. Furthermore, upon reasonable request by Client, Patheon will use commercially reasonable and good faith efforts to discuss with Client and come to an agreement with Client with respect to the terms for the performance of other transition services that are reasonably requested by Client.

Without limiting the foregoing, upon termination of this Agreement by Client pursuant to sections 8.1, 8.2 (a) or (b) or 13.7, Client shall have the right, where applicable, to ****. In such circumstances, Patheon and its affiliates will co-operate, and use its commercially reasonable efforts to cause its approved subcontractors to co-operate, in good faith with Client to ****. Any termination or expiration of this Agreement shall not affect any outstanding obligations or payments due hereunder prior to such termination or expiration, nor shall it prejudice any other remedies that the parties may have under this Agreement. For greater certainty, termination of this Agreement for any reason shall not affect the obligations and responsibilities of the parties pursuant to Articles 6, 8, 9, 10, 11, 12 and 13 and Sections 1.1, 7.3, 7.4, 7.5, 7.6 and 7.7, all of which survive any termination.

ARTICLE 9

REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 Authority.

Each party covenants, represents and warrants that (i) it has the full right and authority to enter into this Agreement, and that it is not aware of any impediment that would inhibit its ability to perform its obligations hereunder and (ii) it is a corporation duly organized, validly existing and in good standing under the laws of its incorporating jurisdiction and has all requisite power and authority to enter into this Agreement.

9.2 Client Warranties.

The Client covenants, represents and warrants that, to the Client's knowledge as of the Effective Date:

(a) the provision of the Manufacturing by Patheon solely in respect of any Product pursuant to this Agreement as directed in the new drug application for the Product that was approved by the U.S. Food and Drug Administration or use or other disposition of any Product by Patheon as may be required to perform its obligations under this Agreement does not and will not infringe any Third Party Rights;

(b) there are no actions or other legal proceedings in the Territory, the subject of which is the infringement of Third Party Rights related to any of the Specifications, or the bulk Product or any of the Active Materials provided by the Client to Patheon, or the sale, use or other disposition of any Product Manufactured in accordance with the Specifications; and

(c) the Products, if labelled and Manufactured in accordance with the Specifications and in compliance with applicable cGMPs, Applicable Laws, the Quality Agreement and other Technical Information and this Agreement (i) may be lawfully sold and distributed in every jurisdiction in which the Client has Regulatory Authority approval to market such Products, (ii) ****, and (iii) will be safe for human consumption as directed on the approved labelling for such Products.

In addition, Client covenants, represents and warrants that:

(i) the Specifications for each of the Products are its or its Affiliate's property or licensed to the Client and that the Client may lawfully disclose the Specifications to Patheon;

(ii) to the Client's knowledge as of the Effective Date, any Intellectual Property provided by the Client to Patheon in connection with the provision of the Manufacturing according to the Specifications (i) is the Client's or its Affiliate's unencumbered property or is licensed to the Client, (ii) may be lawfully used as directed by the Client, and (iii) to the Client's knowledge as of the Effective Date, such use does not infringe and will not infringe any Third Party Rights; and

(iii) the Specifications for all Products, as provided by the Client to Patheon, conform to all applicable cGMPs and Applicable Laws.

9.3 Patheon Warranties.

Patheon covenants, represents and warrants that to Patheon's knowledge as of the Effective Date:

(a) any Intellectual Property owned by Patheon and utilized by Patheon in connection with the provision of the Manufacturing which has not been

provided by Client or used at the direction of Client, (i) is Patheon's or its Affiliate's unencumbered property, (ii) may be lawfully used by Patheon and (iii) does not infringe and will not infringe any Third Party Rights;

(b) it and its Manufacturing Site are in compliance with all laws and regulations applicable to their operations, including, without limitation, cGMPs and Applicable Laws;

(c) all Patheon personnel are fully qualified (by education, training and experience) to properly perform their tasks under this Agreement.

In addition, Patheon covenants, represents and warrants that:

(i) it shall perform the Manufacturing in accordance with the Specifications, cGMPs, Applicable Laws, the Quality Agreement and other Technical Information and this Agreement;

(ii) it will convey good title to the Product, free of all liens of any kind whatsoever; and

(iii) the Products, when delivered to Client, will be Manufactured according to the Specifications. For the sake of clarity, if Patheon performs any additional steps not specified in the Specifications in Manufacturing Products (e.g., by adding one or more additional components to the Products that are not specified in the Specifications), then Patheon will be deemed to have failed to Manufacture such Products in accordance with the Specifications.

The warranties provided in (i), (ii) and (iii) above shall survive inspection, test, acceptance and use of the Product.

9.4 Debarred Persons.

Patheon covenants that it will not in the performance of its obligations under this Agreement use the services of any person debarred or suspended under 21 U.S.C. §335(a) or (b) or by Health Canada or any comparable European regulatory authority. Patheon represents that it does not currently have, and covenants that it will not hire, as an officer, an employee or an independent contractor in connection with the Manufacturing any person who has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the *Federal Food, Drug, and Cosmetic Act* (United States) or any comparable Canadian or European law. If Patheon becomes aware of any breaches of this Section, it will promptly notify the Client.

9.5 Permits.

Patheon shall maintain at all relevant times all governmental permits, licenses, approvals, and authorities to the extent required to enable it lawfully to properly perform

the Manufacturing. The Client shall be solely responsible for obtaining or maintaining, on a timely basis, any permits or other regulatory approvals in respect of the Products or the Specifications, including, without limitation, all marketing and post-marketing approvals.

9.6 No Warranty.

EXCEPT AS OTHERWISE PROVIDED HEREIN, NEITHER PATHEON NOR CLIENT MAKES ANY WARRANTY OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT. PATHEON MAKES NO IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR WARRANTY OF MERCHANTABILITY WITH RESPECT TO THE PRODUCTS. THE CLIENT MAKES NO WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR WARRANTY OF MERCHANTABILITY WITH RESPECT TO THE ACTIVE MATERIALS OR COMPONENTS PROVIDED BY THE CLIENT TO PATHEON.

ARTICLE 10

REMEDIES AND INDEMNITIES

10.1 Consequential Damages.

To the maximum extent permitted by applicable law, except with respect to ****, under no circumstances whatsoever shall **** be liable to the other hereunder in contract, tort, negligence, breach of statutory duty or otherwise for any indirect, punitive, incidental, reliance, special, exemplary or consequential damages, including without limitation direct or indirect loss of profits, of production, of anticipated savings, of business or goodwill, regardless of any notice of the possibility of such damages.

10.2 Limitation of Liability.

(a) Active Materials. Except as expressly set forth in Section 2.2 hereof and this Section 10.2, under no circumstances whatsoever shall Patheon be responsible for any loss or damage to the Active Materials. ****.

(b) Maximum Liability. To the maximum extent permitted by applicable law, except with respect to breaches of confidentiality, Patheon's obligations under Article 6 and amounts owed to **** maximum liability per Year under this Agreement for any reason whatsoever, including, without limitation, any liability arising under Article 6 hereof or resulting from a breach of its representations, warranties or other obligations under this Agreement, shall not exceed the greater of (i) ****

**** and (ii) **** of the total fees paid under this Agreement by Client to Patheon in such Year, up to a maximum value of t**** in the aggregate.

10.3 Patheon.

Patheon agrees to defend, indemnify and hold the Client, its Affiliates and their respective officers, employees and agents harmless against any and all losses, damages, costs, claims, demands, judgments and liability to, from and in favour of third parties (other than Affiliates) resulting from, or relating to ****.

In the event of a claim, the Client shall: (a) promptly notify Patheon of any such claim; (b) use commercially reasonable efforts to mitigate the effects of such claim; (c) reasonably cooperate with Patheon in the defence of such claim; and (d) permit Patheon to control the defence and settlement of such claim, each at Patheon's cost and expense, provided that any settlement of such claim that does not contain an unconditional release of an indemnitee will require the prior written consent of such indemnitee, which such consent will not be unreasonably withheld.

10.4 Client.

The Client agrees to defend, indemnify and hold Patheon, its Affiliates and their respective officers, employees and agents harmless against any and all losses, damages, costs, claims, demands, judgments and liability to, from and in favour of third parties (other than Affiliates) resulting from, or relating to any claim ****.

In the event of a claim, Patheon shall: (a) promptly notify the Client of any such claims; (b) use commercially reasonable efforts to mitigate the effects of such claim; (c) reasonably cooperate with the Client in the defence of such claim; (d) permit the Client to control the defence and settlement of such claim, each at the Client's cost and expense, provided that any settlement of such claim that does not contain an unconditional release of an indemnitee will require the prior written consent of such indemnitee, which such consent will not be unreasonably withheld.

10.5 Reasonable Allocation of Risk.

The provisions of this Agreement (including, without limitation, this Article 10) are reasonable and create a reasonable allocation of risk having regard to the relative profits the parties respectively expect to derive from the Products.

ARTICLE 11

CONFIDENTIALITY

11.1 Confidentiality.

The provisions of the Confidentiality Agreement shall apply to all confidential information of the parties under this Agreement, which agreement remains in effect in accordance with its terms; provided, however, that the terms of the Confidentiality Agreement shall continue to govern the parties' obligations of confidentiality with respect to any confidential or proprietary information of the parties, for the term of this Agreement and for a period of **** following termination or expiration of this Agreement, except that the parties' obligations of confidentiality with respect to any confidential or proprietary information of the parties that is a trade secret under applicable law shall survive and continue in effect thereafter, in each case as though such agreement remained in full force and effect. For the sake of clarity, the Product manufacturing process, including without limitation the Product formulation process, and the analytical methods specific to the Product are all deemed to be the trade secrets of Client for the purposes of this Section 11.1. Promptly following any expiration or termination of this Agreement, each party shall return to the other party all originals and copies of the other party's confidential information and destroy all information, records and materials developed therefrom, unless otherwise expressly provided herein (e.g., under Section 7.3 (Records and Accounting by Patheon)).

Notwithstanding the foregoing, the parties acknowledge that Client will be permitted, and may be required pursuant to the rules and regulations promulgated under the Securities Exchange Act of 1934, as amended, to file a Current Report on Form 8-K disclosing the entry into this Agreement by Client and a brief description of the terms and conditions hereof that are material to Client. To the extent that either party reasonably determines that it is required to make a filing or any other public disclosure (other than as set forth in the preceding sentence) with respect to this Agreement or the terms or existence hereof to comply with the requirements, rules, laws or regulations of any applicable stock exchange, Nasdaq or any governmental or regulatory authority or body,

including without limitation the U.S. Securities and Exchange Commission (the "**SEC**") (collectively, the "**Disclosure Obligations**"), such party shall promptly inform the other party thereof and shall use reasonable efforts to maintain the confidentiality of the other party's confidential information in any such filing or disclosure. To the extent that either party reasonably determines that it is required to file a copy of this Agreement to comply with the Disclosure Obligations, such party shall promptly inform the other party thereof. Prior to making any such filing of a copy of this Agreement, the parties shall mutually agree on the provisions of this Agreement for which the parties shall seek confidential treatment, it being understood that if one party determines to seek confidential treatment for a provision for which the other party does not, then the parties will use reasonable efforts in connection with such filing to seek the confidential treatment of any such provision. The parties shall cooperate, each at its own expense, in such filing, including without limitation such confidential treatment request, and shall execute all documents reasonably required in connection therewith. In furtherance of the foregoing, the parties will agree as promptly as practicable after the Effective Date on the confidential treatment request to be filed with the SEC and the redacted form of this Agreement related thereto. In furtherance thereof, any redaction reasonably requested by either party shall be included in such filing. The parties will reasonably cooperate in responding promptly to any comments received from the SEC with respect to such filing in an effort to achieve confidential treatment of such redacted form; provided, however, that a party shall be relieved of such obligation to seek confidential treatment for a provision requested by the other party if such treatment is not achieved after the **** round of responses to comments from the SEC. Notwithstanding anything to the contrary in this Agreement, Client may make reference to the existence of this Agreement and describe in general terms the relationship between the parties in connection with any required securities filings without seeking Patheon's prior consent. This paragraph shall apply with respect to the filing of a copy of this Agreement or any public disclosure relating to this Agreement to comply with the Disclosure Obligations, notwithstanding the provisions of the Confidentiality Agreement.

ARTICLE 12

DISPUTE RESOLUTION

12.1 Commercial Disputes.

In the event of any dispute arising out of or in connection with this Agreement (other than a dispute determined in accordance with Section 6.1(b) or a Technical Dispute), the parties shall first try to solve it amicably. In this regard, any party may send a notice of dispute to the other, and each party shall appoint, within **** from receipt of such notice of dispute, a single representative having full power and authority to solve the dispute. The representatives so designated shall meet as necessary in order to solve such dispute. If these representatives fail to solve the matter within **** from their appointment, or if a party fails to appoint a representative within the **** period set forth above, such dispute shall immediately be referred to the Chief Operating Officer (or such other officer as he/she

may designate) of each party who will meet and discuss as necessary in order to try to solve the dispute amicably. Should the parties fail to reach a resolution under this Section 12.1, either party may refer the dispute to arbitration in accordance with Section 12.3. Notwithstanding the foregoing, neither party shall be prohibited from seeking injunctive or other equitable relief in any court of competent jurisdiction (including without limitation, in any case where issues involving the protection or unauthorized use or disclosure of a party's confidential information, trade secrets or intellectual property are involved).

12.2 Technical Dispute Resolution.

In the event of a dispute (other than disputes in relation to the matters set out in Sections 6.1(b) and 12.1) between the parties that is exclusively related to technical aspects of the manufacturing, packaging, labelling, quality control testing, handling, storage or other activities under this Agreement (a "**Technical Dispute**"), the parties shall make all reasonable efforts to resolve the dispute by amicable negotiations. In this regard, senior representatives of each party shall, as soon as practicable and in any event no later than **** after a written request from either party to the other, meet in good faith to resolve any Technical Dispute. If, despite such meeting, the parties are unable to resolve a Technical Dispute within a reasonable time, and in any event within **** after such written request, the Technical Dispute shall, at the request of either party, be referred for determination to an expert in accordance with the provisions of Schedule F. In the event that the parties cannot agree whether a dispute is a Technical Dispute, Section 12.1 shall prevail. For greater certainty, the parties agree that the release of the Products for sale or distribution pursuant to the applicable marketing approval for such Products shall not by itself indicate compliance by Patheon with its obligations in respect of the Manufacturing and further that nothing in this Agreement (including Schedule F) shall remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Products are to be released for sale or distribution. Notwithstanding the foregoing, neither party shall be prohibited from seeking injunctive or other equitable relief in any court of competent jurisdiction (including without limitation, in any case where issues involving the protection or unauthorized use or disclosure of a party's confidential information, trade secrets or intellectual property are involved).

