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 March 31, 2014

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 April 30, 2014, there were 33,873,673 shares of the registrant's common stock issued and outstanding.

Vanda Pharmaceuticals Inc.

Quarterly Report on Form 10-Q
For the Quarter Ended March 31, 2014

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Part I — FINANCIAL INFORMATION

ITEM 1 Financial Statements (Unaudited)

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

(in thousands, except for share and per share amounts)	March 31, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 43,260	$ 64,764
Marketable securities	57,142	65,586
Accounts receivable	1,691	2,031
Inventory	192	—
Prepaid expenses and other current assets	3,132	2,703
Restricted cash	100	530
Total current assets	105,517	135,614
Property and equipment, net	2,208	2,198
Intangible asset, net	12,472	5,037
Restricted cash, non-current	785	500
Total assets	$ 120,982	$ 143,349
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 953	$ 661
Accrued liabilities	13,164	5,180
Deferred rent	228	221
Deferred revenues	31,059	26,789
Total current liabilities	45,404	32,851
Deferred rent, non-current	2,831	2,888
Deferred revenues, non-current	51,764	63,486
Total liabilities	99,999	99,225
Commitments and contingencies (Note 13)		
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; 33,873,673 and 33,338,543 shares issued and outstanding at March 31, 2014 and December 31, 2013, respectively	34	33
Additional paid-in capital	355,644	352,240
Accumulated other comprehensive income	8	21
Accumulated deficit	(334,703)	(308,170)
Total stockholders' equity	20,983	44,124
Total liabilities and stockholders' equity	$ 120,982	$ 143,349

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 March 31 2014	Three Months Ended March 31 2013
Revenues:		
Licensing agreement	$ 7,452	$ 6,606
Royalty revenue	1,691	1,462
Total revenues	9,143	8,068
Operating expenses:		
Research and development	7,263	8,111
Selling, general and administrative	27,893	4,153
Intangible asset amortization	565	369
Total operating expenses	35,721	12,633
Loss from operations	(26,578)	(4,565)
Other income	45	46
Loss before tax benefit	(26,533)	(4,519)
Tax benefit	—	—
Net loss	$ (26,533)	$ (4,519)
Basic and diluted net loss per share	$ (0.79)	$ (0.16)
Weighted average shares outstanding, basic and diluted	33,678,706	28,345,555

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 March 31 2014	March 31 2013
Net loss	$(26,533)	$ (4,519)
Other comprehensive loss:		
Change in net unrealized loss on marketable securities	(13)	(10)
Tax provision on other comprehensive income (loss)	—	—
Other comprehensive loss, net of tax:	(13)	(10)
Comprehensive loss	$(26,546)	$ (4,529)

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		Additional Paid-in Capital	Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Par Value				
Balances at December 31, 2013	33,338,543	33	355,432	21	(311,362)	44,124
Adjustment for change in accounting method	—	—	(3,192)	—	3,192	—
Adjusted balance at December 31, 2013	33,338,543	33	352,240	21	(308,170)	44,124
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	567,516	1	2,447	—	—	2,448
Shares withheld upon settlement of restricted stock units	(32,386)	—	(436)	—	—	(436)
Employee and non-employee stock based compensation expense	—	—	1,393	—	—	1,393
Net loss	—	—	—	—	(26,533)	(26,533)
Other comprehensive loss, net of tax	—	—	—	(13)	—	(13)
Balances at March 31, 2014	33,873,673	34	355,644	8	(334,703)	20,983

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)	Three Months Ended March 31 2014	March 31 2013
Cash flows from operating activities		
Net loss	$(26,533)	$ (4,519)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	125	107
Employee and non-employee stock-based compensation	1,393	1,298
Amortization of discounts and premiums on marketable securities	53	120
Intangible asset amortization	565	369
Changes in assets and liabilities:		
Accounts receivable	340	(294)
Prepaid expenses and other current assets	(429)	679
Inventory	(192)	—
Accounts payable	292	826
Accrued liabilities	7,984	(1,313)
Other liabilities	(50)	208
Deferred revenue	(7,452)	(6,606)
Net cash used in operating activities	(23,904)	(9,125)
Cash flows from investing activities		
Acquisition of intangible assets	(8,000)	—
Purchases of property and equipment	(135)	(23)
Purchases of marketable securities	(2,319)	—
Proceeds from sale of marketable securities	7,198	—
Maturities of marketable securities	3,500	30,500
Change in restricted cash	145	—
Net cash provided by investing activities	389	30,477
Cash flows from financing activities		
Tax obligations paid in connection with settlement of restricted stock units	(436)	(195)
Proceeds from exercise of employee stock options	2,447	2
Net cash provided by (used in) financing activities	2,011	(193)
Net (decrease) increase in cash and cash equivalents	(21,504)	21,159
Cash and cash equivalents		
Beginning of period	64,764	88,772
End of period	$ 43,260	$109,931

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

1. Business Organization and Presentation

Business organization

Vanda Pharmaceuticals Inc. (Vanda or the Company) is a biopharmaceutical company focused on the development and commercialization of products for the treatment of central nervous system disorders. Vanda commenced its operations in 2003. Vanda's product portfolio includes HETLIOZ™ (tasimelteon), a product for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) and for which a New Drug Application (NDA) was approved by the U.S. Food and Drug Administration (FDA) in January 2014, Fanapt®, a product for the treatment of schizophrenia, the oral formulation of which is currently being marketed and sold in the U.S. by Novartis Pharma AG (Novartis), and VLY-686, a small molecule neurokinin-1 receptor (NK-1R) antagonist.

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, 2013 included in the Company's annual report on Form 10-K. The financial information as of March 31, 2014 and for the three months ended March 31, 2014 and 2013 is unaudited, but in the opinion of management, all adjustments with the exception of stock-based compensation expense, see Note 3, *Change in Method of Accounting for Stock-based Compensation*, consist only of normal recurring accruals, considered necessary for a fair statement of the results of these interim periods have been included. The condensed consolidated balance sheet data as of December 31, 2013 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, 2013.

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 revenues and expenses during the reporting period. 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. The Company's inventory carrying values do not exceed cost nor do they exceed net realizable value.

Stock-based Compensation

In January 2014, the Company elected to change its method of accounting for the attribution of compensation cost for stock options with graded-vesting and only service conditions to the straight-line method. Previously, attribution was based on the

accelerated attribution method, which treated each vesting tranche as an individual award and amortized them concurrently. Comparative financial statements for prior periods have been adjusted to apply the straight-line method retrospectively. See Note 3, *Change in Method of Accounting for Stock-based Compensation,* for further information. Beginning in 2014, the Company started using a mid-point scenario to calculate the weighted average expected term of stock options granted, which combines the Company's historical exercise data with hypothetical exercise data for unexercised stock options. Prior to 2014, the expected term assumption was determined using the simplified method.

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 $0.9 million for the three months ended March 31, 2014. The Company did not incur any advertising expense during the three months ended March 31, 2013.

Recent accounting pronouncements

In July 2013, the FASB issued Accounting Standard Update (ASU) 2013-11, *Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists.* This new standard requires the netting of unrecognized tax benefits against a deferred tax asset for a loss or other carryforward that would apply in settlement of the uncertain tax positions. Under the new standard, unrecognized tax benefits will be netted against all available same-jurisdiction loss or other tax carryforwards that would be utilized, rather than only against carryforwards that are created by the unrecognized tax benefits. The new standard is effective for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2013. Adoption of this new standard did not have a material impact on the Company's condensed consolidated financial statements.

3. Change in Method of Accounting for Stock-based Compensation

In January 2014, the Company elected to change its method of accounting for the attribution of compensation cost for stock options with graded-vesting and only service conditions to the straight-line method. Previously, attribution was based on the accelerated attribution method, which treated each vesting tranche as an individual award and amortized them concurrently. The straight-line method of accounting was adopted to better align the Company's recognition of stock option compensation cost with its peers and to expense stock options and restricted stock units (RSUs) in a consistent manner. Comparative financial statements for prior periods have been adjusted to apply the straight-line method retrospectively. As a result of the change in method of accounting for stock-based compensation, the expense for stock-based compensation related to option awards was $0.5 million lower than it would have been under the accelerated attribution method for the three months ended March 31, 2014. This resulted in a reduction to the net loss of $0.5 million, or $0.02 per share, for the three months ended March 31, 2014.