12.3 Arbitration.

In the event that any dispute cannot be resolved in accordance with Section 12.1, such dispute shall be finally settled by arbitration in **** using the English language in accordance with the Arbitration Rules and Procedures of Judicial Arbitration and Mediation Services, Inc. ("JAMS") then in effect, by one or more commercial arbitrator(s) with substantial experience in resolving complex commercial contract disputes, who may or may not be selected from the appropriate list of JAMS arbitrators. If the parties cannot agree upon the number and identity of the arbitrators within **** following the date on which a party referred the applicable dispute to arbitration, then a single arbitrator shall be selected on an expedited

basis in accordance with the Arbitration Rules and Procedures of JAMS. Any arbitrator so selected shall have substantial experience in the pharmaceutical industry. The arbitrator(s) shall have the authority to grant specific performance and to allocate between the parties the costs of arbitration (including service fees, arbitrator fees and all other fees related to the arbitration) in such equitable manner as the arbitrator(s) may determine. The prevailing party in the arbitration shall be entitled to receive reimbursement of its reasonable expenses (including reasonable lawyers' fees, expert witness fees and all other expenses) incurred in connection therewith. Judgment upon the award so rendered may be entered in a court having jurisdiction or application may be made to such court for judicial acceptance of any award and an order of enforcement, as the case may be. Notwithstanding the foregoing, each party shall have the right to institute an action in a court of proper jurisdiction for preliminary injunctive relief pending a final decision by the arbitrator(s), provided that a permanent injunction and damages shall only be awarded by the arbitrator(s).

12.4 Dispute and Termination for Breach.

Notwithstanding any statement to the contrary in this Agreement, a non-breaching party shall not be entitled to terminate this Agreement pursuant to Section 8.2(a) on account of a disputed breach until the dispute is resolved by mutual agreement or arbitration pursuant to Section 12.3 confirming the existence of the breach.

ARTICLE 13

MISCELLANEOUS

13.1 Inventions.

(a) For the term of this Agreement, Client hereby grants to Patheon a non-exclusive, paid-up, royalty-free, non-sublicensable, non-transferable license of Client's Intellectual Property, including without limitation that assigned to the Client pursuant to Section 13.1(b) below, which Patheon must use in order to perform the Manufacturing, solely to perform the Manufacturing. ****.

(b) All Inventions (including any and all Intellectual Property Rights therein) conceived, generated, derived or reduced to practice by Patheon in the course of performing the Manufacturing, to the extent it is related to the development,

Manufacture, packaging, use or sale of the Client's Product that is the subject of the Manufacturing or contains the Client's confidential information, shall be the exclusive property of Client. Patheon shall give the Client written notice, as promptly as practicable, of all such Inventions, and all such Inventions shall be deemed to be the confidential information of Client. Patheon hereby makes, and agrees to make, any and all assignments necessary to effect, exclusively and throughout the world, the ownership by the Client of Inventions under Section 13.1(b). Patheon shall, and shall cause its employees and contractors to, fully cooperate with and sign any documents reasonably requested by the Client to evidence, perfect or take any other action with respect to such assignments or to obtain protection, maintain or take any other action regarding such assigned Inventions.

(c) All Intellectual Property generated or derived by Patheon in the course of performing the Manufacturing to the extent it (i) is not related to the development, Manufacture, packaging, use or sale of the Client's Product that is the subject of the Manufacturing and (ii) does not contain the Client's confidential information, shall be the exclusive property of Patheon (the "**Broader Intellectual Property Rights**"). Patheon hereby grants and agrees to grant to the Client a nonexclusive, transferable, perpetual, irrevocable, paid up, royalty-free, worldwide right and license (including the right to sublicense) to practice and use all Broader Intellectual Property Rights solely in connection with the ****.

(d) Each party shall be solely responsible for the costs of filing, prosecution and maintenance of patents and patent applications on its own Inventions.

13.2 Intellectual Property.

Subject to Section 13.1, all Intellectual Property of the Client, including without limitation any Intellectual Property that the Client owns prior to the Effective Date, shall be owned by the Client and all Intellectual Property of Patheon, including without limitation any Intellectual Property that Patheon owns prior to the Effective Date, shall be owned by Patheon. Neither party has, nor shall it acquire, any interest in any of the other party's Intellectual Property unless otherwise expressly agreed to in writing. Neither party shall use any Intellectual Property of the other party, except as specifically authorized by the other party or as required for the performance of its obligations under this Agreement. Except as expressly set forth in Section 13.1, no licenses are granted by either party, whether by implication, estoppel or otherwise, and all other rights are reserved.

13.3 Insurance.

Each party shall maintain commercial general liability insurance, including blanket contractual liability insurance covering the obligations of that party under this Agreement through the term of this Agreement and for a period of **** thereafter, which insurance shall afford limits of not less than (i) **** for each occurrence for personal injury or property damage liability; and (ii) **** in

the aggregate per annum with respect to product and completed operations liability. Each party may satisfy the foregoing minimum limits by any combination of primary liability and umbrella excess liability coverage. If requested each party will provide the other with a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date and the limits of liability. The insurance certificate shall further provide for a minimum of **** written notice to the insured of a cancellation of the insurance. If a party is unable to maintain the insurance policies required under this Agreement through no fault on the part of such party, then such party shall forthwith notify the other party in writing and the parties shall in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances, provided that in no event shall such party terminate its insurance policies until such amendments to the insurance provision of this Agreement that are mutually agreed upon by the parties in writing are enacted.

13.4 Independent Contractors.

The parties are independent contractors and this Agreement shall not be construed to create between Patheon and the Client any other relationship such as, by way of example only, that of employer-employee, principal agent, joint-venturer, co-partners or any similar relationship, the existence of which is expressly denied by the parties hereto.

13.5 No Waiver.

Either party's failure to require the other party to comply with any provision of this Agreement shall not be deemed a waiver of such provision or any other provision of this Agreement. No waiver of any provision of this Agreement shall bind either party unless in writing and signed by the party against which enforcement is sought.

13.6 Assignment.

(a) Patheon may not assign, transfer, delegate or subcontract this Agreement or any of its rights or obligations hereunder except with the written consent of the Client, such consent not to be unreasonably withheld; provided, however, that Patheon may arrange for subcontractors solely to perform specific testing services arising under this Agreement without the consent of the Client. Patheon shall be responsible and liable for any breaches of this Agreement by its subcontractors.

(b) Subject to Section 8.2(d), the Client may assign this Agreement or any of its rights or obligations hereunder without approval from Patheon; provided, however, that the Client shall give prior written notice of any assignment to Patheon, and any assignee shall covenant in writing with Patheon to be bound by the terms of this Agreement. ****

****.

(c) Notwithstanding the foregoing provisions of this Section 13.6, either party may assign this Agreement, without the consent of the other party, to any of its Affiliates or to a successor to or purchaser of all or substantially all of its business to which the subject matter of this Agreement relates, provided that such party provides prior written notice of such assignment to the other party and the assignee executes an agreement with the non-assigning party hereto whereby it agrees to be bound hereunder.

13.7 Force Majeure.

Neither party shall be liable for the failure to perform its obligations under this Agreement if such failure is occasioned by a cause or contingency beyond such party's reasonable control, including, but not limited to, strikes or other labour disturbances, lockouts, riots, quarantines, communicable disease outbreaks, wars, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, defective equipment, lack of or inability to obtain fuel, power or components or compliance with any order or regulation of any government entity acting within colour of right (a "**Force Majeure Event**"). A party claiming a right to excused performance under this Section 13.7 shall promptly notify the other party in writing of the extent of its inability to perform, which notice shall specify the occurrence beyond its reasonable control that prevents such performance, and shall use commercially reasonable efforts to overcome the Force Majeure Event. Notwithstanding the foregoing, if either party is prevented or delayed in performing its obligations under this Agreement on more than (i) **** or (ii) **** in the aggregate during any **** period, then the party not so affected may terminate this Agreement upon written notice to the affected party. Neither party shall be entitled to rely on a Force Majeure Event to relieve it from an obligation to pay money (including any interest for delayed payment) which would otherwise be due and payable under this Agreement.

13.8 Additional Product.

Versions of Products with different packaging configurations than those specified in Schedule B may be added to this Agreement and such additional products shall be governed by the general conditions hereof with any special terms (including, without limitation, price) governed by an addendum hereto.

13.9 Notices.

Any notice, approval, instruction or other written communication required or permitted hereunder shall be sufficient if made or given to the other party by personal delivery, by telecopier or facsimile communication or by sending the same by first class mail, postage prepaid, return receipt requested to the mailing address, or telecopier or facsimile number set forth below:

If to the Client:

Vanda Pharmaceuticals Inc.
2200 Pennsylvania Ave NW, Suite 300E
Washington, DC 20037
U.S.A.

Attention: Legal Department

Fax No.: ****

If to Patheon:

Patheon Inc.
2100 Syntex Court
Mississauga, Ontario L5N 7K9
Canada

Attention: Legal Department

Fax No.: ****

or to such other addresses or telecopier or facsimile numbers provided to the other party in accordance with the terms of this Section 13.9. Notices or written communications made or given by personal delivery or by telecopier or facsimile shall be deemed to have been sufficiently made or given when sent (receipt acknowledged), or if mailed, five (5) days after being deposited in the United States or Canadian mail, postage prepaid, return receipt requested or upon receipt, whichever is sooner.

13.10 Severability.

If any provision of this Agreement is determined by a court of competent jurisdiction to be invalid, illegal or unenforceable in any respect, such determination shall not impair or affect the validity, legality or enforceability of the remaining provisions hereof, and each provision is hereby declared to be separate, severable and distinct.

13.11 Entire Agreement.

This Agreement, together with the Schedules, the Quality Agreement and the Confidentiality Agreement, constitutes the full, complete, final and integrated agreement between the parties hereto relating to the subject matter hereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions or understandings with respect to the subject matter hereof, except the Packaging Services Agreement between the parties, dated August 20, 2012 (the “Packaging Services Agreement”). Any modification, amendment or supplement to this Agreement must be in writing and signed by authorized representatives of both parties. In case of conflict, the

prevailing order of documents shall be this Agreement, the Quality Agreement and the Confidentiality Agreement. Notwithstanding anything to the contrary in the Packaging Services Agreement, the parties hereby agree that the Packaging Services Agreement will automatically terminate on the Effective Date, and the parties will discuss diligently, reasonably and in good faith the parties' obligations under the Packaging Services Agreement following such termination.

13.12 Other Terms.

No terms, provisions or conditions of any purchase order or other business form or written authorization used by the Client or Patheon will have any effect on the rights, duties or obligations of the parties under or otherwise modify this Agreement, regardless of any failure of the Client or Patheon to object to such terms, provisions, or conditions. For greater certainty, the Client's purchase order is only effective as its unqualified commitment to obtain and pay for the Manufacturing upon the terms (and only the terms) set forth herein.

13.13 No Third Party Benefit or Right.

For greater certainty, nothing in this Agreement shall confer or be construed as conferring on any third party any benefit or the right to enforce any express or implied term of this Agreement.

13.14 Execution in Counterparts.

This Agreement may be executed in two counterparts, by original or facsimile signature, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

13.15 Governing Law.

This Agreement shall be construed and enforced in accordance with the laws of the State of ****, without regard to its conflicts of law provisions. The UN Convention on Contracts for the International Sale of Goods shall not apply to this Agreement. Unless expressly provided otherwise, each right and remedy in this Agreement is in addition to any other right or remedy, at law or in equity, and the exercise of one right or remedy will not be deemed a waiver of any other right or remedy.

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Agreement as of the date first written above.

PATHEON INC.

By: /s/ Nick Postic
Name: Nick Postic
Title: Executive Director and General Manager

VANDA PHARMACEUTICALS INC.

By: /s/ Mihael Polymeropoulos
Name: Mihael Polymeropoulos
Title: Chief Executive Officer

SCHEDULE A

PRODUCT LIST

Products

Fanapt™ (Iloperidone Tablets) – ****

Specifications

Prior to the commencement of commercial manufacturing of Product under this Agreement, the Client shall provide Patheon with copies of the FDA approved NDA Specifications. If the Specifications provided are subsequently amended, then the Client shall provide Patheon with copies of such revised Specifications. Upon acceptance of the revised Specifications pursuant to Section 4.4, Patheon shall provide the Client with a signed and dated receipt evidencing such acceptance of the revised Specifications by Patheon.

SCHEDULE B

2016 Price

****

**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

****

**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

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**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

****

**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

SCHEDULE C

STABILITY TESTING

****.

**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

SCHEDULE D

ACTIVE MATERIALS, ACTIVE MATERIALS CREDIT VALUE **

****

**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

MAXIMUM CREDIT VALUE

****

**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

SCHEDULE E

BATCH NUMBERING & EXPIRATION DATES

****

**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

SCHEDULE F

TECHNICAL DISPUTE RESOLUTION

****

**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

****

**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

SCHEDULE G

INTENTIONALLY OMITTED

**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

SCHEDULE H

QUARTERLY ACTIVE MATERIALS INVENTORY REPORT

****

**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

SCHEDULE I

REPORT OF ANNUAL ACTIVE MATERIALS INVENTORY RECONCILIATION AND CALCULATION OF ACTUAL ANNUAL YIELD

****

**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

****

**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

SCHEDULE J

****

SCHEDULE K
INTENTIONALLY OMITTED

SCHEDULE L
EXAMPLE OF PRICE ADJUSTMENTS PER SECTION 4.2

****

**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

Exhibit 10.43

EXECUTION COPY

AMENDMENT NO. 2 TO LEASE

THIS AMENDMENT NO. 2 TO LEASE ("**Amendment**") is made as of the 20th day of June 2016 ("**Effective Date**"), by and between SQUARE 54 OFFICE OWNER LLC, a Delaware limited liability company ("**Landlord**"), and VANDA PHARMACEUTICALS INC., a Delaware corporation ("**Tenant**").

WITNESSETH:

WHEREAS, by Lease dated as of July 25, 2011, as amended by that Amendment No. 1 to Lease dated March 18, 2014 (collectively, the "**Lease**"), Landlord is leasing to Tenant 21,400 square feet of rentable area located on the 3rd floor ("**3rd Floor East Premises**") and 8,860 square feet of rentable area on the 2nd floor ("**2nd Floor East Premises**") of the East Tower of the Building (collectively, the "**Premises**"), located at 2200 Pennsylvania Avenue, NW, Washington, DC (the "**Building**"); and

WHEREAS, the Lease Term with respect to the 3rd Floor East Premises is currently scheduled to expire as of March 31, 2023; and

WHEREAS, Landlord and Tenant desire to amend the Lease to (i) extend the Lease Term as it relates to the 3rd Floor East Premises for an additional period of three (3) years and six (6) months, and (ii) modify certain other terms of the Lease in accordance with and subject to the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the mutual covenants and premises contained herein and other good and valuable consideration the receipt and sufficiency of which hereby are acknowledged, Landlord and Tenant hereby agree to amend the Lease as follows:

1. Defined Terms. All capitalized terms used herein and not otherwise defined herein shall have the same meanings as provided for such terms in the Lease.

2. Lease Term. The Lease Term with respect to the 3rd Floor East Premises is hereby extended to be coterminous with the Lease Term for the 2nd Floor East Premises for a period of three (3) years and six (6) months ("**Extension Term**") commencing on April 1, 2023 ("**Extension Term Commencement Date**"), and expiring on September 30, 2026 ("**Extension Term Expiration Date**"), unless otherwise terminated sooner in accordance with the terms and conditions of the Lease.

3. Base Rent/Operating Expenses. (a) Commencing on the Extension Term Commencement Date, Tenant shall pay to Landlord as annual base rent for the 3rd Floor East Premises, without setoff, deduction or demand, an amount equal to the product of Sixty-One and 66/100 Dollars ($61.66), multiplied by the total number of square feet of rentable area in the 3rd Floor East Premises (i.e., $1,319,523.96, annually). The base rent payable herein shall be divided into equal monthly installments and such monthly installments shall be due and payable in advance on the first (1st) day of each month during the Extension Term (i.e., $109,960.33, monthly) in accordance with the terms set forth in Article III of the Lease.