There was no adjustment as a result of the change in method of accounting for stock-based compensation to amounts previously reported as assets, liabilities and total stockholders' equity in the consolidated balance sheets for prior periods. However, amounts previously reported as additional paid-in capital and accumulated deficit for prior periods have been adjusted to reflect the change in method of accounting for stock-based compensation. The cumulative effect of the change on accumulated deficit as of January 1, 2013, the beginning of the earliest period presented in the financial statements was a reduction of $3.2 million. The adjustments as of December 31, 2013 were as follows:

Balance Sheet	**December 31, 2013**		
(in thousands, except for share and per share amounts)	**As Previously Reported**	**Retrospective Adjustment**	**As Adjusted**
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; 33,338,543 shares issued and outstanding at December 31, 2013	$ 33	$ —	$ 33
Additional paid-in capital	355,432	(3,192)	352,240
Accumulated other comprehensive income	21	—	21
Accumulated deficit	(311,362)	3,192	(308,170)
Total stockholders' equity	$ 44,124	$ —	$ 44,124

The amounts previously reported in the consolidated statement of operations for research and development expense, selling, general and administrative expense and net loss for prior periods have been adjusted as a result of the change in method of accounting for stock-based compensation. The adjustments for the three months ended March 31, 2013 were as follows:

Statement of Operations	**Three Months Ended March 31, 2013**		
(in thousands, except for share and per share amounts)	**As previously Reported**	**Retrospective Adjustment**	**As Adjusted**
Revenues:			
Licensing agreement	$ 6,606	$ —	$ 6,606
Royalty revenue	1,462	—	1,462
Total revenues	8,068	—	8,068
Operating expenses:			
Research and development	7,960	151	8,111
Selling, general and administrative	3,958	195	4,153
Intangible asset amortization	369	—	369
Total operating expenses	12,287	346	12,633
Loss from operations	(4,219)	(346)	(4,565)
Other income	46	—	46
Loss before tax benefit	(4,173)	(346)	(4,519)
Tax benefit	—	—	—
Net loss	$ (4,173)	$ (346)	$ (4,519)
Basic and diluted net loss per share	$ (0.15)	$ (0.01)	$ (0.16)
Weighted average shares outstanding basic and diluted	28,345,555	—	28,345,555

The amounts previously reported for net loss in the consolidated statement of comprehensive loss for prior periods have been adjusted as a result of the change in method of accounting for stock-based compensation. The adjustment for the three months ended March 31, 2013 was as follows:

Statement of Comprehensive Loss	Three Months Ended March 31, 2013		
(in thousands)	As Previously Reported	Retrospective Adjustment	As Adjusted
Net loss	$ (4,173)	$ (346)	$(4,519)
Other comprehensive loss:			
Change in net unrealized loss on marketable securities	(10)	—	(10)
Tax provision on other comprehensive income (loss)	—	—	—
Other comprehensive loss, net of tax:	(10)	—	(10)
Comprehensive loss	$ (4,183)	$ (346)	$(4,529)

There was no adjustment to the amounts previously reported for net cash used in operating activities in the consolidated statements of cash flows for prior periods as a result of the change in method of accounting for stock-based compensation. However, the amounts previously reported as net loss and employee and non-employee stock-based compensation expense in cash flows from operating activities have been adjusted to reflect the change in method of accounting for stock-based compensation. The adjustments for the three months ended March 31, 2013 were as follows:

Statement of Cash Flows	Three Months Ended March 31, 2013		
(in thousands)	As Previously Reported	Retrospective Adjustment	As Adjusted
Cash flows from operating activities			
Net loss	$ (4,173)	$ (346)	$(4,519)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization of property and equipment	107	—	107
Employee and non-employee stock-based compensation	952	346	1,298
Amortization of discounts and premiums on marketable securities	120	—	120
Intangible asset amortization	369	—	369
Changes in assets and liabilities, net	(6,500)	—	(6,500)
Net cash used in operating activities	$ (9,125)	$ —	$(9,125)

4. Earnings per Share

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

The following table presents the calculation of basic and diluted net loss per share of common stock for the three months ended March 31, 2014 and 2013:

(in thousands, except for share and per share amounts)	Three Months Ended March 31 2014	March 31 2013
Numerator:		
Net loss	$ (26,533)	$ (4,519)
Denominator:		
Weighted average shares outstanding, basic and diluted	33,678,706	28,345,555
Net loss per share, basic and diluted:		
Net loss per share	$ (0.79)	$ (0.16)
Antidilutive securities excluded from calculations of diluted net loss per share	3,870,508	5,761,065

The Company incurred net losses for the three months ended March 31, 2014 and 2013 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.

5. Marketable Securities

The following is a summary of the Company's available-for-sale marketable securities as of March 31, 2014:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
U.S. Treasury and government agencies	$ 31,543	$ 5	$ (2)	$31,546
Corporate debt	$ 25,591	$ 6	$ (1)	$25,596
	$ 57,134	$ 11	$ (3)	$57,142

The following is a summary of the Company's available-for-sale marketable securities as of December 31, 2013:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
U.S. Treasury and government agencies	$ 31,557	$ 9	$ —	$31,566
Corporate debt	$ 34,008	$ 18	$ (6)	$34,020
	$ 65,565	$ 27	$ (6)	$65,586

6. Fair Value Measurements

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

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

Marketable securities classified in Level 1 and Level 2 as of March 31, 2014 and December 31, 2013 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 three months ended March 31, 2014.

As of March 31, 2014, the Company held certain assets that are required to be measured at fair value on a recurring basis, as follows:

		Fair Value Measurement as of March 31, 2014 Using		
(in thousands)	March 31, 2014	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	$ 57,142	$ 31,546	$ 25,596	$ —

As of December 31, 2013, 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, 2013 Using		
(in thousands)	December 31, 2013	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	$ 65,586	$ 31,566	$ 34,020	$ —

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, the carrying value of which materially approximate their fair values.

7. 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 consisted of the following as of March 31, 2014 and December 31, 2013:

(in thousands)	March 31, 2014	December 31, 2013
Raw materials	$ 143	$ —
Work-in-process	49	—
Finished goods	—	—
Total	$ 192	$ —

8. Prepaid Expenses and Other Current Assets

The following is a summary of the Company's prepaid expenses and other current assets as of March 31, 2014 and December 31, 2013:

(in thousands)	March 31, 2014	December 31, 2013
Prepaid insurance	$ 33	$ 167
Other prepaid expenses and vendor advances	3,000	2,408
Accrued interest income	99	128
Total prepaid expenses and other current assets	$ 3,132	$ 2,703

9. Intangible Assets

The following is a summary of the Company's intangible asset as of March 31, 2014:

(in thousands)	Estimated Useful Life (Years)	March 31, 2014 Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ™	9	$ 8,000	$ 150	$ 7,850
Fanapt®	7.5	$12,000	$ 7,378	$ 4,622

The following is a summary of the Company's intangible asset as of December 31, 2013:

(in thousands)	Estimated Useful Life (Years)	December 31, 2013 Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Fanapt®	8	$12,000	$ 6,963	$ 5,037

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 Bristol-Myers Squibb (BMS) which 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 the Company expects to last until December 2022.

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 which required the Company to make a license payment of $12.0 million to Novartis. The $12.0 million is being amortized on a straight-line basis over the remaining life of the U.S. patent for Fanapt®, which as of December 31, 2013 the Company expected to last until May 2017. In 2014, the Company became aware of events that led it to believe that Novartis would not complete the ongoing pediatric efficacy studies in a time that would enable it to receive the incremental six-month pediatric term extension. This resulted in a six-month reduction to the estimated patent life from May 2017 to November 2016.

The intangible assets are being amortized over their estimated useful economic life using the straight-line method. Amortization expense was $0.6 million and $0.4 million for the three months ended March 31, 2014 and 2013, respectively. The following is a summary of future intangible asset amortization as of March 31, 2014:

(in thousands)	Total	Remainder of 2014	2015	2016	2017	2018	Thereafter
HETLIOZ™	$ 7,850	$ 673	$ 897	$ 897	$897	$897	$ 3,589
Fanapt®	4,622	1,300	1,733	1,589	—	—	—
	$12,472	$ 1,973	$2,630	$2,486	$897	$897	$ 3,589

10. Accrued Liabilities

The following is a summary of the Company's accrued liabilities as of March 31, 2014 and December 31, 2013:

(in thousands)	March 31, 2014	December 31, 2013
Accrued research and development expenses	$ 1,949	$ 2,324
Accrued consulting and other professional fees	9,839	2,015
Employee benefits	762	176
Other accrued liabilities	614	665
	$ 13,164	$ 5,180

11. Deferred Revenue

The following is a summary of changes in total deferred revenue for the three months ended March 31, 2014 and 2013:

	Three Months Ended	
(in thousands)	March 31 2014	March 31 2013
Balance beginning of period	$90,275	$117,064
Licensing revenue recognized	7,452	6,606
Balance end of period	$82,823	$110,458

The Company entered into an amended and restated sublicense agreement with Novartis in 2009, pursuant to which Novartis has the right to commercialize and develop Fanapt® in the U.S. and Canada. Under the amended and restated sublicense agreement, the Company received an upfront payment of $200.0 million. The Company and Novartis established a Joint Steering Committee (JSC) following the effective date of the amended and restated sublicense agreement. The Company concluded that the JSC constitutes a deliverable under the amended and restated sublicense agreement and that revenue related to the upfront payment will be recognized ratably over the term of the JSC; however, the delivery or performance has no term as the exact length of the JSC is undefined. As a result, the Company deems the performance period of the JSC to be the life of the U.S. patent of Fanapt®. Revenue related to the upfront payment will be recognized ratably from the date the amended and restated sublicense agreement became effective (November 2009) through the expected life of the U.S. patent for Fanapt® (November 2016). See Note 9 *Intangible Assets*, for a discussion of the Fanapt® patent life.

12. 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 March 31, 2014 and December 31, 2013. Changes in ownership may limit the amount of NOL carryforwards that can be utilized in the future to offset taxable income.

13. Commitments and Contingencies

Operating leases

In 2011, the Company entered into an office lease with Square 54 Office Owner LLC (the Landlord) for its current headquarters, consisting of 21,400 square feet at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. (the Lease). Subject to the prior rights of other tenants in the building, the Company has the right to renew the Lease for five years following the expiration of its original term. The Company has the right to sublease or assign all or a portion of the premises, subject to standard conditions. The Lease may be terminated early by the Company or the Landlord upon certain conditions.