(b) Commencing on the first anniversary of the Extension Term Commencement Date and on each anniversary thereafter during the Extension Term, the annual base rent payable by Tenant with respect to the 3rd Floor East Premises shall be increased by two and one-half percent (2.5%) of the amount of annual base rent payable for the 3rd Floor East Premises during the immediately preceding twelve (12) month period.

(c) During the Extension Term, Tenant shall continue to pay its proportionate share of the Operating Expenses incurred by Landlord in connection with the management, operation and ownership of the Building pursuant to the terms set forth in Article IV of the Lease.

4. Condition of the 3rd Floor East Premises. (a) Except as provided herein, Tenant accepts the 3rd Floor East Premises in its existing "as is" condition as of the Extension Term Commencement Date.

(b) During the Extension Term, Tenant shall have the right to make certain alterations, renovations and modifications ("**3rd Floor East Premises Work**") in and to the 3rd Floor East Premises. It is understood and agreed that Landlord will not make and is under no obligation to make, any structural or other alterations, decorations, additions or improvements in or to the 3rd Floor East Premises. All 3rd Floor East Premises Work shall be done in accordance with the requirements set forth in **Exhibit B** to the Lease.

(c) Provided no Event of Default has occurred, Landlord shall grant Tenant an improvement allowance ("**3rd Floor East Premises Allowance**") in an amount equal to (a) Fifteen and 00/100 Dollars ($15.00), multiplied by (b) the number of rentable square feet in the 3rd Floor East Premises (i.e., $321,000.00) to be applied to the 3rd Floor East Premises Work and the design thereof, which such 3rd Floor East Premises Allowance shall be made available to Tenant as of the 3rd Floor East Premises Commencement Date. Any portion of the 3rd Floor East Premises Allowance that remains unreserved and unapplied after the expiration of the first twelve (12) months of the Extension Term shall be deemed waived and forfeited.

(d) Disbursements of the 3rd Floor East Premises Allowance will be made in accordance with the terms and conditions set forth in **Exhibit B** to the Lease.

5. Renewal. Tenant shall maintain the right to extend the term of the Lease as provided in **Rider No. 1** to the Lease upon the Extension Term Expiration Date; provided however, Tenant's right to renew the term of the Lease with respect to the 3rd Floor East Premises is subject and subordinate to the right of Hunton & Williams LLP (and its successors and assigns) to expand into the 3rd Floor East Premises pursuant to expansion rights (including rights to first offer space) contained in Hunton & Williams LLP's lease pursuant to Rider No. 1 in the Lease. Additionally, all other terms and conditions of the Extension Term shall be in accordance with **Rider No. 1** to the Lease; provided however, the first sentence of Section 1(a) of **Rider No. 1** to Lease shall be amended to read as follows:

"1 (a) Tenant shall exercise its right of renewal with respect to the Renewal Term by giving Landlord written notice of the exercise thereof ("**Renewal Option Notice**") not less than twelve (12) months ("**Outside Notice Deadline**") and not more than fourteen (14) months prior to the Extension Term Expiration Date."

6. Ratification. Except as otherwise expressly modified by the terms of this Amendment, the Lease shall remain unchanged and continue in full force and effect. All terms, covenants and conditions of the Lease not expressly modified herein are hereby confirmed and ratified and remain in full force and effect, and, as further amended hereby, constitute valid and binding obligations of Landlord and Tenant enforceable according to the terms thereof.

7. Broker. Landlord recognizes Savills Studley, Inc. (the "**Broker**") as the sole broker procuring this Amendment and shall pay said Broker a commission pursuant to a separate agreement between said Broker and Landlord. Landlord and Tenant each represent and warrant to the other that, except as provided in the preceding sentence, neither of them has employed or dealt with any broker, agent or finder in carrying on the negotiations relating to this Amendment. Landlord and Tenant shall indemnify and hold the other harmless from and against any claim or claims for brokerage or other commissions asserted by any broker, agent or finder engaged by Landlord or Tenant or with whom Landlord or Tenant has dealt in connection with this Amendment, other than the Broker.

8. Authority.

(a) Tenant and each of the persons executing this Amendment on behalf of Tenant hereby represents and warrants to Landlord that Tenant is a duly organized and existing corporation and is in good standing under the laws of the State of Delaware, that all necessary corporate action has been taken to enter into this Amendment and that the person signing this Amendment on behalf of Tenant has been duly authorized to do so.

(b) Landlord and each of the persons executing this Amendment on behalf of Landlord hereby represents and warrants to Tenant that Landlord is a duly organized and existing limited liability company and is in good standing under the laws of the State of Delaware, that all necessary company action has been taken to enter into this Amendment and that the person signing this Amendment on behalf of Landlord has been duly authorized to do so.

9. Landlord and Tenant's Representations and Acknowledgements.

(a) To the best of Tenant's knowledge, Landlord has performed all of its obligations under the Lease. To the best of Tenant's knowledge, Landlord is not in default under the Lease as of the date hereof, and Tenant is unaware of any condition or circumstance which, but for the passage of time or delivery of notice, or both, would constitute an event of default by Landlord under the Lease. Tenant has no current claims, defenses or set-offs of any kind to the payment or performance of Tenant's obligations under the Lease. Nothing contained herein shall be deemed to waive any sums due from Tenant to Landlord, or any default or event which, with the passage of time or delivery of notice, or both, would constitute a default by Tenant under the Lease as of the date hereof.

(b) To the best of Landlord's knowledge, Tenant has performed all of its obligations under the Lease. To the best of Landlord's knowledge, Tenant is not in default under the Lease as of the date hereof, and Landlord is unaware of any condition or circumstance which, but for the passage of time or delivery of notice, or both, would constitute an event of default by Tenant under the Lease. Landlord has no current claims, defenses or set-offs of any kind to the payment or performance of Landlord's obligations under the Lease. Nothing contained herein shall be deemed to waive any sums due from Landlord to Tenant, or any default or event which, with the passage of time or delivery of notice, or both, would constitute a default by Landlord under the Lease as of the date hereof.

10. Mutual Negotiation. Landlord and Tenant each hereby covenant and agree that each and every provision of this Amendment has been jointly and mutually negotiated and authorized by both Landlord and Tenant, and in the event of any dispute arising out of any provision of this Amendment, Landlord and Tenant do hereby waive any claim of authorship against the other party.

11. General Provisions. Landlord and Tenant agree that the terms and conditions of this Amendment shall also be subject to the same provisions regarding confidentiality as are contained within Section 25.20 of the Lease.

12. Binding Effect. This Amendment shall not be effective and binding unless and until fully executed and delivered by each of the parties hereto. All of the covenants contained in this Amendment, including, but not limited to, all covenants of the Lease as modified hereby, shall be binding upon and inure to the benefit of the parties hereto, their respective heirs, legal representatives, and permitted successors and assigns.

[REMAINDER OF PAGE INTENTIONALLY BLANK.
SIGNATURE PAGE FOLLOWS.]

IN WITNESS WHEREOF, Landlord and Tenant have executed this Amendment No. 2 to Lease as of the date and year first above written.

LANDLORD:

SQUARE 54 OFFICE OWNER LLC,
a Delaware limited liability company

By: BP/DC PROPERTIES, INC.,
a Maryland corporation, its sole member and manager

By: /s/ Jonathan L. Kaylor [SEAL]

Name: Jonathan L. Kaylor

Title: Senior Vice President

TENANT:

VANDA PHARMACEUTICALS INC.,
a Delaware corporation

By: /s/ Mihael H. Polymeropoulos [SEAL]

Name: Mihael H. Polymeropoulos

Title: CEO

Exhibit 10.44

AGREEMENT OF SUBLEASE

THIS AGREEMENT OF SUBLEASE (this "Sublease"), made as of June 22, 2016, between HUNTON & WILLIAMS LLP, a Virginia registered limited liability partnership ("Sublessor"), having an office at 2200 Pennsylvania Avenue, N.W., Washington, DC 20037, and VANDA PHARMACEUTICALS INC., a Delaware corporation ("Sublessee"), having an office at 2200 Pennsylvania Avenue, N.W., Washington, DC 20037, recites and provides:

RECITALS

Sublessor is the tenant under that certain Lease dated December 18, 2008 (including Rider Number 1 to Lease thereto), as amended by that certain Amendment No. 1 to Lease dated as of August 16, 2011 and that certain Declaration of Lease Commencement dated as of November 18, 2011, between SQUARE 54 OFFICE OWNER LLC, a Delaware limited liability company, as landlord ("Landlord"), and Sublessor, as tenant, and as further amended by that certain Non-Disturbance and Attornment Agreement dated as of December 18, 2008, between Landlord, Sublessor and The George Washington University, a federally chartered nonprofit corporation, as ground lessor (collectively, the "Lease").

Pursuant to the Lease, Sublessor presently leases, in addition to other space, the fifth floor in the East Tower of the building located at 2200 Pennsylvania Avenue, N.W., Washington, DC 20037 (the "Building"), for a term expiring on July 31, 2026 (unless extended or sooner terminated pursuant to the terms of the Lease). The space in the Building leased by Sublessor pursuant to the Lease is referred to herein as the "Lease Premises").

Sublessor now desires to sublease to Sublessee a portion of the Lease Premises on the fifth floor of the East Tower of the Building containing approximately 9,928 rentable square feet, more particularly shown by black, bold highlighting around the perimeter thereof on Exhibit A hereto (the "Sublease Premises"), and Sublessee desires to sublease the Sublease Premises from Sublessor, all on the terms set forth below.

AGREEMENT

NOW, THEREFORE, in consideration of the mutual agreements herein contained and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows.

1. Demise.

(a) Subject to and in accordance with the provisions of this Sublease, Sublessor does hereby sublease to Sublessee and Sublessee does hereby sublease from Sublessor the Sublease Premises for the Sublease Term (defined below). The sublease of the Sublease Premises includes the right, together with Sublessor and other tenants of the Building, to use the common and public areas within the Building and the Project (as defined in the Lease) that Sublessor is entitled to use from time to time pursuant to and in accordance with this Sublease and the Lease, which areas at present include, without limitation, the fitness center, the rooftop terrace (including, without limitation, the right to hold "events" on the rooftop terrace in accordance with Section 14.10 of the Lease), loading dock, freight elevator, communication risers and the parking garage (for monthly contract parkers). Notwithstanding the foregoing, Sublessee shall not have any of the rights of Sublessor to install antennas or other equipment on the Building roof pursuant to Article XXVIII of the Lease.

(b) Sublessor agrees that, at no charge, it shall arrange for Sublessee to be provided with forty (40) key fobs which provide access to the Sublease Premises as well as to the fitness center, the rooftop terrace, the parking garage (for monthly contract parkers) and such other common areas that Sublessee is entitled to access pursuant to this Sublease. Any additional or replacement key fobs requested by Sublessee shall be obtained by Sublessee directly from Datawatch at Sublessee's sole cost and expense. Sublessee shall take appropriate security measures to limit the use of such key fobs to persons authorized by Sublessee, and shall store any unused key fobs in a secure location to prevent their use by unauthorized persons. Sublessee shall notify Datawatch (by telephone at (301) 280-4321 or (800) 899-9872, and by email to Helpdesk@datawatchsystems.com) and Sublessor immediately if it should learn that any of such key fobs are stolen or otherwise cannot be accounted for. At the end of the Sublease Term, Sublessee shall return all of such key fobs to Sublessor, and if any of such key fobs are missing or not operational, Sublessee shall pay any replacement fees charged by Landlord.

(c) Prior to the November 1, 2016, Sublessor will, at its expense, create a multitenant corridor on the 5th Floor, as more particularly shown on Exhibit A ("Sublessor's Work") and upon completion of Sublessor's Work the Sublease Premises shall be made available to Sublessee.

2. Sublease Term.

(a) The term of this Sublease will commence on the Commencement Date and end on July 31, 2026 (the "Sublease Term"). The "Commencement Date" shall be January 1, 2017. Sublessee shall be entitled to take possession of the Sublease Premises on the later of (i) October 1, 2016, or (ii) thirty (30) days following approval from Landlord of the Sublease. On or before the Commencement Date, Sublessee shall have delivered to Sublessor the Security Deposit (defined below) and the Base Rent (defined below) for the first full month of the Sublease Term. Notwithstanding the foregoing, if completion of Sublessee Improvements is delayed beyond January 1, 2017, after Sublessee used all reasonable efforts to complete same in accordance with this Sublease, due to failure of Sublessor to review and approve Plans and Specifications or contractors, as and when required in Sections 15(b) and (c) below, the Commencement Date shall be extended by one day for each day of delay. If the Sublease Premises have not been delivered to Sublessee with Sublessor's Work completed by November 1, 2016, Sublessee may terminate this Sublease.

(b) Notwithstanding any other provision of this Sublease, the termination or expiration of the Lease for any reason shall automatically result in the termination of this Sublease immediately upon any such termination or expiration of the Lease, and, except as otherwise expressly provided herein, the obligations of the parties hereunder to be performed from and after such termination or expiration shall cease as of the date of such expiration or termination of the Lease. Sublessor shall in no event be liable to Sublessee for any loss or damage occasioned by, or resulting from, the expiration or termination of the Lease unless the Lease is terminated by the Landlord as a direct result of any default by Sublessor under any provision of the Lease that Sublessee is either not obligated to perform pursuant to this Sublease or is obligated to perform pursuant to this Sublease but Sublessor's default is not due to the nonperformance of such provision by Sublessee. Notwithstanding anything in the foregoing to the contrary, should Sublessor terminate the Lease for any reason, other than as a result of casualty or eminent domain, and such termination results in the termination of this Sublease and whether or not any direct lease is entered into between Sublessee and Landlord, then Sublessor shall be obligated to pay to Sublessee a sum equal to any Base Rent not abated under Section 3(b) and Allowance under Section 15(a) remaining unpaid due to any such early termination, as Sublessee's sole and exclusive remedy hereunder.

3. Base Rent.

(a) The annual base rent (the "Base Rent") for the Sublease Premises shall be increased by four percent (4.0%) on each anniversary of the Commencement Date as follows:

	Base Rate/RSF	Annual Base Rent	Monthly Base Rent
January 1, 2017 through December 31, 2017	$ 59.00	$585,752.00	$ 48,812.66
January 1, 2018 through December 31, 2018	$ 61.36	$609,182.08	$ 50,765.17
January 1, 2019 through December 31, 2019	$ 63.81	$633,505.68	$ 52,792.14
January 1, 2020 through December 31, 2020	$ 66.37	$658,921.36	$ 54,910.11
January 1, 2021 through December 31, 2021	$ 69.02	$685,230.56	$ 57,102.55
January 1, 2022 through December 31, 2022	$ 71.78	$712,631.84	$ 59,385.99
January 1, 2023 through December 31, 2023	$ 74.65	$741,125.20	$ 61,760.43
January 1, 2024 through December 31, 2024	$ 77.64	$770,809.92	$ 64,234.16
January 1, 2025 through December 31, 2025	$ 80.75	$801,686.00	$ 66,807.17
January 1, 2026 through July 31, 2026	$ 83.98	$833,753.44	$ 69,479.45

(b) Provided that no default by Sublessee then exists under this Sublease, and Sublessee fails to cure such default within any applicable notice and cure period set forth in (including those incorporated by reference into) this Sublease, then the Base Rent shall be abated for a period of nine (9) months commencing on the Commencement Date.