In March 2014, the Company and the Landlord entered into a lease amendment (the Lease Amendment). Under the Lease Amendment, the Company has the right to occupy an additional 8,860 square feet in the building. The Lease Amendment has a 12 year and one month term beginning on September 1, 2014, but may be terminated early by either the Landlord or the Company upon certain conditions. The Company will pay approximately $0.4 million in annual rent over the term of the Lease Amendment, however rent will be abated for the first nine months. The Landlord will provide the Company with an allowance of approximately $0.8 million for construction on the premises to the Company's specifications, subject to certain conditions. Subject to the prior rights of other tenants in the building, the Company will have the right to renew the Lease Amendment for five years following the expiration of its original term. The Company paid advanced rent of approximately $32,000 upon execution of the Lease Amendment. The Company will also have the right to sublease or assign all or a portion of the premises, subject to standard conditions.

The following is a summary of the minimum annual future payments under operating leases as of March 31, 2014:

(in thousands)	Total	Remainder of 2014	2015	2016	2017	2018	Thereafter
Operating leases	$15,502	$ 851	$1,337	$1,500	$1,538	$1,576	$ 8,700

Rent expense under operating leases, was $0.4 million and $0.2 million for the three months ended March 31, 2014 and 2013, respectively.

Consulting fees

The Company engaged a regulatory consultant to assist the Company's efforts to prepare, file and obtain FDA approval of an NDA for HETLIOZ™. As a result of the FDA approval of the NDA for HETLIOZ™, the Company made a milestone payment of $2.0 million, which is included in research and development expenses in the consolidated statement of operations for the three months ended March 31, 2014. In addition to consulting fees and milestone payments, the Company is obligated to reimburse the consultant for ordinary and necessary business expenses. In March 2014, the Company terminated the engagement.

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 the Company received an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize HETLIOZ™. As a result of the FDA approval of the NDA for HETLIOZ™ in January 2014, the Company made a milestone payment of $8.0 million in the first quarter of 2014. The Company will be obligated to make a future milestone payment to BMS of up to $25.0 million in the event that cumulative sales of HETLIOZ™ reach $250.0 million. Additionally, the Company will be obligated to make royalty payments equal to 10% of net sales of HETLIOZ™. 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 the Company receives from a third party in connection with any sublicensing arrangement, at a rate which is in the mid-twenties. Under the license agreement with BMS for HETLIOZ™, the Company is obligated to use commercially reasonable efforts to develop and commercialize HETLIOZ™ and to meet certain milestones in initiating and completing certain clinical work.

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®. The Company acquired exclusive worldwide rights to patents and patent applications for Fanapt® in 2004 through a sublicense agreement with Novartis. As a result of the FDA's approval of the NDA for Fanapt® in May 2009, the Company met a milestone under the sublicense agreement, which required the Company to make a payment of $12.0 million to Novartis.

In 2009, the Company entered into an amended and restated sublicense agreement with Novartis, which amended and restated the 2004 sublicense agreement. Pursuant to the amended and restated sublicense agreement, the Company received an upfront payment of $200.0 million and is eligible for additional payments totaling up to $265.0 million upon Novartis' achievement of certain commercial and development milestones for Fanapt® in the U.S. and Canada. Based on the current sales performance of Fanapt® in the U.S., the Company expects that some or all of these commercial and development milestones will not be achieved by Novartis. The Company also receives royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanapt® in the U.S. and Canada.

The Company retains exclusive rights to Fanapt® outside the U.S. and Canada, and the Company has exclusive rights to use any of Novartis' data for Fanapt® for developing and commercializing Fanapt® outside the U.S. and Canada. Novartis has chosen not to co-commercialize Fanapt® with the Company in Europe and certain other countries and will instead receive a royalty on net sales in those countries. These include, but are not limited to, the countries in the European Union as well as Switzerland, Norway, Liechtenstein and Iceland. The Company has entered into agreements with the following partners for the commercialization of Fanapt® in the countries set forth below:

Country	Partner
Mexico	Probiomed S.A. de C.V.
Israel	Megapharm Ltd.

In 2012, the Israeli Ministry of Health and Argentina granted market approval for Fanapt® for the treatment of schizophrenia. In October 2013, the Mexican Federal Commission for Protection Against Sanitary Risks (COFEPRIS) granted market approval for Fanapt® for the treatment of schizophrenia.

VLY-686. In 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, VLY-686, for all human indications. The patent describing VLY-686 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 will be responsible for all development costs, and Lilly is eligible to receive 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 VLY-686.

Either party may terminate the license agreement under certain circumstances, including a material breach of the license agreement by the other. In the event 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 VLY-686.

Future milestone payments. No amounts were recorded as liabilities nor were any future contractual obligations relating to the license agreements included in the consolidated financial statements as of March 31, 2014 because the criteria for recording the future milestone payments have not yet been met. These criteria include the successful outcome of future clinical trials, regulatory filings, favorable FDA regulatory approvals, growth in product sales and other factors.

14. Employee 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 generally recognizes the expense over the award's vesting period.

In January 2014, the Company elected to change its method of accounting for the attribution of compensation cost for stock options with graded-vesting and only service conditions from the accelerated attribution method to the straight-line method. See Note 3, *Change in Method of Accounting for Stock-based Compensation* for additional discussion. The fair value of stock options granted and 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. Beginning in 2014, the Company started using a mid-point scenario to calculate the weighted average expected term of stock options granted, which combines the Company's historical exercise data with hypothetical exercise data for unexercised stock options. Prior to 2014, the expected term assumption was determined using the simplified method. 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 three months ended March 31, 2014 and 2013 were as follows:

	Three Months Ended	
	March 31 2014	March 31 2013
Expected dividend yield	0%	0%
Weighted average expected volatility	66%	62%
Weighted average expected term (years)	5.85	6.03
Weighted average risk-free rate	1.79%	1.05%
Weighted average fair value per share	$ 7.90	$ 2.25

Total employee stock-based compensation expense related to stock-based awards for the three months ended March 31, 2014 and 2013 was comprised of the following:

	Three Months Ended	
(in thousands)	March 31 2014	March 31 2013
Research and development	$ 442	$ 597
Selling, general and administrative	912	707
	$ 1,354	$ 1,304

As of March 31, 2014, the Company had two equity incentive plans, the Second Amended and Restated Management Equity Plan (the 2004 Plan) and the 2006 Equity Incentive Plan (the 2006 Plan). There were 652,810 shares subject to outstanding options granted under the 2004 Plan as of March 31, 2014, and no additional options will be granted under this plan. As of March 31, 2014, there were 10,329,472 shares of common stock reserved for issuance under the 2006 Plan, of which 5,786,979 shares were subject to outstanding options and RSUs granted to employees and non-employees and 2,476,074 shares remained available for future grant.

The Company has granted option awards with service conditions 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 2007, 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 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 March 31, 2014, there was $9.0 million of unrecognized compensation costs related to unvested service option awards expected to be recognized over a weighted average period of 1.7 years. No service option awards are classified as a liability as of March 31, 2014.

A summary of option activity for the 2004 Plan for the three months ended March 31, 2014 follows:

(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, 2013	670,744	$ 1.79	1.78	$ 7,124
Expired	—			
Exercised	(17,934)			
Outstanding at March 31, 2014	652,810	1.74	1.53	9,472
Exercisable at March 31, 2014	652,810	1.74	1.53	9,472

There are no options expected to vest as of March 31, 2014 under the 2004 Plan, given that the Company stopped issuing options from this plan in 2006.

A summary of option activity for the 2006 Plan for the three months ended March 31, 2014 follows:

(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, 2013	5,533,618	$ 10.98	6.93	$ 21,264
Granted	103,500	13.23		
Forfeited	(165,340)	6.38		
Expired	—			
Exercised	(340,020)	7.01		2,644
Outstanding at March 31, 2014	5,131,758	11.43	6.74	34,827
Exercisable at March 31, 2014	3,267,469	13.19	5.44	20,125
Expected to vest at March 31, 2014	1,766,665	8.28	8.99	14,079

Proceeds from the exercise of stock options amounted to $2.4 million for the three months ended March 31, 2014.

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 with service conditions that vest in four equal annual installments provided that the employee remains employed with the Company. As of March 31, 2014, there was $5.2 million of unrecognized compensation costs related to unvested RSUs expected to be recognized over a weighted average period of 2.1 years. No RSUs are classified as a liability as of March 31, 2014.

A summary of RSU activity for the 2006 Plan for the three months ended March 31, 2014 follows:

	Number of Shares Underlying RSUs	Weighted Average Grant Date Fair Value
Unvested at December 31, 2013	883,690	$ 7.70
Granted	41,500	13.23
Forfeited	(60,407)	6.23
Vested	(209,562)	6.67
Unvested at March 31, 2014	655,221	8.52

The grant date fair value for the 209,562 shares underlying RSUs that vested during the three months ended March 31, 2014 was $1.4 million. In order for certain employees to satisfy the minimum statutory employee tax withholding requirements related to the issuance of common stock underlying certain of RSUs that vested and settled during the three months ended March 31, 2014, the Company withheld 32,386 shares of common stock and paid employee payroll withholding taxes of $0.4 million relating to the vesting and settlement of the RSUs.

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

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:

- our ability to successfully commercialize HETLIOZ™ (tasimelteon) for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in the U.S.;
- uncertainty as to market awareness of Non-24 and the market acceptance of HETLIOZ™;
- our dependence on third-party manufacturers to manufacture HETLIOZ™ in sufficient quantities and quality;
- our limited sales and marketing infrastructure;
- the regulatory status of tasimelteon in Europe;
- 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 and sublicense agreements;
- the failure to obtain, or any delay in obtaining, regulatory approval for our products, particularly HETLIOZ™ outside the U.S., or to comply with ongoing regulatory requirements;
- the extent and effectiveness of the development, sales and marketing and distribution support Fanapt® receives;
- our inability to successfully commercialize Fanapt® outside of the U.S. and Canada;
- a failure of our products to be demonstrably safe and effective;
- our expectations regarding trends with respect to our revenues, costs, expenses and liabilities;
- 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 potential litigation; and
- losses incurred from product liability claims made against us.