(c) Base Rent shall be payable in twelve (12) equal monthly installments in advance in immediately available funds on the first day of each and every calendar month during the Sublease Term, without prior demand therefor and without setoff or reduction whatsoever, except for any holdback, setoff or reduction permitted under Section 3(d) of this Sublease and further except that Base Rent for any partial month at the beginning or end of the Sublease Term shall be prorated on a daily basis. Base Rent and all Additional Rent (defined below) under this Sublease shall be payable in United States Dollars.

(i) Base Rent shall be paid by check to:

Hunton & Williams LLP
PO BOX 405759
Atlanta, GA 30384-5759

(ii) or by wire transfer of immediately available fed funds to:

Bank: SunTrust Bank, Richmond, VA
Account Name: Hunton & Williams Operating Account
Account Number: 001458094
ABA Transit Routing No: 061000104

(d) If Sublessor shall be entitled to holdback, set-off or abate "Base Rent" under the Lease for the Sublease Premises on account of any casualty, failure of the Landlord to deliver services required by the Lease or other matter that adversely affects Sublessee's occupancy of the Sublease Premises, then Sublessee shall be entitled to the same holdback, set-off or abatement right for Base Rent hereunder on a pro-rata basis. For illustrative purposes only, if Sublessor is entitled to abate 50% of the base rent payable under the Lease for the Sublease Premises, then Sublessee shall be entitled to abate 50% of the Base Rent hereunder.

4. Additional Rent.

(a) In addition to Base Rent and the other amounts provided for in this Sublease, Sublessee shall be responsible for paying any amounts charged by Landlord or incurred by Sublessor under the Lease on account of any additional services that are not included in Operating Expenses under the Lease which are requested or incurred by Sublessee and provided by Landlord or Sublessor in respect of the Sublease Premises, including, but not limited to, additional cleaning charges, additional HVAC or overtime charges for HVAC, excess use charges for electricity, water or other utilities, security services, supplies and materials, freight elevator services, parking charges, and construction or construction-related charges. For the avoidance of doubt, Sublessee shall not have any obligation to pay any "Operating Expenses" (which term includes, among other things, "Real Estate Taxes," "Project Common Expenses" and standard utility charges as contemplated by Section 4.1(b)(1)(i) of the Lease), as defined in the Lease, and Sublessor and Sublessee acknowledge that the Base Rent and escalations provided for herein includes 100% of Sublessee's required contribution towards Operating Expenses.

(b) In addition to Base Rent and the other amounts provided for in this Sublease, Sublessee shall be responsible for paying, or reimbursing Sublessor for, any charges or costs imposed by Landlord on account of any failure of Sublessee to perform or comply with its obligations under this Sublease which result in a default or other charge under the Lease including, without limitation, the following: any increases in insurance premiums under Article XIII of the Lease resulting from Sublessee's use of the Sublease Premises; any charges imposed by Landlord under Article VIII of the Lease as a result of Sublessee's failure to properly maintain or repair the Sublease Premises; any charges imposed by Landlord under Article IX of the Lease for discharging any liens arising from any work performed, material furnished or obligations incurred by or for Sublessee or the Sublease Premises; any amounts imposed by Landlord under Article XIX of the Lease for curing any defaults of Sublessee in respect of the Sublease Premises, any parking charges imposed under the Lease for reserved or non-reserved parking spaces assigned to or requested by Sublessee, including any reserved or non-reserved parking spaces in excess of the number provided for in Section 27 below.

(c) In addition to Base Rent and the other amounts provided for in this Sublease, Sublessee shall be responsible for paying, prior to delinquency, all personal property taxes assessed in respect of Sublessee's personal property, if any.

(d) All amounts that are payable by Sublessee under this Sublease (including, without limitation, the provisions incorporated by reference from the Lease) other than Base Rent shall be referred to in this Sublease as "Additional Rent." Unless specifically provided otherwise herein, all

Additional Rent shall be payable by Sublessee directly to Landlord as and when due or to Sublessor within thirty (30) days after Sublessee's receipt of an invoice for the same from Sublessor. The remedies afforded Sublessor for the non-payment of Additional Rent by Sublessee shall be the same as for nonpayment of Base Rent.

(e) Any installment of Base Rent or Additional Rent not received by Sublessor within ten (10) days following the due date thereof shall be subject to a late payment charge equal to five percent (5%) of the amount due, which charge Sublessee shall pay to Sublessor upon demand.

(f) Additional Rent payable to Sublessor shall be paid to Sublessor at the address or per the wiring instructions provided in Section 3(c). Additional Rent payable to Landlord shall be paid to Landlord at the address that Sublessor shall designate in writing to Sublessee.

(g) Subject to Sublessee's compliance with its payment and reimbursement obligations under this Sublease including, without limitation, those under Section 3 above and this Section 4, Sublessor shall pay all "Base Rent", "Additional Rent" and "Operating Expenses" as such terms are defined in the Lease, as and when such payments are required to be made under the Lease. Consequently, only Sublessor shall be entitled to dispute or audit such amounts, or to receive refunds of any overpayments of such amounts or the benefit of any reductions in such amounts.

5. Insurance and Casualty.

(a) In addition to any insurance required by the Lease, Sublessee shall obtain, at Sublessee's sole cost and expense, and maintain during the Sublease Term, the following insurance coverage: (i) a general liability insurance policy with a combined property damage, bodily injury and death liability limit or combination thereof of at least $5,000,000, which policy shall be primary and non-contributing as to claims relating to injury or damage that occurs within the Sublease Premises, and (ii) a property insurance policy covering all office furniture, business and trade fixtures, office equipment, movable partitions, merchandise and all other items of Sublessee's property in the Sublease Premises, and Sublessee's Improvements (such insurance shall be written on an "all risks" of physical loss or damage basis, for the full replacement cost value new without deduction for depreciation of the covered items and in amounts that meet any co-insurance clauses of the policies of insurance, and shall include coverage for damage or other loss caused by fire or other peril, including vandalism and malicious mischief, theft, water damage of any type, including sprinkler leakage, bursting or stoppage of pipes, and explosion. Sublessee shall deliver a certificate of such insurance coverage including coverage required by the Lease), in the form required by the Lease, to Sublessor contemporaneously with Sublessee's execution of this Sublease, and shall from time to time thereafter deliver renewal certificates to Sublessor prior to the expiration of such insurance coverage. The company or companies writing such insurance, as well as the form of such insurance, shall at all times be subject to the Landlord's approval in accordance with the provisions of the Lease and Sublessor's reasonable approval and any such company or companies shall be licensed to do business in the jurisdiction in which the Sublease Premises are located. In addition to any others required by the Lease, the Landlord and Sublessor shall be named as additional insureds on all general liability insurance policies and as loss payee on all property insurance policies Sublessee is required to maintain hereunder, which policies shall contain provisions that they cannot be canceled except upon not less than thirty (30) days' prior written notice to all additional insureds.

(b) Sublessee hereby releases the Landlord, Sublessor, and any superior mortgagee or superior lessor from any and all liability or responsibility (to Sublessee or anyone claiming through or under Sublessee by way of subrogation or otherwise) for any loss or damage to real or personal property in or around the Sublease Premises caused by fire or any other insured peril, even if such fire or other casualty shall have been caused by the fault or negligence of the released party or anyone for whom such

party may be responsible, to the extent such loss or damage is covered by insurance policies actually maintained by Sublessee or which would have been covered by the policies required hereunder to be maintained by Sublessee. Sublessee shall procure insurance policies with such a waiver of subrogation and with a clause or endorsement to the effect that any such release shall not adversely affect or impair said policies or prejudice the right of the releasor to recover thereunder. Sublessor hereby releases Sublessee from any and all liability or responsibility (to Sublessor or anyone claiming through or under Sublessor by way of subrogation or otherwise) for any loss or damage to real or personal property in or around the Sublease Premises caused by fire or any other insured peril, even if such fire or other casualty shall have been caused by the fault or negligence of the released party or anyone for whom such party may be responsible, to the extent such loss or damage is covered by insurance policies actually maintained by Sublessor or required to be maintained by Sublessor under the Lease. Sublessor shall procure insurance policies with such a waiver of subrogation and with a clause or endorsement to the effect that any such release shall not adversely affect or impair said policies or prejudice the right of the releasor to recover thereunder.

(c) In the event of fire or other casualty affecting all of any part of the Building, if Landlord or Sublessor shall elect to terminate the Lease in accordance with the provisions of Article XVII thereof, then this Sublease automatically shall terminate as of the date the Lease is terminated. In the event of a fire or other casualty affecting the Sublease Premises, then (i) except as otherwise provided below, Sublessee shall be required to repair and restore, but only to the extent of the proceeds of the insurance actually maintained by Sublessee or required to be maintained by Sublessee under this Sublease, and any deductible thereunder, all of Sublessee's Improvements and all decorations, trade fixtures, furnishings, equipment and personal property in the Sublease Premises (including, without limitation, the furnishings and equipment provided by Sublessor for Sublessee's use pursuant to Section 16 hereof) (the "Sublessee Repair Obligation") and (ii) Landlord and Sublessor shall have the respective repair obligations set forth in Article XVII of the Lease, except that Sublessor shall not have any responsibility for the work included within the Sublessee Repair Option.. If a fire or other casualty occurs in respect of all or any part of the Building, Sublessor will provide to Sublessee a copy of the "Restoration Notice" that Landlord is required to provide to Sublessor pursuant to Section 17.1(b) of the Lease promptly after Sublessor's receipt of same. If such fire or other casualty affects the Sublease Premises, and (x) either (1) such Restoration Notice states that the "Estimated Restoration Date" is more than 60 days after the occurrence of such fire or other casualty, (2) the casualty is of a nature that will not reasonably allow Sublessee (or Sublessor, if Sublessor so elects as provided above in this Section 5(c)) to complete the Sublessee Repair Obligation and, taking into account the repairs that Landlord and Sublessor need to make, be able to recommence normal business operations in the Sublease Premises within 90 days after the occurrence of such fire or casualty, or (3) such fire or other casualty occurs within the last year of the Sublease Term, and (y) in either case if such fire or casualty was not caused by the negligence or willful misconduct of Sublessee or any affiliate of Sublessee, any permitted subtenant or any other permitted occupant of the Sublease Premises, and each of their respective direct or indirect partners, officers, shareholders, directors, members, trustees, beneficiaries, servants, employees, principals, contractors, licensees, agents, invitees or representatives (each a "Sublessee Party"), and (z) if no default on the part of Sublessee is then existing, then Sublessee shall be entitled to terminate this Sublease, effective as of the date of such fire or other casualty, by giving written notice of termination to Sublessor within forty-five (45) days after Sublessor provides to Sublessee a copy of Landlord's Restoration Notice. If Sublessee so elects to terminate this Sublease, Sublessee shall remain liable for all of its obligations and liabilities under this Sublease accruing up through the date of such termination, except that Sublessee shall be entitled to its set-off and abatement rights under Section 3(d) and Sublessee shall not be required to perform the Sublessee Repair Obligation so long as Sublessee assigns to Sublessor the proceeds of Sublessee's property insurance in respect of such fire or other casualty actually maintained by Sublessee or required to be maintained by Sublessee under this Sublease, and pays to Sublessor the amount of any deductible under such insurance.

6. Compliance with Lease.

(a) Sublessor covenants that it shall comply with the terms, covenants and conditions of the Lease in all material respects. Sublessee acknowledges that it has read and examined a redacted copy of the Lease and (except for the provisions thereof which were redacted) is fully familiar with the terms, covenants and conditions on the Sublessor's part to be performed thereunder, and Sublessor and Sublessee agree that except as expressly set forth in this Sublease, all of the unredacted terms, covenants and conditions of the Lease which relate to the Sublease Premises, the use thereof, the conduct of the Sublessor's activities or operations therein or in the common areas of the Building or the Project are incorporated herein by reference and made a part hereof as if set forth in length and are hereby assumed by Sublessee and shall be applicable to this Sublease with the same force and effect as if Sublessor were the lessor under the Lease and Sublessee were the lessee thereunder, with the exception that (i) Sublessee shall only pay Base Rent and Additional Rent to Sublessor in such amounts and on such dates as are provided in this Sublease; (ii) the Sublease Term is as set forth herein and references to the "Lease Term" in the Lease shall be considered references to the Sublease Term; (iii) references to the "Premises" in the Lease shall be considered references to the Sublease Premises herein and references to the "Lease Commencement Date" in the Lease shall be considered references to the Commencement Date hereunder; (iv) Sublessee shall have no right to renew, extend or terminate the Sublease Term except as expressly set forth in this Sublease, or to expand or contract the Sublease Premises except as expressly set forth in this Sublease; (v) the Sublease Premises are being subleased to Sublessee in their "as is" condition and Sublessor shall have no obligation to make or contribute to the costs of any alterations to prepare the same for occupancy by Sublessee (other than the performance of Sublessor's Work); (vi) Sublessee shall not be entitled to receive any allowances or rent abatements provided for in the Lease except as provided in Section 3(d) above; (vii) Sublessor shall not be liable for performing any of the obligations of the Landlord; (viii) references in the Lease to the expiration or sooner termination of the term of the Lease shall be deemed to refer instead to the expiration or sooner termination of the Sublease Term (except that the reference to the last 24 months of the Lease Term provided in Section 12.1 of the Lease shall not be deemed to refer to the last 24 months of the Sublease Term and instead shall mean and refer to the last six (6) months of the Sublease Term); (ix) Sublessee shall not be responsible to comply with any provisions of the Lease which were redacted and those provisions are not incorporated herein; and (x) the provisions which are expressly excluded as provided in Section 6(b) below shall not be a part of this Sublease. Sublessee shall have no liability under this Sublease for any Hazardous Materials brought onto the Project by Landlord or Sublessor.

(b) Notwithstanding any other provision of this Sublease to the contrary, the following provisions of the Lease shall not be part of this Sublease: (i) any provisions for the construction of any improvements to the Premises made by Landlord for Sublessor; (ii) any provision pursuant to which Sublessor is entitled to renew the Lease; (iii) any provision of the Lease that is personal to Sublessor or not applicable to any assignees or sublessees of Sublessor; (iv) any provisions relating to Sublessor's right to make use of the Building roof (other than Sublessor's right to use the rooftop terrace as provided for in Section 1(a) above); (v) any provisions granting to Sublessor any Building exterior or monument signage; (vi) any provisions relating to storage areas outside the Lease Premises used by Sublessor; (vii) the casualty (damage or destruction) provisions which conflict with Section 5(c) above; (viii) the security deposit and tenant improvement allowance provisions; (ix) the provisions of Section 7.4 (Business Invitees) of the Lease; and (x) the following provisions shall not apply to this Sublease: Article II, Article IV, Section 5.1 (other than Section 5.1(b)), Section 9.1, Section 10.1(d), Section 14.8, the provisions of Section 14.10 which relate to Personal Terraces (as defined in the Lease), the first sentence of Section 15.5, Section 25.3, Section 25.6, any provisions of Article XXV after Section 25.27, Articles XXVII, XXVIII, XXIX, XXX, Rider No. 1, and Exhibit F. In addition, the terms of this Sublease shall not include any of the discretionary elections and consents provided to Sublessor under the Lease. The right to make all such elections and provide all such consents shall be reserved solely to Sublessor, and

Sublessor shall in no event be liable to Sublessee for any loss or damage occasioned by or resulting from any elections made or consents given by Sublessor as lessee under the Lease. In no event shall Sublessor be deemed to have made any of the certifications, representations, warranties or indemnifications made by the Landlord under the Lease.

7. Use.

(a) Sublessee shall use and occupy the Sublease Premises for general office use, including ancillary uses thereto permitted by the Lease, in accordance with the provisions of the Lease, and Sublessee shall not use or permit the use of the Sublease Premises for any other purpose whatsoever. Sublessee shall be responsible for obtaining a certificate of occupancy for Sublessee to use the Sublease Premises (if one is required).

(b) Sublessee shall promptly provide Sublessor with notice of any change in the name of Sublessee.

8. Indemnity.

(a) Sublessee agrees to indemnify Sublessor in accordance with the terms of Section 13.1 of the Lease, as incorporated herein pursuant to Section 7(a) above, which terms Sublessee agrees shall apply to Sublessee's construction of the Sublessee Improvements. Sublessee agrees that this Sublease is separate from and subordinate in all respects to the Lease and to any agreement to which the Lease is subject. In the event a default shall occur on the part of Sublessee and shall be continuing, then Sublessor shall have the same rights and remedies with respect to such default as are given to Landlord with respect to defaults by Sublessor after the notice and applicable cure periods under this Sublease (shortened by three days as provided in Section 17 below), all with the same force and effect as though the provisions of the Lease with respect to defaults, and the rights and remedies of Landlord in the event thereof, were set forth at length herein. Sublessee acknowledges that if any default by Sublessee under this Sublease or the provisions of the Lease incorporated herein results in Landlord's termination of any rights of Sublessor under the Lease that are conditioned on the absence of default by Sublessor under the Lease, then Sublessor's damages shall include, without limitation, all of Sublessor's damages for loss of such rights. Any conflicts between the terms, covenants and conditions of this Sublease and the Lease shall be resolved in favor of this Sublease provided they are not prohibited by the express terms of the Lease.

(b) Sublessor shall not be liable to Sublessee for any damage to property or bodily injury incurred by Sublessee except to the extent of the terms of Section 13.2 of the Lease.

9. Sublessor's Option to Perform. If a default on the part of Sublessee shall occur under this Sublease, Sublessor, without thereby waiving such default, may, at Sublessor's option, after 10 days' notice to Sublessee, perform the same for the account of Sublessee. If Sublessor makes any expenditures or incurs any obligations for the payment of money, including attorneys' fees and related costs, in connection with curing Sublessee's default, instituting, prosecuting or defending any action or proceeding, by reason of any default of Sublessee hereunder, such sums paid or obligations incurred, with interest thereon at the rate of 1.5% per month, shall be paid by Sublessee to Sublessor as Additional Rent within five days of rendition of any bill or statement to Sublessee therefor.

10. Obligations of Landlord. So long as a default on the part of Sublessee shall not be continuing, Sublessee shall be entitled to receive all services to be rendered to Sublessor under the Lease insofar as such services pertain to the Sublease Premises or to the Sublessor's use thereof or the conduct of the activities or operations therein or in the common areas of the Building and shall be entitled to the

benefit of all rights to be afforded to Sublessor under the Lease insofar as such rights pertain to the Sublease Premises or to the use thereof or the conduct of the activities or operations therein or in the common areas of the Building. Except as otherwise specified herein (e.g., with respect to the fact that Sublessee shall not be responsible for paying for "Operating Expenses" under the Lease), Sublessee shall be responsible for all charges relating thereto as provided in the Lease. Sublessor shall in good faith cooperate and coordinate with Sublessee and Landlord, at its sole cost and expense, in using commercially reasonable efforts to obtain Landlord's performance under the Lease should Sublessee provide notice to Sublessor of any deficiency or default by Landlord, except that Sublessor shall not be required to commence any legal proceedings or arbitration or terminate the Lease. Sublessor shall have no liability of any nature whatsoever to Sublessee for Landlord's failure to perform or render such services, and shall look solely to Landlord for all such services and shall not, under any circumstances, seek nor require Sublessor to perform any of such services, nor shall Sublessee seek to recover on any claim against Sublessor or sue Sublessor for any damages which may arise by reason of Landlord's default under the Lease (including, without limitation, Landlord's breach of a covenant of quiet enjoyment), or Landlord's negligence, whether by omission or commission. No such default of Landlord shall excuse Sublessee from the performance of any of its obligations to be performed under this Sublease or entitle Sublessee to terminate this Sublease or to reduce or abate or offset any of the rents provided for in this Sublease except to the extent that Sublessor is entitled to exercise such rights under the Lease as a result of such default by Landlord.

11. Attornment.

(a) Sublessee agrees that if, by reason of default on the part of Sublessor under the Lease, Landlord or any successor-in-interest to Landlord shall request that Sublessee attorn to it as the direct tenant of Landlord or such successor-in-interest under the terms and provisions of this Sublease, then Sublessee shall attorn to Landlord or such successor-in-interest as its landlord as the direct tenant of Landlord or such successor-in-interest under the terms and provisions of this Sublease; in such event, Landlord or such successor-in-interest shall not be liable to Sublessee for any defaults theretofore committed by Sublessor and no such default shall give rise to any rights of offset or deduction against the Base Rent and Additional Rent payable under this Sublease.

(b) The provisions for attornment set forth above shall be self-operative and shall not require the execution of any further instrument. However, if Landlord or any such successor-in-interest requests a further instrument expressing such attornment, Sublessee agrees to execute the same promptly.

12. Consent to Sublease. Landlord's written consent to this Sublease is a condition precedent to the effectiveness hereof. If such consent is not received within sixty (60) days after the date of this Sublease, then this Sublease will terminate and be of no further force and effect. In such event, neither party shall have any rights against, or obligations to the other, except (i) those set forth in any provisions of this Sublease that expressly survive termination of this Sublease, and (ii) that Sublessor shall return all monies deposited hereunder (including, without limitation, any advance Base Rent and the Security Deposit).

13. Brokers. Sublessee covenants, warrants and represents to Sublessor that it has not dealt with, or had any conversations or prior discussions with, any broker, finder or similar person in connection with the subleasing of the Sublease Premises except Savills Studley (the "Sublessee's Broker") and Jones Lang LaSalle Brokerage, Inc. ("Sublessor's Broker," and together with Sublessee's Broker, the "Brokers"), and to its actual knowledge (i) there is no broker, finder or similar person other than the Brokers who is entitled to claim a commission, fee or other compensation in connection with this Sublease, and (ii) there is no other broker, finder or similar person who was instrumental in consummating this Sublease. Sublessor shall pay a commission to each of the Brokers pursuant to

separate agreements with each of the Brokers. Sublessee shall indemnify and hold Sublessor harmless against and from all costs, expenses, damages and liabilities, including reasonable attorneys' fees and court costs, arising from any claims for brokerage commissions, finder's fees or other compensation if the foregoing covenant, warranty and representation is untrue in any material respect. The provisions of this Section 13 shall survive the expiration or earlier termination of this Sublease.

14. Condition of Sublease Premises. Subject to Sublessor completing Sublessor's Work, Sublessee shall accept the Sublease Premises in their current "as-is" condition. Sublessee acknowledges that, except as expressly set forth in this Sublease, neither Sublessor, nor Sublessor's agents, have made any representations or warranties in regard to the Sublease Premises. The taking of possession of the Sublease Premises by Sublessee shall be conclusive evidence that Sublessee accepts the same "as-is" and that the Sublease Premises were in good and satisfactory condition at the time such possession was taken.

15. Allowance; Sublessee Improvements.

(a) Sublessor shall provide a tenant improvement allowance of up to $99,280.00 (the "Allowance") to be used by Sublessee for tenant improvements (both hard and soft costs), telephone and data cabling, furniture, fixturing, interior suite signage and moving expenses incurred within one year (except as otherwise set forth below) after the Commencement Date (the "Sublessee Improvements"). Sublessor shall fund the Allowance to Sublessee on a monthly basis, based on invoices, receipts, lien waivers and other back-up documentation provided by Sublessee and reasonably satisfactory to Sublessor. Except as otherwise set forth below, to the extent that the total cost of the Sublessee Improvements exceeds the Allowance, Sublessee shall pay the full amount of the excess. Any portion of the Sublessee Improvement costs that has not been incurred within one year after the Commencement Date shall not be available for disbursement to Sublessee and shall be retained by Sublessor without any change in the other terms of this Sublease. Notwithstanding the foregoing, if a default occurs and Sublessee fails to cure such default as permitted hereunder, then Sublessor shall have no further obligation to provide the Allowance.

(b) Prior to commencing work on the Sublessee Improvements, Sublessee shall engage SKB Architects to prepare plans and specifications and a schedule for the completion of the Sublessee Improvements (the "Plans and Specifications"). The Plans and Specifications shall be prepared at Sublessee's expense (although subject to reimbursement from the Allowance) and submitted to Sublessor for its approval (not to be unreasonably withheld) and the approval of Landlord pursuant to the Lease (to the extent Landlord's consent is required under the Lease). Sublessor shall use all reasonable efforts to review and either approve or request changes to the Plans and Specifications within 10 business days after receiving them from Sublessor, and shall cooperate with Sublessee to obtain Landlord's approval or requested changes as soon as reasonably practical.

(c) Sublessee shall obtain at its expense (subject to reimbursement from the Allowance) all licenses, permits and approvals for the Sublessee Improvements. Sublessee shall engage a contractor reasonably approved by Sublessor (and Landlord, if required by the Lease), to perform the work needed to construct the Sublessee Improvements in accordance with the Plans and Specifications approved by Landlord and Sublessor and the Building Code. Sublessee shall be responsible for the cost of all permits, inspections, occupancy permits and corrective work that may be required by the applicable building inspectors (subject to reimbursement from the Allowance).

(d) Intentionally Deleted.

(e) All of the Sublessee Improvements shall be made in accordance with the provisions of the Lease, including the provisions thereof regarding any obligation to remove such

improvements at the end of the Lease Term. Sublessor shall cooperate with Sublessee to ascertain from Landlord, prior to construction of the Sublessee Improvements, whether any of the Sublessee Improvements will need to be removed at the end of the Lease Term, but Sublessee shall be responsible for removing any of the Sublessee Improvements at the end of the Sublease Term, at Sublessee's expense, if required by Landlord pursuant to the Lease. Should the Landlord charge any fees or costs on account of Sublessee's work, Sublessee shall pay Landlord for such amounts, or reimburse Sublessor for any such amounts paid by Sublessor (subject to reimbursement from the Allowance). If any of the Sublessee Improvements involve supplying greater capacities or different types of electricity or other utilities to the Sublease Premises, Sublessee shall be solely liable for paying for all costs of installing (subject to reimbursement from the Allowance) and consuming same.

(f) Except for the Sublessee Improvements, Sublessee shall not make any alterations, additions, improvements or renovations to or affecting the Sublease Premises without the prior written consent of the Sublessor (which consent of Sublessor shall not be unreasonably withheld) and the Landlord (to the extent Landlord's consent is required under the Lease). Any such alterations, additions, improvements or renovations approved by Sublessor and the Landlord (to the extent Landlord's consent is required under the Lease) shall be constructed, maintained and removed (if required by Landlord pursuant to the Lease) by Sublessee at Sublessee's sole cost and expense and in accordance with the requirements of the Lease. In addition, if any such alterations, additions, improvements or renovations involve supplying greater capacities or different types of electricity or other utilities to the Sublease Premises, Sublessee shall be solely liable for paying for all costs of installing and consuming same. The contractor that Sublessee uses for any construction or tenant improvements work in the Sublease Premises shall be subject to Sublessor's reasonable approval and to Landlord's approval (if required under the Lease) in accordance with the Lease. Notwithstanding anything in Sections 15(e) or (f) to the contrary, if Landlord does not require removal of Sublessee Improvements or Sublessee's other approved alterations, additions, improvements or renovations, then Sublessor shall likewise not require removal of same.

16. Furniture. Sublessor shall leave in the Sublease Premises in its current as-is condition a portion of the furniture and equipment that are presently located in the Sublease Premises. Sublessor and Sublessee shall agree on an inventory of such portion of the furniture and equipment that is to remain in the Sublease Premises, which Sublessee shall approve and execute on or prior to the Commencement Date and all such portion of the furniture and equipment will thereafter become the personal property of Sublessee. Sublessee shall remove all such portion of the furniture and equipment in the Sublease Premises upon expiration or earlier termination of the term of this Sublease.

17. Default. Notwithstanding anything contained in any provision of this Sublease to the contrary, Sublessee agrees, with respect to the Sublease Premises, to comply with and remedy any default claimed by Landlord under the Lease and caused by any act or omission of Sublessee, within the period allowed to Sublessor as tenant under the Lease minus three days (the "Sublessee Cure Period"), even if such time period is shorter than the period otherwise allowed in the Lease due to the fact that notice of default from Sublessor to Sublessee is given after the corresponding notice of default from Landlord to Sublessor as tenant under the Lease. Sublessor agrees to forward to Sublessee, promptly upon receipt thereof by Sublessor, a copy of each notice of default received by Sublessor in its capacity as tenant under the Lease. Sublessee agrees to forward to Sublessor, promptly upon receipt thereof, copies of any notices received by Sublessee with respect to the Sublease Premises from Landlord or from any governmental authorities. In no event shall Sublessee be deemed to have a cure period under this Sublease that is longer than any corresponding cure period in the Lease.

18. Security Deposit.

(a) Sublessee shall provide to Sublessor at execution of the Sublease a security deposit in the amount of $97,625.32 (the "Security Deposit").

(b) The Security Deposit shall be held by Sublessor, without liability for interest, as security for the faithful performance and observance by Sublessee of the terms, covenants and conditions of this Sublease. The Security Deposit shall not be considered advance rent or a limit on Sublessee's liability for any breach of this Sublease or any indemnity obligation. In the event of a default by Sublessee in respect of any of the terms, covenants and conditions of this Sublease, including, but not limited to, the payment of Base Rent and Additional Rent, Sublessor may use, apply or retain the whole or any part of the Security Deposit to the extent required for the payment of any Base Rent and Additional Rent or any other sum as to which Sublessee is in default or for any sum which Sublessor may expend or may be required to expend by reason of Sublessee's default in respect of any of the terms, covenants and conditions of this Sublease, including but not limited to, any damages or deficiency in the re-letting of the Sublease Premises, whether such damages or deficiency accrued before or after summary proceedings or other re-entry by Sublessor. To the extent that Sublessor shall apply all or any portion of the Security Deposit as provided above and this Sublease has not been terminated, Sublessee shall, within five business days after written demand by Sublessor, pay to Sublessor a sum sufficient to restore the Security Deposit to the full amount required by this Section 18, and Sublessee's failure to pay such amount within such time shall constitute a default under this Sublease, in respect of which Sublessor shall be entitled to exercise all of its right and remedies for nonpayment of Base Rent. In the event that Sublessee shall fully and faithfully comply with all of the terms, provisions, covenants and conditions of this Sublease, the Security Deposit shall be returned to Sublessee after the date fixed as the end of the Sublease and after delivery of entire possession of the Sublease Premises to Sublessor in the condition required by this Sublease. In the event of an assignment of Sublessor's leasehold interest in the Sublease Premises, Sublessor shall have the right to transfer the Security Deposit to the assignee and Sublessor shall thereupon be released by Sublessee from all liability for the return of the Security Deposit, and Sublessee agrees to look to the new Sublessor solely for the return of the Security Deposit; and it is agreed that the provisions hereof shall apply to every transfer or assignment made of the Security Deposit to a new Sublessor. Sublessee further covenants that it will not assign or encumber or attempt to assign or encumber the monies deposited herein as security and that neither Sublessor nor its successors or assigns shall be bound by any such assignment, encumbrance, attempted assignment or attempted encumbrance.