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. We also encourage you to read Item 1A of Part I of our annual report on Form 10-K for the fiscal year ended December 31, 2013, which contains a more complete discussion of the risks and uncertainties associated with our business. 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, 2013, other unknown or unpredictable factors also could affect our results. Therefore, the information in this report should be read together with other reports and documents that we file with the Securities and Exchange Commission (SEC) 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.

Overview

Vanda Pharmaceuticals Inc. (we, our, or Vanda) is a biopharmaceutical company focused on the development and commercialization of products for the treatment of central nervous system disorders. Vanda commenced its operations in 2003 and our product portfolio includes:

- 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 April 2014 in the U.S.;
- Fanapt®(iloperidone), a product for the treatment of schizophrenia, the oral formulation of which is currently being marketed and sold in the U.S. by Novartis Pharma AG (Novartis); and
- VLY-686 (tradipitant), a small molecule neurokinin-1 receptor (NK-1R) antagonist.

Since we began operations in March 2003, we have devoted substantially all of our resources to the in-licensing and clinical development of our products. Our products target prescription markets with significant unmet medical needs. Our ability to generate revenue and achieve profitability largely depends on our ability, alone or with others, to complete the development of our products, and to obtain the regulatory approvals for and manufacture, market and sell our products, including HETLIOZ™ for the treatment of Non-24 and Novartis' ability to successfully commercialize Fanapt® in the U.S. The results of our operations will vary significantly 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 Item 1A of Part I, entitled "Risk Factors," of our annual report on Form 10-K for the fiscal year ended December 31, 2013.

Our activities will necessitate significant uses of working capital throughout 2014 and beyond. We are currently concentrating our efforts on the U.S. commercial launch of HETLIOZ™. Additionally, we and our partners continue to pursue market approval of Fanapt® in a number of foreign jurisdictions, with Mexico, Israel and Argentina having already approved Fanapt® for the treatment of schizophrenia.

Revenues

Our revenues are derived primarily from our amended and restated sublicense agreement with Novartis and include an upfront payment, product sales and future milestone and royalty payments. Revenues are considered both realizable and earned when the following four conditions are met: (i) persuasive evidence of an arrangement exists, (ii) the arrangement fee is fixed or determinable, (iii) delivery or performance has occurred, and (iv) collectability is reasonably assured. Revenue related to the $200.0 million upfront payment is being recognized ratably on a straight-line basis from the date the amended and restated sublicense agreement became effective (November 2009) through the expected life of the U.S. patent for Fanapt® which we expect to last until November 2016. See *Intangible Assets* footnote to the condensed consolidated financial statements included in Part I of this quarterly report on Form 10-Q for further information. This includes the Hatch-Waxman extension that extends patent protection for drug compounds for a period of five years to compensate for time spent in development, for which Fanapt® has qualified. We recognize revenues from Fanapt® royalties and commercial and development milestones from Novartis when realizable.

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 employee 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. We incurred selling, general and administrative expenses of $27.9 million for the three months ended March 31, 2014.

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.

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. Our inventory carrying values do not exceed cost nor do they exceed net realizable value. We evaluate expiry risk by evaluating current and future product demand relative to product shelf life. We build demand forecasts by considering factors such as, but not limited to, overall market potential, market share, market acceptance and patient usage.

Stock-based Compensation

In January 2014, we elected to change our method of accounting for the attribution of compensation cost for stock options with graded-vesting and only service conditions to the straight-line method. Previously, attribution was based on the accelerated attribution method, which treated each vesting tranche as an individual award and amortized them concurrently. The straight-line method of accounting was adopted to better align our recognition of stock option compensation cost with our peers and to expense stock options and restricted stock units in a consistent manner. Comparative financial statements for prior periods have been adjusted to apply the straight-line method retrospectively. See *Change in Method of Accounting for Stock-based Compensation* footnote to the condensed consolidated financial statements included in Part I of this quarterly report on Form 10-Q for further information. Beginning in 2014, we started using a mid-point scenario to calculate the weighted average expected term of stock options granted, which combines our historical exercise data with hypothetical exercise data for unexercised stock options. Prior to 2014, the expected term assumption was determined using the simplified method.

Total employee stock-based compensation expense related to stock-based awards for the three months ended March 31, 2014 and 2013 was comprised of the following:

	Three Months Ended	
(in thousands)	**March 31 2014**	**March 31 2013**
Research and development	$ 442	$ 597
Selling, general and administrative	912	707
	$ 1,354	$ 1,304

With the exception of accounting for stock-based compensation, there have been no significant changes in our critical accounting policies including estimates, assumptions and judgments as described in 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, 2013.

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 $334.7 million as of March 31, 2014. Our total stockholders' equity was $21.0 million as of March 31, 2014.

Three months ended March 31, 2014 compared to three months ended March 31, 2013

Revenues. Total revenues increased by $1.0 million, or 12%, to $9.1 million for the three months ended March 31, 2014 compared to $8.1 million for the three months ended March 31, 2013. Revenues for the three months ended March 31, 2014 and 2013 include licensing revenue of $7.5 million and $6.6 million, respectively, representing amortization of deferred revenue from the $200.0 million up-front license fee received from Novartis. Revenues for the three months ended March 31, 2014 included royalty revenue of $1.7 million from Novartis based on quarterly sales of Fanapt® by Novartis compared to $1.5 million for the three months ended March 31, 2013. In April 2014, we announced the commercial launch of HETLIOZ™.

Research and development expenses. Research and development expenses decreased by $0.8 million, or 10%, to $7.3 million for the three months ended March 31, 2014 compared to $8.1 million for the three months ended March 31, 2013. The following table summarizes the costs of our product development initiatives for the three months ended March 31, 2014 and 2013. Included in this table are the research and development expenses recognized in connection with the clinical development of HETLIOZ™, VLY-686 and Fanapt®:

	Three Months Ended	
(in thousands)	**March 31, 2014**	**March 31, 2013**
Direct project costs (1)		
HETLIOZ™	$ 5,691	$ 6,853
VLY-686	586	231
Fanapt®	77	156
Other direct project costs	8	—
	6,362	7,240
Indirect project costs (1)		
Employee stock-based compensation	442	597
Other indirect overhead	459	274
	901	871
Total research & development expense	$ 7,263	$ 8,111

(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 employee stock-based compensation.

Direct HETLIOZ™ project costs decreased $1.2 million, or 17%, to $5.7 million for the three months ended March 31, 2014 compared to $6.9 million for the three months ended March 31, 2013. Lower research and development expenses were primarily due to the completion of Non-24 and Major Depressive Disorder efficacy studies during the first quarter of 2013, partially offset by a $2.0 million milestone payment related to our regulatory consulting agreement as a result of the FDA approval of our NDA for HETLIOZ™ and third-party manufacturing costs incurred in anticipation of HETLIOZ™ approval.

Direct VLY-686 project costs increased $0.4 million, or 200%, to $0.6 million for the three months ended March 31, 2014 compared to $0.2 million for the three months ended March 31, 2013 due to increased activity related to the Phase II clinical study, which commenced in 2014.

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 $23.7 million, or 564%, to $27.9 million for the three months ended March 31, 2014 compared to $4.2 million for the three months ended March 31, 2013. During the three months ended March 31, 2014, we added a field based sales force and a national accounts team. In addition, a medical affairs team has been deployed to support HETLIOZ™ and Non-24 medical education. We expanded the Non-24 Disease Awareness campaign with radio and television advertisements broadcast nationwide. Salaries and benefit costs increased approximately $1.5 million to $2.5 million during the quarter primarily due to increases in our employee headcount. Costs are expected to increase in future periods as we continue to build our marketing and sales organization for the commercial launch of HETLIOZ™.

Intangible asset amortization. Intangible asset amortization was $0.6 million for the three months ended March 31, 2014 compared to $0.4 million for the three months ended March 31, 2013. The increase is due to amortization related to the $8.0 million milestone payment made to BMS as a result of receiving FDA approval for HETLIOZ™ that was capitalized in the first quarter of 2014.

Liquidity and Capital Resources

As of March 31, 2014, our total cash and cash equivalents and marketable securities were $100.4 million, compared to $130.4 million as of December 31, 2013. 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 March 31, 2014 and December 31, 2013 are summarized as follows:

(in thousands)	March 31, 2014	December 31, 2013
Cash and cash equivalents	$ 43,260	$ 64,764
Marketable securities:		
U.S. Treasury and government agencies	31,546	31,566
Corporate debt	25,596	34,020
Total marketable securities	57,142	65,586
Total cash and cash equivalents	$100,402	$ 130,350

As of March 31, 2014 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 as a result of the FDA approval of our NDA for HETLIOZ™ and the U.S. commercial launch of HETLIOZ™. In the first quarter of 2014, we made milestone payments of $8.0 million under the license agreement with BMS and $2.0 million under a regulatory consulting agreement as a result of HETLIOZ™ being approved by the FDA.