19. Letter of Credit.

(a) At Sublessee's election, in lieu of the cash Security Deposit required by Section 18 of this Sublease, Sublessee may deliver to Sublessor with Sublessee's execution and delivery of this Sublease an irrevocable letter of credit payable in either Washington, D.C. or New York City in the amount of the Security Deposit, issued for the benefit of the Sublessor by a bank reasonably satisfactory to Sublessor (the "Issuing Bank"); provided, however, if such letter of credit provides that draws thereunder may be submitted to the Issuing Bank by fax without the requirement to submit the original of credit or the imposition of any requirements that would make the submission of such draws materially more difficult than an in-person submission in Washington, D.C., then such letter of credit may provide that in-person submission of draws thereunder may be made in Scranton, Pennsylvania or Tampa, Florida. If, during the Sublease Term, the Issuing Bank enters into any form of regulatory or governmental receivership or other similar regulatory or governmental proceeding including, without limitation, any receivership instituted or commenced by the Federal Deposit Insurance Corporation (FDIC) or is otherwise declared insolvent or downgraded by the FDIC or put on an FDIC "watchlist," or if the financial condition of the Issuing Bank changes in any other materially adverse way, as reasonably determined by Sublessor, then Sublessee shall within 10 days after written notice from Sublessor deliver

to Sublessor a replacement letter of credit which meets the requirements of this Section 19 and issued by a new Issuing Bank reasonably satisfactory to Sublessor. Sublessee's failure to do so within 10 days after written request of Sublessor will constitute a default for which there will be no notice or cure period, and will give Sublessor the immediate right, without further notice to Sublessee, to draw upon such letter of credit. If Sublessee replaces such letter of credit pursuant to the foregoing, Sublessor will, within 10 days after Sublessor's receipt of the replacement letter of credit, deliver to Sublessee the letter of credit so replaced. Each letter of credit will be irrevocable for the term of such letter of credit and will provide that it is automatically renewable for a period ending not earlier than 60 days after the expiration of the Sublease Term (the "Final L/C Expiration Date") without any action whatsoever on the part of Sublessor. However, the Issuing Bank will have the right not to renew said letter of credit on written notice to Sublessor given not less than 60 days before the expiration of the then current term thereof (it being understood, however, that the privilege of the Issuing Bank not to renew said letter of credit will not, in any event, diminish the obligation of Sublessee to maintain such irrevocable letter of credit with Landlord through the date which is 60 days after the expiration of the Sublease Term). Sublessee must be the applicant of the letter of credit.

(b) The letter of credit must be issued by a bank reasonably satisfactory to Sublessor, must be in the form of Exhibit B hereto, and must provide, among other things, in effect that:

(i) Sublessor will have the right to draw down an amount up to the face amount of the letter of credit upon the presentation to the Issuing Bank of Sublessor's sight draft;

(ii) The letter of credit will be honored by the Issuing Bank within one business day after presentment;

(iii) In the event of a transfer of Sublessor's leasehold interest in the Lease Premises, Sublessor will have the right to transfer the letter of credit to the transferee without the payment of any transfer fees, and thereupon the Sublessor will, without any further agreement between the parties, be released by Sublessee from all liability therefor, and it is agreed that the provisions hereof shall apply to every transfer or assignment of said letter of credit to a new Sublessor; and

(iv) If the expiration date of the letter of credit is a day on which the issuer's offices are closed, the expiration date shall automatically be extended pursuant to Section 3.13 or Section 3.14 of International Standby Practices ISP98 (International Chamber of Commerce Publication no. 590).

(c) Sublessor may draw upon the letter of credit at any time and from time to time if:

(i) Sublessee has failed to fulfill one or more of its obligations under this Sublease and failed to cure the same within any applicable notice and cure period, in which case Sublessor shall not draw more than the amount that Sublessor is entitled to apply from the Security Deposit pursuant to Section 18 above; or

(ii) the letter of credit held by Sublessor will expire earlier than the Final L/C Expiration Date (whether by reason of a stated expiration date or a notice of termination or non-renewal given by the Issuing Bank), and Sublessee fails to deliver to Sublessor, at least 10 days prior to the expiration date of the letter of credit then held by Sublessor, a renewal or substitute letter of credit that is in effect and that complies with the requirements of this Section 19.

(d) If, as a result of any such application of all or any part of the Security Deposit, the amount available to be drawn under the letter of credit is less than the amount of the required Security Deposit as set forth in Section 18, Sublessee will forthwith provide Sublessor with additional letter(s) of credit in an amount equal to the deficiency.

(e) Sublessee further covenants that it will not assign or encumber said letter of credit or any part thereof and that neither Sublessor nor its successors or assigns will be bound by any such assignment, encumbrance, attempted assignment or attempted encumbrance.

(f) Without limiting the generality of the foregoing, if the letter of credit expires earlier than 60 days after the expiration of the Sublease Term, or the Issuing Bank notifies Sublessor that it will not renew the letter of credit, Sublessor will accept a renewal thereof or substitute letter of credit (such renewal or substitute letter of credit to be in effect not later than 10 days prior to the expiration thereof), irrevocable and automatically renewable as above provided to the Final L/C Expiration Date upon the same terms as the expiring letter of credit or such other terms as may be acceptable to Sublessor. However, if the letter of credit is not timely renewed or a substitute letter of credit is not timely received, Sublessor may present such letter of credit to the bank, in accordance with the terms of Section 19(c), and the entire sum secured thereby will be paid to Sublessor, to be held by Sublessor as provided in this Section 19 and as provided in Section 18 above. If Sublessee fails to maintain the letter of credit in the amount and terms set forth in this Section 19, Sublessee must immediately deposit with Sublessor a replacement letter of credit complying with the requirements of this Section 19, failing which the Sublessor may present such letter of credit to the bank, in accordance with the terms of this Section 19, and the entire sum secured thereby will be paid to Sublessor, to be held by Sublessor as provided in this Section 19 and Section 18.

20. Notices. All notices required by, or provided in connection with, this Sublease shall be sent by certified mail, return receipt requested, or by nationally recognized overnight delivery service, or by personal delivery, to the Sublessor at its address in the preamble of this Sublease, to the attention of "Office Managing Partner," with a copy to Sublessor at Hunton & Williams LLP, 951 East Byrd Street, Richmond, Virginia 23219, Att'n: Chief Administrative Officer, and to Sublessee at 2200 Pennsylvania Avenue, N.W., Washington, DC 20037, Attn: Chief Executive Officer, with a copy to Sublessee at the Sublease Premises, Attn: Legal Department. Either party may change its notice address by providing notice of such new addresses by notice to the other party as provided herein. Any notice sent in the manner provided herein shall be deemed to be received three days after posting certified mail with the U.S. Postal Service, or the business day after delivery of such notice to such overnight delivery service, or upon personal delivery. Refusal to accept delivery shall constitute receipt of any such notice.

21. Holdover. In the event Sublessee, or anyone claiming through or on behalf of Sublessee, remains in possession of the Sublease Premises after the expiration or earlier termination of this Sublease without the execution of a new sublease or a direct lease with Landlord, (i) Sublessor shall be entitled to all of the rights and remedies which are available to a landlord against a tenant holding over after the expiration of a term, at law and in equity, and to such other rights and remedies as may be provided for the Landlord in the Lease or the Sublessor in this Sublease, and (ii) Sublessee, at the option of Sublessor, shall be deemed to be occupying the Sublease Premises as a tenant from month to month, at a monthly rental equal to 150% of the Base Rent that was payable for the last month of the Sublease Term, plus the Additional Rent payable hereunder, subject to all of the other terms of this Sublease insofar as the same are applicable to a month-to-month tenancy. In addition, Sublessee shall be liable to Sublessor for any damages (actual or consequential) that Sublessor incurs due to Sublessee's holdover and shall indemnify, defend and hold harmless Sublessor for any claims or liabilities attributable to any such holding over.

22. No Damages for Consents. The provisions of the Lease notwithstanding, and in addition thereto, with respect to any provision of this Sublease which provides, in effect, that Sublessor shall not unreasonably withhold or unreasonably delay any consent or any approval, Sublessee shall, in no event, be entitled to make, nor shall Sublessee claim any money damages by way of setoff, counterclaim or defense, based upon any claim or assertion by Sublessee that Sublessor has unreasonably withheld or unreasonably delayed any consent or approval if such withholding or delay is due to the action or inaction of Landlord, in which case, Sublessee's sole remedy shall be an action or proceeding to enforce any such provision, or for specific performance, injunction or declaratory judgment.

23. Costs. Whenever Sublessee requests the consent or approval of Sublessor under this Sublease, Sublessee shall pay to Sublessor, as Additional Rent within ten (10) days after demand therefor, all reasonable costs assessed by Landlord against Sublessor resulting therefrom.

24. Assignments and Subletting. Sublessee may not further sublease or allow any other person to use all or any portion of the Sublease Premises or assign, mortgage, pledge or otherwise encumber all or any of Sublessee's rights under this Sublease without the prior written consent of both the Sublessor (which consent by Sublessor shall not be unreasonably withheld, conditioned or delayed) and Landlord (if and to the extent required by the Lease). In all events, Sublessee shall comply with the provisions of Article VII (Assignment and Subletting) of the Lease, and any event or transaction that requires the consent of the Landlord under the Lease shall require the consent of the Sublessor under this Sublease (which consent by Sublessor shall not be unreasonably withheld, conditioned or delayed). Sublessor have the right, effective as of the date of any proposed assignment or sublease requiring its consent, to (a) terminate this Sublease with respect to an assignment; (b) recapture the space to be re-sublet if more than 50% of the Sublease Premises is sublet (but only if Landlord exercises its recapture rights), (c) intentionally deleted; or (d) approve or not approve the proposed transfer (not to be unreasonably withheld, conditioned or delayed), subject to all of Landlord's rights under the Lease and Sublessor's rights under this Sublease. Notwithstanding the forgoing, but subject to the provisions of the Lease, Sublessor's consent shall not be required for Sublessee's assignment of this Sublease to a successor by merger, or the purchaser of the stock or substantially all of the assets of Sublessee or to an affiliate or subsidiary of Sublessee. In the event of a sublease or an assignment by Sublessee that does not require Sublessor's consent, Sublessee shall provide to Sublessor written notice of such sublease or assignment.

25. Authorization.

(a) Sublessee hereby covenants, represents and warrants that Sublessee is a duly organized and validly existing corporation under the laws of the State of Delaware, that Sublessee has obtained, or prior to the commencement of its business in the Sublease Premises shall obtain, all licenses, permits and approvals to carry on its business in the District of Columbia, that the person(s) executing this Sublease on behalf of Sublessee is a duly authorized officer of Sublessee, that such person(s) are duly authorized to execute, acknowledge and deliver this Sublease to Sublessor, confirmation thereof to be received by Sublessee on or before June 17, 2016; and that this Sublease constitutes the valid and binding agreement of Sublessee and is enforceable in accordance with its terms. Sublessee shall provide copies of such documents as Sublessor may require to evidence and confirm all of the foregoing.

(b) Sublessor hereby covenants, represents and warrants that Sublessor is a duly organized and validly existing registered limited liability partnership under the laws of the Commonwealth of Virginia, that Sublessor has obtained all licenses, permits and approvals to carry on its business in the District of Columbia, that the person(s) executing this Sublease on behalf of Sublessor are duly authorized to execute, acknowledge and deliver this Sublease to Sublessee; and that this Sublease constitutes the valid and binding agreement of Sublessor and is enforceable in accordance with its terms. Sublessor shall provide copies of such documents as Sublessee may require to evidence and confirm all of the foregoing.

26. Access to Sublease Premises. Subject to the applicable regulations of Landlord and the terms of the Lease, Sublessee shall have access to the Sublease Premises twenty-four (24) hours a day, seven (7) days a week. In addition to Landlord's access rights under the Lease, Sublessor shall have access to the Sublease Premises to exercise its rights under Section 12.1 of the Lease as incorporated herein upon 24 hours' prior notice except in the case of emergency, in which case Sublessor shall be entitled to immediate access.

27. Parking.

(a) Sublessor shall make available to Sublessee, from parking spaces available to Sublessor under the Lease, one unreserved parking space in the Building garage for each 1,500 rentable square feet within the Sublease Premises, rounded to the nearest whole number. Sublessee will contract directly with the parking garage operator for the parking contracts.

(b) Sublessee acknowledges that it is familiar with the provisions of the Lease governing parking, and accepts full responsibility for complying with such provisions. Sublessee shall pay all parking fees and charges imposed from time to time by Landlord or the parking garage operator for any parking spaces used by Sublessee. Sublessor shall comply with all parking regulations set forth in the Lease or otherwise promulgated by Landlord.

28. Signage. Sublessor, at Sublessor's cost and in accordance with the Lease, shall provide Sublessee with one directory listing in the Building's electronic directory in the Building lobby, subject to Landlord's rules and requirements. Sublessee, at Sublessee's cost and in coordination with Sublessor, shall have the right to install one suite entry sign for the Sublease Premises in the 5th Floor elevator lobby subject to and in accordance with the provisions of the Lease. Immediately upon the execution of this Lease, Sublessor and Sublessee shall coordinate such signage with each other and the Landlord. Nothing in this provision shall preclude Sublessor from changing or adding additional signs in such elevator lobby (provided that Sublessee's sign is not affected) subject to and in accordance with the Lease. At the end of the Sublease Term, Sublessee, at Sublessee's expense (or at Sublessor's option, Sublessor, at Sublessee's reasonable expense) shall remove the sign from the elevator lobby and repair any damage resulting from the installation or removal of such sign, and comply with any provisions of the Lease pertaining to its sign.

29. Confidentiality. Sublessee agrees to keep the provisions of the Lease and this Sublease, and all related correspondence, plans and other documents, strictly confidential in accordance with the provisions of the Confidentiality Agreement dated as of May 5, 2016 (the "Confidentiality Agreement"), between Sublessor and Sublessee, the terms of which are incorporated herein as if set forth in full herein, except that (i) the term "Information" as used in the Confidentiality Agreement shall also include this Sublease and all related correspondence, plans and other documents and (ii) notwithstanding the provisions of Section 4 of the Confidentiality Agreement, the provisions of the Confidentiality Agreement incorporated herein as provided above shall not be deemed to have terminated with the termination of the Confidentiality Agreement pursuant to such Section 4. The provisions of this Section 29 shall survive the expiration or earlier termination of this Sublease for the maximum period permitted by applicable law. Notwithstanding the foregoing, Sublessee, which is a public company, may publicly disclose information in its quarterly, annual, and other filings as is required by law to be disclosed in the periodic filings required of public companies.

30. Expansion Rights.

(a) Sublessee shall have a one-time right of first offer to lease any space on the 5th Floor contiguous to the Sublease Premises that becomes available during the Sublease Term (the "ROFO Space"). The ROFO Space shall be subject and subordinate to all existing renewal and expansion rights granted to existing tenants on the 5th Floor of the East Tower and to any need Sublessor shall have for the ROFO Space. The ROFO Space will not be available unless (i) Sublessee has not been in default beyond any applicable grace or cure period under the Sublease within the twelve (12) month period immediately prior to the ROFO notification, and (iii) Sublessee is occupying at least seventy-five percent (75%) of the Sublease Premises.