Because of the uncertainties discussed above, the costs to advance our research and development projects and the commercial launch of HETLIOZ™, are difficult to estimate and may vary significantly. It is uncertain whether our existing funds will be sufficient to meet our operating needs. 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. 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 cash flows for the three months ended March 31, 2014 and 2013:

	Three Months Ended March 31,	
	2014	2013
Net cash provided by (used in):		
Operating activities	$ (23,904)	$ (9,125)
Investing activities	389	30,477
Financing activities	2,011	(193)
Net increase (decrease) in cash and cash equivalents	$ (21,504)	$ 21,159

In assessing cash used in operating activities, we consider several principal factors: (i) net loss for the period; (ii) adjustments for non-cash charges including stock-based compensation expense, amortization of intangible assets and depreciation and amortization of property and equipment; and (iii) the extent to which receivables, accounts payable and other liabilities, or other working capital components increase or decrease.

Net cash used in operating activities was $23.9 million for the three months ended March 31, 2014, an increase of $14.8 million from net cash used in operating activities of $9.1 million for the three months ended March 31, 2013. The increase in net cash used for operating activities resulted from an increase in net loss of $22.0 million, which was partially offset by an increase of $0.2 million in non-cash charges, and a net increase of $7.0 million in the working capital components that provided operating cash flow in the three months ended March 31, 2014 and 2013.

Net cash provided by investing activities of $0.4 million for the three months ended March 31, 2014 primarily resulted from $8.4 million in net proceeds from sales, maturities and purchases of marketable securities, which was partially offset by an $8.0 million milestone payment to BMS as a result of the FDA approval of HETLIOZ™ in January 2014. Net cash provided by investing activities of $30.5 million for the three months ended March 31, 2013 consisted of maturities of marketable securities.

Net cash provided by financing activities of $2.0 million for the three months ended March 31, 2014, an increase of $2.2 million, from net cash used in financing activities of $0.2 million for the three months ended March 31, 2013. The increase is primarily due to $2.4 million in cash proceeds from the exercise of employee stock options.

Off-balance sheet arrangements

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

Contractual obligations and commitments

Other than as set forth below, there have been no material changes to our contractual obligations from the information provided 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, 2013.

Operating leases

In March 2014, we entered into a lease amendment (Lease Amendment) with Square 54 Office Owner LLC (the Landlord) to

occupy an additional 8,860 square feet in our headquarters building located in Washington, D.C. The Lease Amendment has a 12 year and one month term beginning on September 1, 2014, but may be terminated early by either the Landlord or us upon certain conditions. We will pay approximately $0.4 million in annual rent over the term of the Lease Amendment, however rent will be abated for the first nine months. Subject to the prior rights of other tenants in the building, we will have the right to renew the Lease Amendment for five years following the expiration of its original term. We paid advanced rent of approximately $32,000 upon execution of the Lease Amendment. We will also have the right to sublease or assign all or a portion of the premises, subject to standard conditions.

ITEM 3 Quantitative and Qualitative Disclosures about Market Risk

Interest rates

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.

Marketable securities

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.

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 (Exchange Act)) as of March 31, 2014. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of March 31, 2014, 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 controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the first quarter of 2014 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

None

ITEM 1A Risk Factors

In our annual report on Form 10-K for the fiscal year ended December 31, 2013, we identify under Part I, Item IA important factors which could affect our business, financial condition, results of operations and future operations and could cause our actual results for future periods to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statements made in this quarterly report on Form 10-Q. 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, 2013.

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
10.53†	Manufacturing Agreement between the Registrant and Patheon Pharmaceuticals Inc. dated January 24, 2014 (relating to HETLIOZ™).
10.54	Amendment to Lease agreement dated July 25, 2011 by and between Registrant and Square 54 Office Owner LLC, dated March 18, 2014, by and between the Registrant and Square 54 Office Owner LLC.
18.1	Preferability Letter of Independent Public Accounting Firm dated May 7, 2014.
31.1	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer), as required by Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from this quarterly report on Form 10-Q for the fiscal quarter ended March 31, 2014 formatted in XBRL (eXtensible Business Reporting Language) and furnished electronically herewith: (i) Condensed Consolidated Balance Sheets as of March 31, 2014 and December 31, 2013; (ii) Condensed Consolidated Statements of Operations for the three months ended March 31, 2014 and 2013; (iii) Condensed Consolidated Statement of Comprehensive Loss for the three months ended March 31, 2014 and 2013; (iv) Condensed Consolidated Statement of Changes in Stockholders' Equity for the three months ended March 31, 2014; (v) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2014 and 2013; 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 SEC.

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.

May 8, 2014 /s/ Mihael H. Polymeropoulos, M.D.

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

May 8, 2014 /s/ James P. Kelly

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

VANDA PHARMACEUTICALS INC.

EXHIBIT INDEX

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EXHIBIT 10.53

CONFIDENTIAL TREATMENT REQUESTED

Manufacturing Agreement

January 24, 2014

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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.

EXHIBIT 10.53

CONFIDENTIAL TREATMENT REQUESTED

MANUFACTURING AGREEMENT

THIS MANUFACTURING AGREEMENT (the "Agreement") is made as of January 24, 2014 (the "**Effective Date**")

B E T W E E N:

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

(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**").

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;

"**Actual Annual Yield**" or "AAY" has the meaning specified in Section 2.2(a);

"**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 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 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 Volume**" means 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 State of Ohio and the United States, 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, whether federal, state, provincial, county or municipal;

"Bill Back Items" means the expenses for all third party supplier fees for the purchase or use of columns, standards, tooling, non-standard pallets, PAPR or PPE suits (where applicable), RFID tags and supporting equipment, and other project-specific items necessary for Patheon to perform the Manufacturing Services, and which are not included as Components;

"**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 State of Ohio (with respect to Patheon only) or a day that is a statutory holiday in Washington, D.C. (with respect to Client only);

"**cGMPs**" means current good manufacturing practices, regulations and guidelines as described in:

(a) Division 2 of Part C of the Food and Drug Regulations (Canada);

(b) Parts 210 and 211 of Title 21 of the United States' Code of Federal Regulations; and

(c) EC Directive 2003/94/EC,

together with the latest Health Canada, FDA and EMA guidance documents pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time;

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

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

"**Components**" means, collectively, all packaging components, raw materials and ingredients (including labels, product inserts and other labelling for the Products), required to be used in order to produce the Products in accordance with the Specifications, other than the 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 September 28, 2009 and February 7, 2013.

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

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

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

"**Firm Order(s)**" 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 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;

"**Inventory**" means all inventories of Components and work-in-process produced or held by Patheon for the manufacture of the Products but, for greater certainty, does not include the Active Materials;

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

"**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 and Components;

"**Manufacturing Site**" means the facility owned and operated by Patheon that is located at 2110 E Galbraith Rd, Cincinnati, OH 45237;

"**Maximum Credit Value**" means the maximum value of Active Materials that may be credited by Patheon pursuant to this Agreement, as set forth on Schedule D;

"**Minimum Order Quantity**" means the minimum number of units of a Product to be ordered in order to obtain the Price as set forth in Schedule B hereto.

"**MSDS**" has the meaning specified in Section 5.2;

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

"**Patheon Requirement**" has the meaning specified in 2.1(h);

"**Packaged Product(s)**" means Product(s) packaged into primary and (where applicable) secondary packaging Components, including printed packaging Components where specified;

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

"**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 dated August 22, 2013 between the parties hereto setting out the quality assurance standards to be applicable to the Manufacturing performed by Patheon, which agreement is attached hereto as Schedule G;

"**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);

"**SEC**" has the meaning set forth in Section 11.1;

"**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 and 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;

"**Target Yield**" has the meaning specified in Section 2.2(a);

"**Target Yield Determination Batches**" has the meaning specified in Section 2.2(a);

"**Technical Dispute**" has the meaning specified in Section 12.2;

"**Territory**" means in the geographic area of the United States of America;

"**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 & Maximum Credit Value
Schedule E		Batch Numbering & Expiration Dates
Schedule F	-	Technical Dispute Resolution
Schedule G	-	Quality Agreement
Schedule H	-	Quarterly Active Materials Inventory Report
Schedule I	-	Report of Annual Active Materials Inventory Reconciliation and Calculation of Actual Annual Yield

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 ****. 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 all Components (with the exception of those that are supplied by the Client, which for certainty excludes Active Materials), in accordance with the Specifications. Patheon shall test all Components and Active Materials in accordance with the Specifications.

(d) Stability Testing. 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. 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 and Client Supplied Components. Client will **** deliver the Active Materials and any Client-supplied Components to the Manufacturing Site DDP (Incoterms 2010) at least **** before the scheduled production date, at no cost to Patheon, in sufficient quantity to enable Patheon to manufacture the desired quantities of Product and to ship Product on the Delivery Date. If the Active Materials and/or Client-supplied Components are not received at least **** before the scheduled production date, Patheon will make commercially reasonable efforts to expedite analytical testing at the Client's expense to maintain the scheduled production date. If the Active Materials and/or Client-supplied Components are not received at least **** before the scheduled production date and expedited release cannot be accomplished to maintain the scheduled production date (after use of commercially reasonable efforts by Patheon), Patheon may ****

****. ****. All shipments of Active Materials will be accompanied by certificate(s) of analysis from the Active Materials manufacturer and the Client, confirming the identity and purity of the Active Materials and its compliance with the Active Materials specifications.

(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 that are necessary for Patheon to perform the Manufacturing (or which are not included as Components or part of the Manufacturing fees in Schedule B), 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.

(h) Requirements. Client hereby agrees to order **** of its total Yearly requirement in the Order Countries for new units of Products **** (the "**Patheon Requirement**") from Patheon. However, Client may order the Patheon Requirement, in whole or in part, from a third party supplier if Patheon ****. In addition, ****. Notwithstanding the foregoing, Patheon acknowledges and agrees that **** shall not be counted in determining Client's "total Yearly requirement in the Order Countries for new units of Products" (i.e., Client may ****). 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 **** of its total Yearly requirement for new units of Products in the Order Countries from Patheon.

(i) Product Rejection for Finished Product Specification Failure. Patheon shall manufacture Product in accordance with agreed upon Specifications, including Specifications for Patheon's internal process. If Patheon manufactures Product in accordance with the such Specifications, the batch production record, Patheon's standard operating procedures for manufacturing (including, without limitation, for cleaning and calibration), all applicable laws, this Agreement and the Quality Agreement, and **** Client will pay Patheon ****. The API in the non-conforming Product will ****.

(j) Patheon shall maintain and service all equipment that Client has authorized Patheon to purchase on Client's behalf, such equipment to be returned promptly by Patheon to Client in good working order, reasonable wear and tear excepted, following the termination or expiration of this Agreement. Unless otherwise agreed in a separate written equipment agreement, Patheon shall not use all or any part of such equipment for any purpose other than supplying Product to Client under this Agreement.

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 or this Agreement.

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:

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

After ****, the Parties will mutually agree on the target yield in respect of the Products at the Manufacturing Site (a "**Target Yield**"); provided, however, that ****. Thereafter, Patheon shall strive to maintain Actual Annual Yield levels for the Products equal to or above the Target Yield. For the sake of clarity, if applicable, the AAY and the Target Yield are each calculated for ****.

(b) Shortfall Calculation. If the Actual Annual Yield falls **** 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 ****.

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. Client's obligation will include obtaining the proper release of the Active Materials from the applicable Customs Agency and Regulatory Authority. Client or Client's designated broker will be the "**Importer of Record**" for Active Materials imported to the Manufacturing Site. 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).

If Client asks Patheon to qualify an additional source for the Active Material or any Component, Patheon will evaluate the Active Material or Component to be supplied by the additional source to determine if it is suitable for use in the Product. The parties will agree on the scope of work to be performed by Patheon at Client's cost. For an Active Material, this work at a minimum will include:

(a) laboratory testing to confirm the Active Material meets existing specifications;

(b) manufacture of an experimental batch of Product that will be placed on **** accelerated stability; and

(c) manufacture of **** full-scale validation batches that will be placed on concurrent stability (one batch may be the registration batch if manufactured at full scale).

Section 2.1(i) will apply to all Product manufactured using the newly approved Active Material or Component because of the limited material characterization that is performed on additional sources of supply.

ARTICLE 4

CONVERSION FEES AND COMPONENT COSTS

4.1 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 **** shall be determined in accordance with the following:

(a) Manufacturing and Component Costs. On each **** 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 and is subject to change following good faith discussions by the parties if the specified Annual Volume or Minimum Order Quantity increases or decreases. For greater certainty, if Patheon and the Client agree that the Annual Volume or Minimum Order Quantity in respect of a Product shall be reduced beyond the range of such values provided in the tables in Schedule B, whether as a result of a decrease in estimated annual volume or otherwise, 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 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.

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 ****.

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) Annual Quantity. 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 Annual Volume or Minimum Order Quantity 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/or the actual Annual Volume, 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.

(b) Extraordinary Increase in Component Costs. If at any time market conditions result in Patheon's cost of Components being **** greater than normal forecasted increases, then Patheon shall be entitled to an adjustment to the fee for Manufacturing in respect of any affected Product solely to compensate it for such increased Component 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 shall be considered to have occurred only if ****. 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 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 Component (or 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, adjusted Component costs 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 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 ****. Open purchase orders for Components 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 Packaged Product(s) for the specific markets in the Territory requested by Client. Should Client wish to have Patheon provide Manufacturing in respect of the Product for countries in addition to those countries listed in Schedule B, then the Client shall inform Patheon of the packaging requirements for each new country and Patheon shall, in good faith, prepare a quotation for consideration by the Client of the additional Component costs, if any, and the change over fees for the Product destined for each such new country. 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 each **** 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 **** have 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 delivered to the Client on one 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"**). 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 ****. If 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 Delivery Date of any Firm Order, 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 each ****, 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.

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) 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 of the Product unique to the Client (e.g., packaging labels), 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 unique Components have expired during such period, then the Client shall pay to Patheon ****. Patheon shall be responsible for obtaining material safety data sheets ("MSDS") of all Components purchased by Patheon pursuant to this Agreement. The MSDS will be used to establish conformance of the Components to the Specifications and to advise Patheon as to any safety or special handling requirements related to the Components.

5.3 Minimum Orders.

The Client may only order Manufacturing in respect of batches of Products in multiples of the Minimum Order Quantities as set out in Schedule B.

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 **** 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.

5.5 On Time Delivery.

(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 by **** following the Delivery Date ****, 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 if 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 ****.

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 Inventory or Components which are to be purchased by Patheon pursuant to the terms of this Agreement. 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 such undisputed invoices within **** of the date thereof, provided, however, that payment will only be for ****. ****. ****. Patheon shall fax or email a copy of the invoice to fax number or email address provided by Client on the date of invoice

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 **** without invalidating 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 **** 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 ****, 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. If: (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, **** will co-operate as reasonably required by ****, 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. If 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 ****. If 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.

(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 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 the Annual Product Review Report. Patheon will also 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. Any additional reports requested by Client beyond the scope of cGMPs and customary FDA requirements will be subject to an additional fee to be agreed upon in writing. 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 **** (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.

(e) Client Responsibility. For clarity, the parties agree that ****. Subject to the foregoing, Patheon will not assume any responsibility for the accuracy of any application for receipt of an approval by a Regulatory Authority. The Client is solely responsibility for the preparation and filing of the application for approval by the Regulatory Authority and any relevant costs will be borne by the Client.

(f) Inspection by Regulatory Authorities. If Client does not ****.

ARTICLE 8

TERM AND TERMINATION

8.1 Initial Term.

This Agreement shall become effective as of the Effective Date and shall continue for five 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 year each unless either party gives written notice to the other party of its intention to terminate this Agreement at least 12 months prior to the end of the then current term.

8.2 Termination for Cause.

(a) Either party at its sole option may terminate this Agreement 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 upon **** prior written notice if any governmental agency takes any action, or raises any objection, that prevents the Client from importing, exporting, purchasing or selling such Product. In addition, the Client may terminate this Agreement **** written notice to Patheon in the event that any governmental agency in the Territory makes a decision not to grant marketing authorization to the Client with respect to 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 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 at any time, for any or no reason, upon not less than **** notice to Patheon, provided that ****. The Client may, upon the completion of **** of this Agreement, terminate this Agreement at any time, for any or no reason, upon not less than **** notice to Patheon, provided that ****. ****.

8.3 Obligations on Termination.

If this Agreement expires or is terminated in whole or in part 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 ****, (i) the remaining Components applicable to the Products 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.

(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, Inventory and supplies, undelivered Product, 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 or in part 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 promptly all unused Active Materials and provide to the Client all Inventory purchased by the Client (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 Services 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.

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 Product or any of the Active Materials and the Components 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 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) ****; 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 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 the 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 ****, **** maximum liability per Year under this Agreement for any reason whatsoever, including, without limitation, any liability resulting from a breach of its representations, warranties or other obligations under this Agreement, shall not exceed **** of the total fees paid under this Agreement by Client to Patheon in such Year, up to a maximum value **** 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 ****.

If a claim occurs, 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 ****

****.

If a claim occurs, 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 five years 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 there from, 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 second round of responses to comments from the SEC. 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.

If any dispute arises 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.

If a dispute (other than disputes in relation to the matters set out in Sections 6.1(b) and 12.1) arises 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.

If 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 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. Without limitation, Patheon agrees that it shall not

use any such Client Intellectual Property or Client confidential information to enable itself or any third party to develop, make, have made, offer, sell or exploit the Products.

(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 ****

(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, bodily injury or property damage liability; and (ii) **** in the aggregate per annum with respect to product and completed operations liability. 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, or material change in, 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 ****, 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.

Additional products 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: Chief Financial Officer

Telecopier No.: ****

If to Patheon:

Patheon Pharmaceuticals Inc.
2110 East Galbraith Road
Cincinnati, OH 45237-1625
Attention: Director of Legal Services
Telecopier No.: ****

Email address: ****

With a copy to:

Patheon Inc.
4721 Emperor Boulevard
Research Triangle Park,
NC 27703
Attention: General Counsel
Telecopier No.: ****
Email address: ****

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 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. 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.

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 PHARMACEUTICALS INC.

By /s/ Dean Wilson
Name: Dean Wilson
Title: VP corporate controller 1/24/2014

VANDA PHARMACEUTICALS INC.

By /s/ M. H. Polymeropoulos, M.D.
Name: M. H. Polymeropoulos, M.D.
Title: CEO

SCHEDULE A

PRODUCT LIST

Products

Hetlioz™ 20 mg Capsules in ****

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 revised 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.

CONFIDENTIAL TREATMENT REQUESTED

SCHEDULE B

COMMERCIAL PRICING

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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.

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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.

CONFIDENTIAL TREATMENT REQUESTED

SCHEDULE C

STABILITY TESTING

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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.

EXHIBIT 10.53

CONFIDENTIAL TREATMENT REQUESTED

SCHEDULE D

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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.

CONFIDENTIAL TREATMENT REQUESTED

SCHEDULE E

BATCH NUMBERING & EXPIRATION DATES

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SCHEDULE F

TECHNICAL DISPUTE RESOLUTION

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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.

SCHEDULE G

QUALITY AGREEMENT

SCHEDULE H

QUARTERLY ACTIVE MATERIALS INVENTORY REPORT

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SCHEDULE I

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

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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.