(b) When Sublessor determines the date the ROFO Space will be or is available, Sublessor shall notify Sublessee in writing, informing Sublessee of the anticipated delivery date for the ROFO Space (the "ROFO Notice"). Sublessee shall have ten (10) business days to elect to exercise its option to lease the ROFO Space by written notice to Sublessor, which election shall be binding on Sublessee. After the ROFO Notice has been provided to Sublessee, and either accepted or declined by Sublessee, Sublessee thereafter shall no longer have any right of first offer to any space on the 5th Floor. Upon receipt of Sublessee's written notice exercising its option to lease the ROFO Space, Sublessor and Sublessee shall have thirty (30) days to negotiate mutually acceptable business terms for the sublease of the ROFO Space. The rental terms for any ROFO Space shall be one hundred percent (100%) of the then prevailing "Fair Market Rental Rate" (as defined below) for comparable space in comparable buildings taking into account all relevant factors. The parties agree that there shall be no Tenant Improvement Allowance provided to Sublessee by Sublessor for the ROFO Space.

(c) "Fair Market Rental Rate" shall mean Sublessor's good faith determination of the per square foot rental rate a typical office tenant in a first-class office building of similar location, age, quality and condition to the Building in the Washington, D.C. submarket (the "Submarket") would, at that time, pay for the ROFO Space or space comparable thereto, including lease concessions, free rent, tenant improvement allowances and other incentives then being offered by landlords to office tenants at similar office buildings in the Submarket (subject to being equitably adjusted to reflect variations in circumstances and other appropriate factors). Sublessor shall communicate its determination of Fair Market Rental Rate, made in its sole discretion but in good faith as aforesaid, to Sublessee as soon as practicable, but not later than fifteen (15) days after Sublessee delivers notice of its intention to exercise the option to lease the ROFO Space. If such rate is agreed upon by Sublessee, then the Fair Market Rental Rate shall be equal to such rate and shall be binding and conclusive upon the parties. Should Sublessee disagree with Sublessor's determination of Fair Market Rental Rate, then Sublessee shall notify Sublessor of such disagreement within ten (10) business days after its receipt of Sublessor's determination. The Fair Market Rental Rate for the Premises shall then be determined by a board of three (3) licensed commercial real estate brokers, one of whom shall be named by the Sublessor, one of whom shall be named by Sublessee, and the two so appointed shall select a third. Each real estate broker so selected shall be licensed in the jurisdiction in which the Building is located as a real estate broker specializing in the field of commercial office leasing in the Washington, D.C. Submarket, having no less than ten (10) years' experience in such field, and recognized as ethical and reputable within the field. Sublessor and Sublessee agree to make their appointments promptly within ten (10) days after Sublessor's receipt of Sublessee's notice of such disagreement, or sooner if mutually agreed upon. The two (2) brokers selected by Sublessor and Sublessee shall promptly select a third broker within ten (10) days after they both have been appointed, and each broker, within fifteen (15) days after the third broker is selected, shall submit his or her determination of the Fair Market Rental Rate. The Fair Market Rental Rate shall be the mean of the two closest rental rate determinations. Sublessor and Sublessee shall each pay the fee of the broker selected by it, and they shall share equally the payment of the fee of the third broker.

(d) The ROFO Space premises shall be delivered in its then “as-is” condition with a rent free period of up to ninety (90) days for the purpose of constructing any improvements to the ROFO Space premises.

(e) The right of first offer set forth in this Section 30, shall be personal to Sublessee only, and shall not be transferrable to any assignee or sublessee, even if permitted hereunder.

31. Miscellaneous Provisions.

(a) Headings used herein are for convenience only and shall not be construed to limit or extend the meaning of any provision of this Sublease.

(b) The provisions of this Sublease are severable and, if any clause or provision shall be held invalid or unenforceable in whole or in part in any jurisdiction, then such invalidity or unenforceability shall affect only such clause or provision or part thereof in such jurisdiction and shall not in any manner affect such clause or provision in any other jurisdiction or any other clause or provision of this Sublease in any jurisdiction.

(c) This Sublease shall be governed by and construed in accordance with the laws of the jurisdiction in which the Sublease Premises are located, without regard to conflicts of laws principles.

(d) This Sublease may be executed in two or more counterparts, each of which shall be deemed an original and which together shall constitute one and the same instrument.

(e) This Sublease constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior discussions, understandings, agreements and negotiations between the parties hereto. This Sublease shall not be modified or amended and no waiver of any provision hereof shall be effective unless set forth in an instrument duly executed by the parties hereto.

(f) The provisions of this Sublease shall extend to and shall bind and inure to the benefit of the parties hereto and their respective heirs, personal representatives, and permitted successors and assigns. If Sublessor transfers its estate in the Sublease Premises, Sublessor shall thereafter be relieved of all obligations of Sublessor expressed in this Sublease or implied by law, except those arising out of a breach or default by Sublessor prior to such transfer.

(g) One or more waivers of any covenant or condition by Sublessor shall not be construed as a waiver of a further breach of the same or other covenant or condition, and any consent or approval shall not be deemed to waive or render unnecessary Sublessor’s consent or approval to any subsequent similar action. Sublessor’s acceptance of Base Rent or Additional Rent during the continuance of any breach of this Sublease shall not constitute a waiver of such breach. Any payment by Sublessee of a lesser amount of Base Rent or Additional Rent than is due shall be applied to such arrearage as Sublessor may designate irrespective of any contrary designation by Sublessee and Sublessor’s acceptance of any such payment shall not be deemed an accord and satisfaction or waiver of any default by Sublessee, and shall be without prejudice to Sublessor’s right to pursue all if its remedies.

(h) Notwithstanding any provision to the contrary contained in this Sublease, Sublessee’s obligations to indemnify Sublessor hereunder shall survive the expiration of the Sublease Term or any earlier termination of this Sublease.

(i) TIME SHALL BE OF THE ESSENCE with regard to each date by which performance is required by the parties under this Sublease.

(j) Sublessee hereby represents and warrants to Sublessor that: (i) Sublessee is not, nor is it owned or controlled directly or indirectly by, any person, group, entity or nation named on any list issued by OFAC pursuant to Executive Order 13224 or any similar list or by any law, order, rule or regulation or any Executive Order of the President of the United States as a terrorist, "Specially Designated National and Blocked Person" or other banned or blocked person (any such person, group, entity or nation being hereinafter referred to as a "Prohibited Person"; (ii) Sublessee is not (nor is it owned or controlled, directly or indirectly, by any person, group, entity or nation which is) acting directly or indirectly for or on behalf of any Prohibited Person; and (iii) from and after the effective date of the above-referenced Executive Order, Sublessee (and any person, group, or entity which Sublessee controls, directly or indirectly) has not conducted nor will conduct business nor has engaged nor will engage in any transaction or dealing with any Prohibited Person in violation of the U.S. Patriot Act or any OFAC rule or regulation, including, without limitation, the making or receiving of any contribution of funds, good or services to or for the benefit of a Prohibited Person in violation of the U.S. Patriot Act or any OFAC rule or regulation. In connection with the foregoing, it is expressly understood and agreed that the representations and warranties contained in this subsection shall be continuing in nature and shall survive the expiration or earlier termination of this Sublease.

(k) This Sublease has been fully negotiated at arm's length between Sublessor and Sublessee, and Sublessor and Sublessee are fully informed with respect thereto. No party shall be deemed the scrivener of this Sublease and the provisions of this Sublease and the exhibits or schedules hereto shall be construed as a whole according to their common meaning and not strictly for or against either Sublessor or Sublessee.

32. Waiver of Jury Trial. INSOFAR AS PERMITTED BY LAW, SUBLESSOR AND SUBLESSEE HEREBY EXPRESSLY WAIVE THE RIGHT TO TRIAL BY JURY IN ANY ACTION OR PROCEEDING OR COUNTERCLAIM BETWEEN THE PARTIES HERETO, OR THEIR SUCCESSORS OR PERMITTED ASSIGNS, ARISING OUT OF OR IN ANY WAY CONNECTED WITH THIS SUBLEASE OR ANY OF ITS PROVISIONS, SUBLESSEE'S USE OR OCCUPANCY OF THE PREMISES, AND/OR CLAIM OF INJURY OR DAMAGE. THE PROVISIONS OF THIS SECTION 32 SHALL SURVIVE THE EXPIRATION OR EARLIER TERMINATION OF THIS SUBLEASE.

33. Notice. THIS DOCUMENT DOES NOT CONSTITUTE AN ACTUAL OR IMPLIED OFFER OR ACCEPTANCE OF AN OFFER TO SUBLEASE THE PREMISES. THIS DOCUMENT SHALL NOT BE BINDING ON ANY PERSON OR ENTITY UNLESS AND UNTIL IT IS DULY EXECUTED BY AND DELIVERED TO EACH PARTY TO THIS DOCUMENT.

34. Quiet Enjoyment. Sublessor covenants that if Sublessee shall pay all Base Rent and Additional Rent due from Sublessee under this Sublease when the same shall be due and perform all of the covenants of Sublessee set forth herein, Sublessee shall, during the Sublease Term, freely, peaceably and quietly occupy and enjoy the full possession of the Sublease Premises without molestation or hindrance by Sublessor or any party claiming by or through Sublessor, subject to the provisions of this Sublease.

35. Non-Recourse. Sublessee acknowledges that Sublessor is a Virginia registered limited liability partnership and agrees that, notwithstanding anything to the contrary provided in this Sublease, (a) no present, future or past partner, officer, member or employee of Hunton & Williams LLP or any successor of Hunton & Williams LLP that is a natural person, (b) natural person that is an owner of a

professional corporation that is a present, future or past partner or member of Hunton & Williams LLP or any successor of Hunton & Williams LLP, and (c) no professional corporations that are a present, future or past partner or member of Hunton & Williams LLP or any successor of Hunton & Williams LLP, and none of the estates, beneficiaries or family members of any of the foregoing, shall have any personal liability to Sublessee for any of the obligations of Sublessor under this Sublease. Sublessor (including any successor in interest as tenant under the Lease) shall be solely and exclusively liable for all of the obligations of Sublessor under this Sublease.

36. Representations of Sublessor. Sublessor hereby represents that (i) to its knowledge, neither Sublessor nor Landlord are in default under the Lease, and (ii) there is no litigation pending or to Sublessor's knowledge threatened which would, if adversely determined, affect the ability of Sublessor to enter into this Sublease or perform its obligations or the ability of Landlord to consent to this Sublease.

37. Damages. Notwithstanding anything herein to the contrary and except as provided in Section 21 above, each party's liability under this Sublease shall be limited to actual damages, not consequential damages.

[The rest of this page is blank; signature page follows.]

IN WITNESS WHEREOF, Sublessor and Sublessee have executed this Sublease as of the date first above written.

SUBLESSOR:

HUNTON & WILLIAMS LLP, a Virginia registered limited liability partnership

By: /s/ Daniel M. Campbell
Print name: Daniel M. Campbell
Title: Partner

SUBLESSEE:

VANDA PHARMACEUTICALS INC., a Delaware corporation

By: /s/ Mihael H. Polymeropoulos
Print name: Mihael H. Polymeropoulos
Title: Chief Executive Officer

EXHIBIT A: 2200 Penn Floor Plan – 5th Floor
9,928 RSF shown below in blue:

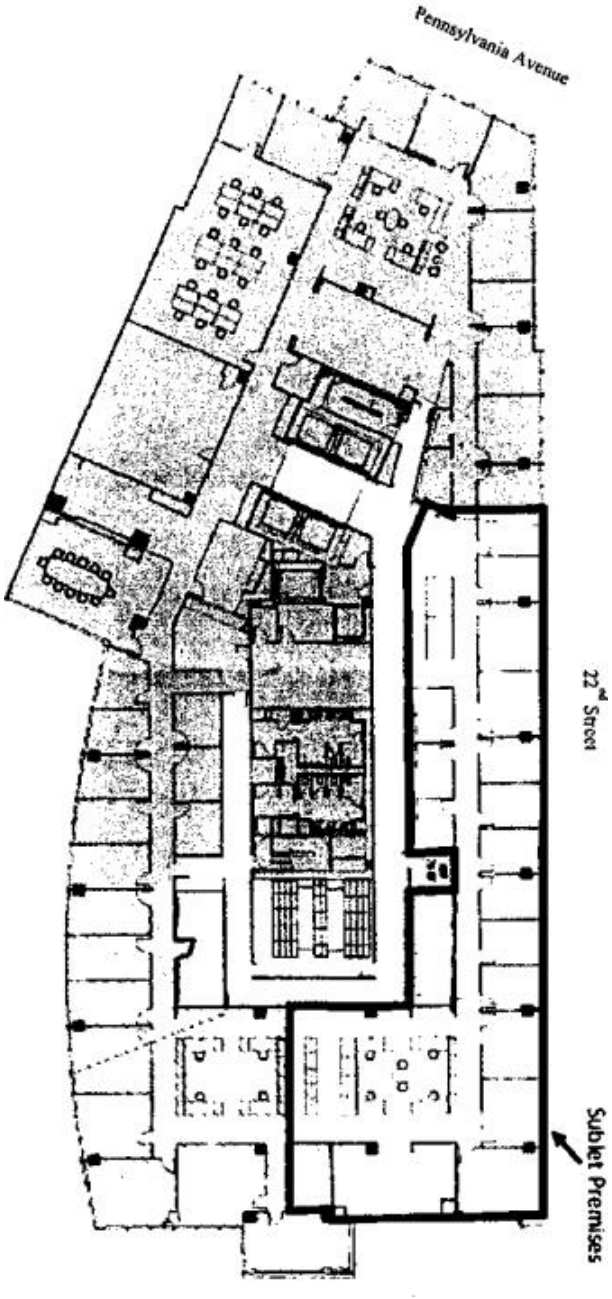

Exhibit B Form of Letter of Credit

IRREVOCABLE STANDBY LETTER OF CREDIT NUMBER _____

ISSUE DATE: _____

ISSUING BANK:

SILICON VALLEY BANK
3003 TASMAN DRIVE
2ND FLOOR, MAIL SORT HF210
SANTA CLARA, CALIFORNIA 95054

BENEFICIARY:

HUNTON & WILLIAMS LLP DC 20037
2200 Pennsylvania Avenue NW, Suite 300-E
WASHINGTON DC 20037

APPLICANT:

VANDA PHARMACEUTICALS INC
2200 PENNSYLVANIA AVENUE NW
SUITE 300-E
WASHINGTON DC 20037

AMOUNT: US $97,625.32 (NINTY SEVEN THOUSAND SIX HUNDRED TWENTY FIVE AND 32/100 U.S. DOLLARS)

EXPIRATION DATE: _____ (ONE YEAR FROM ISSUANCE)

LOCATION: SANTA CLARA, CALIFORNIA

DEAR SIR/MADAM:

WE HEREBY ESTABLISH OUR IRREVOCABLE STANDBY LETTER OF CREDIT NO. SVBSF IN ____ YOUR FAVOR AVAILABLE BY YOUR DRAFTS DRAWN ON US AT SIGHT IN THE FORM OF EXHIBIT "A" ATTACHED AND ACCOMPANIED BY THE FOLLOWING DOCUMENTS:

1. THE ORIGINAL OF THIS LETTER OF CREDIT AND ALL AMENDMENT(S), IF ANY.

2. BENEFICIARY'S SIGNED STATEMENT STATING AS FOLLOWS:

"AN EVENT OF DEFAULT (AS DEFINED IN THE SUBLEASE) HAS OCCURRED BY _____ AS SUBTENANT UNDER THAT CERTAIN SUBLEASE AGREEMENT BETWEEN SUBTENANT, AND _____ AS SUBLANDLORD."