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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.

EXHIBIT 10.54

FINAL EXECUTION COPY

AMENDMENT NO. 1 TO LEASE

THIS AMENDMENT NO. 1 TO LEASE ("**Amendment**") is made as of the 18 day of March 2014 ("**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 ("**Lease**"), Landlord is leasing to Tenant 21,400 square feet of rentable area located on the 3rd floor of the East Tower of the Building (the "**Premises**"), located at 2200 Pennsylvania Avenue, NW, Washington, DC (the "**Building**"); and

WHEREAS, Landlord desires to lease to Tenant and Tenant desires to lease from Landlord in accordance with the terms hereof, eight thousand eight hundred sixty (8,860) rentable square feet of office space ("**2nd Floor East Premises**") on the second (2nd) floor of the East Tower of the Building, as shown on **Exhibit A** attached hereto; and

WHEREAS, Landlord and Tenant desire to amend certain terms and conditions of the Lease as set forth herein.

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. 2nd Floor East Premises; Lease Term.

(a) Notwithstanding anything to the contrary contained in the Lease, Landlord does hereby lease to Tenant and Tenant does hereby lease from Landlord the 2nd Floor East Premises. The 2nd Floor East Premises shall be subject to, and have the benefits of, all of the terms and conditions of the Lease applicable with respect to the original Premises for the entire 2nd Floor East Premises Lease Term (as hereinafter defined), except as otherwise expressly provided herein.

(b) The term of the Lease with respect to the 2nd Floor East Premises will commence on September 1, 2014 ("**2nd Floor East Premises Lease Commencement Date**"), and shall expire on September 30, 2026 ("**2nd Floor East Premises Lease Term**"), unless such 2nd Floor East Premises Lease Term shall be terminated earlier in accordance with the provisions of the Lease or shall be extended in accordance with the provisions in Paragraph 8 below and **Rider No. 1** to the Lease. Tenant shall be deemed to have commenced beneficial use of the 2nd Floor East Premises when Tenant commences business operations in the 2nd Floor

East Premises. Landlord anticipates delivering the 2nd Floor East Premises twenty-four (24) hours following the Effective Date of this Amendment. The term "Lease Term" in the Lease shall include the period of the 2nd Floor East Premises Lease Term and, if applicable, the 2nd Floor East Premises Renewal Term, with respect to the 2nd Floor East Premises so that the Lease Term will continue with respect to the 2nd Floor East Premises even if the only space leased under the Lease is the 2nd Floor East Premises.

(c) The term "Premises" as used in the Lease (but not as used herein) shall mean the original Premises and the 2nd Floor East Premises.

3. 2nd Floor East Premises Base Rent; Operating Expenses.

(a) Commencing on the 2nd Floor East Premises Lease Commencement Date, and continuing thereafter during the 2nd Floor East Premises Lease Term, Tenant shall pay to Landlord as annual base rent for the 2nd Floor East Premises, without set off, deduction or demand, an amount equal to the product of Forty-Three and 00/100 Dollars ($43.00) multiplied by the total number of square feet of rentable area in the 2nd Floor East Premises (i.e, 8,860 rentable square feet). In addition, Tenant shall pay to Landlord on or prior to the Effective Date, the sum of Thirty-One Thousand Seven Hundred Forty-Eight and 34/100 Dollars ($31,748.34) ("**2nd Floor East Premises Advanced Rent**"), which sum shall be credited by Landlord toward the monthly installment of annual base rent due on the first (1st) day of the tenth (10th) calendar month falling after the month in which the 2nd Floor East Premises Lease Commencement Date occurs.

(b) Notwithstanding anything to the contrary contained in this Paragraph 3 and provided no Event of Default by Tenant has occurred, Landlord hereby agrees to grant Tenant an abatement of one hundred percent (100%) of the annual base rent and Operating Expenses payable hereunder for the first nine (9) full calendar months of the 2nd Floor East Premises Lease Term (the "**2nd Floor East Premises Rent Abatement**"); provided however, if Tenant cures such Event of Default in full prior to the end of the first nine (9) full calendar months of the 2nd Floor East Premises Lease Term, then Tenant shall be entitled to the abatement as of the day following such cure. Thereafter Tenant shall pay the full amount of annual base rent due in accordance with the provisions of this Paragraph 3. Notwithstanding anything to the contrary in this Paragraph 3(b), the rent escalation, as required by Paragraph 3(c) below, shall be based on the full and unabated amount of rent payable for the first (1st) Lease Year of the 2nd Floor East Premises Lease Term as set forth in Paragraph 3(a) above.

(c) Commencing on the first anniversary of the 2nd Floor East Premises Lease Commencement Date and each anniversary thereafter during the 2nd Floor East Premises Lease Term, the base rent for the 2nd Floor East Premises payable by Tenant shall be increased by two and one-half percent (2.5%) of the amount of base rent payable for the preceding Lease Year.

(d) Commencing on the 2nd Floor East Premises Lease Commencement Date, Tenant shall pay Landlord, as additional rent for the 2nd Floor East Premises, Tenant's proportionate share of the Operating Expenses incurred by Landlord during any calendar year

falling entirely or partly within the 2nd Floor East Premises Lease Term. Such Operating Expenses for the 2nd Floor East Premises shall be calculated in the same manner as is set forth in Article IV of the Lease, with the proportionate share adjusted during the 2nd Floor East Premises Lease Term to reflect the 2nd Floor East Premises leased pursuant to this Amendment.

4. Security Deposit; Reductions in Letter of Credit.

(a) On or before the Effective Date, pursuant to the terms of Article V of the Lease, Tenant shall deliver to Landlord Two Hundred Eighty-Five Thousand and 00/100 Dollars ($285,000.00) in the form of a Letter of Credit as an additional Security Deposit under the Lease for the 2nd Floor East Premises ("**Second Floor East Premises Security Deposit**").

(b) Provided that, as of the applicable Reduction Date (as defined below) (x) no Event of Default shall then be in existence under the Lease, (y) Tenant's then-current Liquidity (as defined in the Lease) is equal to or greater than the sum of Tenant's remaining obligations under the Lease, and (z) if Cash Flow from Operations (as defined in the Lease) is negative, Tenant's then current Liquidity also is equal to or greater than the product of (I) the annual Cash Flow from Operations multiplied by (II) the number of years remaining in the 2nd Floor East Premises Lease Term (i.e., the cash burn), Tenant shall have the right with respect to each Reduction Date to reduce the 2nd Floor East Premises Security Deposit to the amount of the 2nd Floor East Premises Security Deposit set forth below as of each Reduction Date. The following chart reflects the potential dates on which a reduction in the amount of the 2nd Floor East Premises Security Deposit may occur, and the resulting required amount of the 2nd Floor East Premises Security Deposit in the event of the applicable reduction:

Reduction Date	**Required Amount of 2nd Floor East Premises Security Deposit**
being later of (A) 30 days after the Audited Financial Statements (as defined in the Lease) are delivered to Landlord for fiscal year ending immediately prior to start of applicable Lease Year below or (B) first day of applicable Lease Year below:	
Fourth Lease Year of 2nd Floor East Premises Lease Term	$228,000.00
Sixth Lease Year of 2nd Floor East Premises Lease Term	$171,000.00
Eighth Lease Year of 2nd Floor East Premises Lease Term	$114,000.00

"Lease Year" for the purposes of the above chart shall only mean each 12 month period commencing on the 2nd Floor East Premises Lease Commencement Date.

If all of the aforesaid conditions are met, within ten (10) business days after Landlord's receipt of Tenant's written request certifying that all conditions to the applicable reduction have been met, Landlord shall notify the issuer of the Letter of Credit that the Letter of Credit may be reduced in the amount of the reduction so authorized and the security deposit shall be so reduced in accordance with Section 5.1(d) of the Lease.

5. Condition of the Premises.

(a) Tenant shall accept the 2nd Floor East Premises in Ready for Buildout Condition as described in Section 2.2 of the Lease and the condition generally described in **Exhibit B – Schedule I** of the Lease. All Tenant improvements to the 2nd Floor East Premises ("**2nd Floor East Premises Related Work**") shall be done in accordance with the requirements set forth in **Exhibit B** to the Lease.

(b) Provided no Event of Default has occurred, Landlord shall grant Tenant an improvement allowance ("**2nd Floor East Premises Related Allowance**") in an amount equal to the product of (a) Eighty-Five and 00/100 Dollars ($85.00), multiplied by (b) the number of rentable square feet in the 2nd Floor East Premises (i.e., $753,100.00) to be applied to the 2nd Floor East Premises Related Work in compliance with the provisions set forth in (i) – (iii) below. If Tenant cures such Event of Default prior to the end of the first twelve (12) months of the 2nd Floor East Premises Lease Term, then Tenant shall be entitled to the allowance as of the day following such cure. Any portion of the 2nd Floor East Premises Related Allowance that remains unreserved and unapplied after the expiration of the first twelve (12) months of the 2nd Floor East Premises Lease Term shall be deemed waived and forfeited. Notwithstanding anything contained in the Lease or this Amendment to the contrary:

(i) At least eighty percent (80%) (i.e., $602,480.00) of the 2nd Floor East Premises Related Allowance must be applied toward hard construction costs.

(ii) Tenant may apply up to twenty percent (20%) (i.e., $150,620.00) of the 2nd Floor East Premises Related Allowance toward architectural design fees, engineering fees, telephone/data installation, security systems, cabling and wiring and construction management fees ("**Soft Construction Costs**"), but not toward any abatement of rent, furniture, fixtures and equipment, moving costs or move-related expenses.