PARTIAL DRAWS AND MULTIPLE PRESENTATIONS ARE ALLOWED.

THIS LETTER OF CREDIT SHALL BE AUTOMATICALLY EXTENDED FOR AN ADDITIONAL PERIOD OF ONE YEAR, WITHOUT AMENDMENT, FROM THE PRESENT OR EACH FUTURE EXPIRATION DATE UNLESS AT LEAST 60 DAYS PRIOR TO THE THEN CURRENT EXPIRATION DATE WE SEND YOU A

ALL THE DETAILS SET FORTH HEREIN IN THIS LETTER OF CREDIT DRAFT IS APPROVED BY APPLICANT. IF THERE IS ANY DISCREPANCY BETWEEN THE DETAILS OF THIS LETTER OF CREDIT DRAFT AND THE LETTER OF CREDIT APPLICATION, BETWEEN APPLICANT AND SILICON VALLEY BANK, THE DETAILS HEREOF SHALL PREVAIL."

_____ _____

APPLICANT'S SIGNATURE(s) DATE

NOTICE BY REGISTERED MAIL OR OVERNIGHT COURIER SERVICE AT THE ABOVE ADDRESS (OR ANY OTHER ADDRESS INDICATED BY YOU, IN A WRITTEN NOTICE TO US THE RECEIPT OF WHICH WE HAVE ACKNOWLEDGED, AS THE ADDRESS TO WHICH WE SHOULD SEND SUCH NOTICE) THAT THIS LETTER OF CREDIT WILL NOT BE EXTENDED BEYOND THE CURRENT EXPIRATION DATE. IN NO EVENT SHALL THIS LETTER OF CREDIT BE AUTOMATICALLY EXTENDED BEYOND _____. IN THE EVENT OF SUCH NOTICE OF NON-EXTENSION, YOU MAY DRAW HEREUNDER WITH A DRAFT STATED ABOVE AND ACCOMPANIED BY THIS ORIGINAL LETTER OF CREDIT AND AMENDMENT(S), IF ANY, ALONG WITH YOUR SIGNED STATEMENT STATING THAT YOU HAVE RECEIVED A NON-EXTENSION NOTICE FROM SILICON VALLEY BANK AND YOU HAVE NOT RECEIVED A REPLACEMENT LETTER OF CREDIT ACCEPTABLE TO YOU.

THIS LETTER OF CREDIT IS TRANSFERABLE ONE OR MORE TIMES, AT NO CHARGE TO ANY TRANSFEREE OF BENEFICIARY, BUT IN EACH INSTANCE ONLY TO A SINGLE BENEFICIARY AS TRANSFEREE AND ONLY UP TO THE THEN AVAILABLE AMOUNT, ASSUMING SUCH TRANSFER TO SUCH TRANSFEREE WOULD BE IN COMPLIANCE WITH THEN APPLICABLE LAW AND REGULATION, INCLUDING BUT NOT LIMITED TO THE REGULATIONS OF THE U. S. DEPARTMENT OF TREASURY AND U. S. DEPARTMENT OF COMMERCE. AT THE TIME OF TRANSFER, THE ORIGINAL LETTER OF CREDIT AND ORIGINAL AMENDMENT(S), IF ANY, MUST BE SURRENDERED TO US AT OUR ADDRESS INDICATED IN THIS LETTER OF CREDIT TOGETHER WITH OUR TRANSFER FORM ATTACHED HERETO AS EXHIBIT “B” DULY EXECUTED. THE CORRECTNESS OF THE SIGNATURE AND TITLE OF THE PERSON SIGNING THE TRANSFER FORM MUST BE VERIFIED BY BENEFICIARY’S BANK. NO FEES, CHARGES, REIMBURSEMENT WILL BE IMPOSED ON YOU OR SUCH TRANSFEREE IN CONNECTION WITH SUCH TRANSFER, NOTWITHSTANDING ANYTHING TO THE CONTRARY CONTAINED IN ANY TRANSFER FORM ATTACHED TO THIS LETTER OF CREDIT.
APPLICANT SHALL PAY OUR TRANSFER FEE OF ¼ OF 1% OF THE TRANSFER AMOUNT (MINIMUM US$250.00) UNDER THIS LETTER OF CREDIT.

DRAFT(S) AND DOCUMENTS MUST INDICATE THE NUMBER AND DATE OF THIS LETTER OF CREDIT.

ALL DEMANDS FOR PAYMENT SHALL BE MADE BY PRESENTATION OF THE ORIGINAL APPROPRIATE DOCUMENTS ON A BUSINESS DAY AT OUR OFFICE (THE “BANK’S OFFICE”) AT: SILICON VALLEY BANK, 3003 TASMAN DRIVE, SANTA CLARA, CA 95054, ATTENTION: STANDBY LETTER OF CREDIT NEGOTIATION SECTION

FACSIMILE PRESENTATIONS ARE PERMITTED. SHOULD BENEFICIARY WISH TO MAKE PRESENTATIONS UNDER THIS LETTER OF CREDIT ENTIRELY BY FACSIMILE TRANSMISSION IT NEED NOT TRANSMIT THIS LETTER OF CREDIT AND AMENDMENT(S), IF ANY. EACH FACSIMILE TRANSMISSION SHALL BE MADE AT: (408) 496-2418 OR (408) 969-6510 ; AND SIMULTANEOUSLY UNDER TELEPHONE ADVICE TO: (408) 654-6274 OR (408) 654-7716, ATTENTION: STANDBY LETTER OF CREDIT NEGOTIATION SECTION WITH ORIGINALS TO FOLLOW BY OVERNIGHT COURIER SERVICE; PROVIDED, HOWEVER, THE BANK WILL DETERMINE HONOR OR DISHONOR ON THE BASIS OF PRESENTATION BY FACSIMILE ALONE, AND WILL NOT EXAMINE THE ORIGINALS. IN ADDITION, ABSENCE OF THE AFORESAID TELEPHONE ADVICE SHALL NOT AFFECT OUR OBLIGATION TO HONOR ANY DRAW REQUEST.

IF THE ORIGINAL OF THIS STANDBY LETTER OF CREDIT NO.SVBSF ____ IS LOST, STOLEN OR DESTROYED, WE WILL ISSUE YOU A “CERTIFIED TRUE COPY” OF THIS STANDBY LETTER OF

ALL THE DETAILS SET FORTH HEREIN IN THIS LETTER OF CREDIT DRAFT IS APPROVED BY APPLICANT. IF THERE IS ANY DISCREPANCY BETWEEN THE DETAILS OF THIS LETTER OF CREDIT DRAFT AND THE LETTER OF CREDIT APPLICATION, BETWEEN APPLICANT AND SILICON VALLEY BANK, THE DETAILS HEREOF SHALL PREVAIL.”

_____ _____

APPLICANT’S SIGNATURE(s) DATE

CREDIT NO.SVBSF ____ UPON OUR RECEIPT OF YOUR INDEMNITY LETTER TO SILICON VALLEY BANK WHICH WILL BE SENT TO YOU UPON OUR RECEIPT OF YOUR WRITTEN REQUEST THAT THIS STANDBY LETTER OF CREDIT NO.SVBSF ____ IS LOST, STOLEN, OR DESTROYED. IF THE ORIGINAL OF THIS STANDBY LETTER OF CREDIT NO. SVBSF ____ IS MUTILATED, WE WILL ISSUE YOU A REPLACEMENT STANDBY LETTER OF CREDIT WITH THE SAME NUMBER, DATE AND TERMS AS THE ORIGINAL UPON OUR RECEIPT OF THE MUTILATED STANDBY LETTER OF CREDIT.

WE HEREBY AGREE WITH THE BENEFICIARY THAT DRAFTS DRAWN UNDER AND IN ACCORDANCE WITH THE TERMS AND CONDITIONS OF THIS LETTER OF CREDIT WILL BE DULY HONORED UPON PRESENTATION TO US ON OR BEFORE THE EXPIRATION DATE OF THIS LETTER OF CREDIT OR ANY AUTOMATICALLY EXTENDED EXPIRATION DATE.

IF ANY INSTRUCTIONS ACCOMPANYING A DRAWING UNDER THIS LETTER OF CREDIT REQUEST THAT PAYMENT IS TO BE MADE BY TRANSFER TO YOUR ACCOUNT WITH ANOTHER BANK, WE WILL ONLY EFFECT SUCH PAYMENT BY FED WIRE TO A U.S. REGULATED BANK, AND WE AND/OR SUCH OTHER BANK MAY RELY ON AN ACCOUNT NUMBER SPECIFIED IN SUCH INSTRUCTIONS EVEN IF THE NUMBER IDENTIFIES A PERSON OR ENTITY DIFFERENT FROM THE INTENDED PAYEE.

THIS LETTER OF CREDIT IS SUBJECT TO THE INTERNATIONAL STANDBY PRACTICES (ISP98), INTERNATIONAL CHAMBER OF COMMERCE, PUBLICATION NO. 590.

AUTHORIZED SIGNATURE

AUTHORIZED SIGNATURE

ALL THE DETAILS SET FORTH HEREIN IN THIS LETTER OF CREDIT DRAFT IS APPROVED BY APPLICANT. IF THERE IS ANY DISCREPANCY BETWEEN THE DETAILS OF THIS LETTER OF CREDIT DRAFT AND THE LETTER OF CREDIT APPLICATION, BETWEEN APPLICANT AND SILICON VALLEY BANK, THE DETAILS HEREOF SHALL PREVAIL."

APPLICANT'S SIGNATURE(s)

DATE

IRREVOCABLE STANDBY LETTER OF CREDIT NUMBER _____

EXHIBIT A

DATE:_____ REF. NO. _____

AT SIGHT OF THIS DRAFT

PAY TO THE ORDER OF _____ US$ _____

US DOLLARS _____

DRAWN UNDER SILICON VALLEY BANK, SANTA CLARA, CALIFORNIA, STANDBY LETTER OF CREDIT NUMBER NO. _____ DATED _____

TO: SILICON VALLEY BANK
3003 TASMAN DRIVE
SANTA CLARA, CA 95054

_____
(BENEFICIARY'S NAME)

_____
Authorized Signature

GUIDELINES TO PREPARE THE DRAFT

1. DATE: ISSUANCE DATE OF DRAFT.
2. REF. NO.: BENEFICIARY'S REFERENCE NUMBER, IF ANY.
3. PAY TO THE ORDER OF: NAME OF BENEFICIARY AS INDICATED IN THE L/C (MAKE SURE BENEFICIARY ENDORSES IT ON THE REVERSE SIDE).
4. US$: AMOUNT OF DRAWING IN FIGURES.
5. USDOLLARS: AMOUNT OF DRAWING IN WORDS.
6. LETTER OF CREDIT NUMBER: SILICON VALLEY BANK'S STANDBY L/C NUMBER THAT PERTAINS TO THE DRAWING.
7. DATED: ISSUANCE DATE OF THE STANDBY L/C.
8. BENEFICIARY'S NAME: NAME OF BENEFICIARY AS INDICATED IN THE L/C.
9. AUTHORIZED SIGNATURE: SIGNED BY AN AUTHORIZED SIGNER OF BENEFICIARY.

ALL THE DETAILS SET FORTH HEREIN IN THIS LETTER OF CREDIT DRAFT IS APPROVED BY APPLICANT. IF THERE IS ANY DISCREPANCY BETWEEN THE DETAILS OF THIS LETTER OF CREDIT DRAFT AND THE LETTER OF CREDIT APPLICATION, BETWEEN APPLICANT AND SILICON VALLEY BANK, THE DETAILS HEREOF SHALL PREVAIL."

_____ _____
APPLICANT'S SIGNATURE(s) DATE

IF YOU HAVE QUESTIONS RELATED TO THIS STANDBY LETTER OF CREDIT PLEASE CONTACT US AT _____.

IRREVOCABLE STANDBY LETTER OF CREDIT NUMBER _____

EXHIBIT B
TRANSFER FORM

DATE: _____

TO: SILICON VALLEY BANK
3003 TASMAN DRIVE
SANTA CLARA, CA 95054
ATTN:INTERNATIONAL DIVISION.
STANDBY LETTERS OF CREDIT

RE: IRREVOCABLE STANDBY LETTER OF CREDIT
NO. _____ ISSUED BY
SILICON VALLEY BANK, SANTA CLARA
L/C AMOUNT: _____

GENTLEMEN:

FOR VALUE RECEIVED, THE UNDERSIGNED BENEFICIARY HEREBY IRREVOCABLY TRANSFERS TO:

_____
(NAME OF TRANSFEREE)

_____
(ADDRESS)

ALL RIGHTS OF THE UNDERSIGNED BENEFICIARY TO DRAW UNDER THE ABOVE LETTER OF CREDIT UP TO ITS AVAILABLE AMOUNT AS SHOWN ABOVE AS OF THE DATE OF THIS TRANSFER.

BY THIS TRANSFER, ALL RIGHTS OF THE UNDERSIGNED BENEFICIARY IN SUCH LETTER OF CREDIT ARE TRANSFERRED TO THE TRANSFEREE. TRANSFEREE SHALL HAVE THE SOLE RIGHTS AS BENEFICIARY THEREOF, INCLUDING SOLE RIGHTS RELATING TO ANY AMENDMENTS, WHETHER INCREASES OR EXTENSIONS OR OTHER AMENDMENTS, AND WHETHER NOW EXISTING OR HEREAFTER MADE. ALL AMENDMENTS ARE TO BE ADVISED DIRECTLY TO THE TRANSFEREE WITHOUT NECESSITY OF ANY CONSENT OF OR NOTICE TO THE UNDERSIGNED BENEFICIARY.

THE ORIGINAL OF SUCH LETTER OF CREDIT IS RETURNED HEREWITH, AND WE ASK YOU TO ENDORSE THE TRANSFER ON THE REVERSE THEREOF, AND FORWARD IT DIRECTLY TO THE TRANSFEREE WITH YOUR CUSTOMARY NOTICE OF TRANSFER.

SINCERELY,

_____
(BENEFICIARY'S NAME)

_____
(SIGNATURE OF BENEFICIARY)

_____
(NAME AND TITLE)

SIGNATURE AUTHENTICATED
The name(s), title(s), and signature(s) conform to that/those on file with us for the company and the signature(s) is/are authorized to execute this instrument.

_____
(Name of Bank)

_____
(Address of Bank)

_____
(City, State, ZIP Code)

ALL THE DETAILS SET FORTH HEREIN IN THIS LETTER OF CREDIT DRAFT IS APPROVED BY APPLICANT. IF THERE IS ANY DISCREPANCY BETWEEN THE DETAILS OF THIS LETTER OF CREDIT DRAFT AND THE LETTER OF CREDIT APPLICATION, BETWEEN APPLICANT AND SILICON VALLEY BANK, THE DETAILS HEREOF SHALL PREVAIL."

_____ _____
APPLICANT'S SIGNATURE(s) DATE

EXHIBIT 31.1

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

I, Mihael H. Polymeropoulos, certify that:

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

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

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

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

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

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

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

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

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

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

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

July 28, 2016

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

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

EXHIBIT 31.2

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

I, James P. Kelly, certify that:

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

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

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

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

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

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

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

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

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

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

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

July 28, 2016

/s/ James P. Kelly

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

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER

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

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

The Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 (the Form 10-Q) of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the consolidated financial condition and results of operations of the Company.

July 28, 2016

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

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

July 28, 2016

/s/ James P. Kelly

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

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