(iii) At least Four Hundred Forty Three Thousand and No/100 Dollars ($443,000.00) of the 2nd Floor East Premises Related Allowance (i.e., $50.00 per rentable square feet of the 2nd Floor East Premises) must be applied toward hard construction costs within the 2nd Floor East Premises, specifically excluding any costs related to the Interconnecting Stair, as defined below. No more than Three Hundred Ten Thousand and No/100 Dollars ($310,000.00) of the 2nd Floor East Premises Related Allowance (i.e., $35.00 per rentable square foot of the 2nd Floor East Premises) may be applied toward hard construction costs and/or Soft Construction Costs on the Interconnecting Stair and/or tenant improvements on the third floor portion of the Premises.

(c) Disbursements of the 2nd Floor East Premises Related Allowance will be made in accordance with the terms and conditions set forth in **Exhibit B** to the Lease.

6. Internal Stairwell. Subject to Landlord's approval of size, location and design, Tenant shall have the right to install a communicating stair ("**Interconnecting Stair**") between the 2nd Floor East Premises and Tenant's original Premises located on the 3rd Floor East of the Building ("**Interconnecting Stair Area**"). At the direction of Landlord, Tenant must remove or demise-off the Interconnecting Stair to meet Legal Requirements upon the expiration or earlier termination of either (i) the Lease Term with respect to the portion of the Premises located on the third floor only, (ii) the 2nd Floor East Premises Lease Term or (iii) the Lease Term for all of the space leased to Tenant under the Lease and this Amendment, and Tenant shall restore the Interconnecting Stair Area to its condition prior to installation of the Interconnecting Stair in compliance with Legal Requirements. The slab shall be restored such that the stair opening will be in-filled with concrete on metal deck supported by edge angles. The in-fill will achieve the same load capacity as that of the existing slab around the opening and will be a 2 hour rated assembly. The slab levelness and load capacity will comply with specifications in **Exhibit B – Schedule I** to the Lease, including the specifications in Section 1(d). Additionally, the in-fill will be constructed in a manner that does not exceed the capacity of the adjacent floor slab or adversely impact the ceiling plenum of the space below. Notwithstanding the foregoing, however, Tenant shall not be responsible for the removal of the Interconnecting Stair and restoration or demising-off of the Interconnecting Stair Area if Hunton & Williams LLP exercises its right to expand into Tenant's original Premises and the 2nd Floor East Premises at the same time, and provided Hunton & Williams LLP elects to keep the Interconnecting Stair in place.

7. Parking. In accordance with Article XXIV of the Lease, Landlord agrees to make available to Tenant and its employees and to Tenant's permitted subtenants, at the then prevailing monthly market rate for non-reserved parking permits in comparable Trophy Class and Class A buildings in downtown Washington, D.C., monthly parking permits in an aggregate amount not to exceed one (1) monthly parking permit for each one thousand three hundred fifty (1,350) square feet of above-grade rentable area in the 2nd Floor East Premises (i.e., seven (7) monthly parking permits).

8. Renewal. In addition to the renewal rights granted in Rider No 1 to the Lease, upon the expiration of the 2nd Floor East Premises Lease Term, Tenant shall have the conditional right to renew the term of the Lease with respect to the 2nd Floor East Premises for one (1) additional term of five (5) years ("**2nd Floor East Premises Renewal Term**"). Tenant's right to renew the term of the Lease with respect to the 2nd Floor East Premises hereunder is subject and subordinate to the right of Hunton & Williams LLP to expand into the 2nd Floor East Premises pursuant to expansion rights contained in Hunton & Williams LLP's lease pursuant to a mutual agreement of Landlord and Hunton & Williams LLP. In addition, all other terms and conditions of the 2nd Floor East Premises Renewal Term shall be in accordance with **Rider No. 1** to the Lease; provided however, the Renewal Option Notice and Outside Notice Deadline shall be based on the 2nd Floor East Premises Lease Expiration Date.

9. Access Control. In accordance with Article XIV of the Lease, Landlord shall, at its cost, provide an initial set of access cards to the Building and Garage in an amount equal to the number of initial employees of Tenant who work on a full-time basis at the 2nd Floor East Premises as of the 2nd Floor East Premises Lease Commencement Date, in an aggregate amount not to exceed one (1) for each five hundred (500) square feet of above grade rentable area in the 2nd Floor East Premises (excluding any storage space leased by Tenant).

10. Signage. Subject to the terms and conditions of Article X of the Lease, Tenant shall be permitted, at its sole cost, to install its own unique signage on or next to its suite entrance on the 2nd Floor East. Any signage installed by Tenant shall be removed by Tenant, at its sole cost and expense upon the expiration of the 2nd Floor East Premises Lease Term (and Tenant shall repair any damage to the Building or the 2nd Floor East Premises caused by such removal).

11. 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.

12. Broker. Landlord recognizes Studley and Cushman and Wakefield (collectively, the "**Brokers**") as the sole brokers procuring this Amendment and shall pay said Brokers a commission pursuant to separate agreements between said Brokers 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 Brokers.

13. 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.

14. 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.

15. 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.

16. 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.

17. 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. 1 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/ Peter D. Johnston [SEAL]

Name: Peter D. Johnston

Title: Senior Vice President

TENANT:

VANDA PHARMACEUTICALS INC.,
a Delaware corporation

By: /s/ James Kelly [SEAL]

Name: James Kelly

Title: SVP & CFO

EXHIBIT A
DIAGRAM OF 2nd Floor East Premises

EXHIBIT A
OUTLINE OF THE EXPANSION PREMISES
2nd Floor East

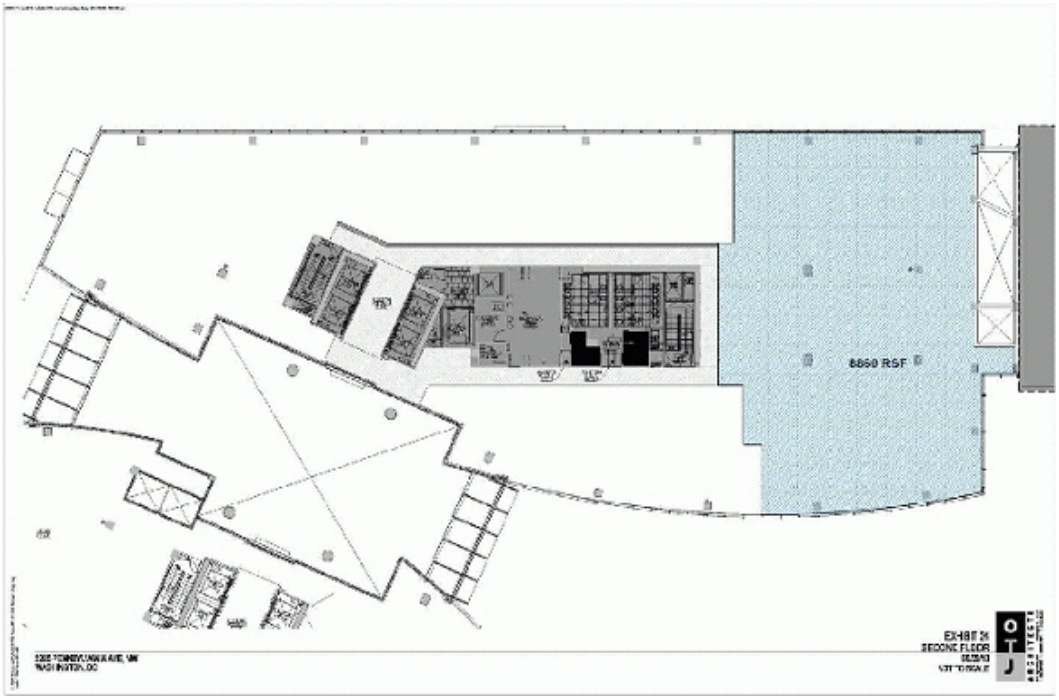

Exhibit A

2200 Pennsylvania Avenue NW
Vanda Pharmaceuticals Amendment No. 1

EXHIBIT 18.1

May 8, 2014

Board of Directors
Vanda Pharmaceuticals, Inc.
2200 Pennsylvania Avenue, Suite 300
Washington DC, 20037

Dear Directors:

We are providing this letter to you for inclusion as an exhibit to your Form 10-Q filing pursuant to Item 601 of Regulation S-K.

We have been provided a copy of the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2014. Note 3 therein describes a change in accounting principle from the accelerated attribution method to the straight-line method of recording certain share-based compensation costs. It should be understood that the preferability of one acceptable method of accounting over another for the attribution of share-based compensation costs has not been addressed in any authoritative accounting literature, and in expressing our concurrence below we have relied on management's determination that this change in accounting principle is preferable. Based on our reading of management's stated reasons and justification for this change in accounting principle in the Form 10-Q, and our discussions with management as to their judgment about the relevant business planning factors relating to the change, we concur with management that such change represents, in the Company's circumstances, the adoption of a preferable accounting principle in conformity with Accounting Standards Codification 250, *Accounting Changes and Error Corrections*.

We have not audited any financial statements of the Company as of any date or for any period subsequent to December 31, 2013. Accordingly, our comments are subject to change upon completion of an audit of the financial statements covering the period of the accounting change.

Very truly yours,

PricewaterhouseCoopers, LLP

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.

May 8, 2014

/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.

May 8, 2014

/s/ James P. Kelly

James P. Kelly
Senior Vice President, Chief Financial Officer,
Secretary 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 March 31, 2014 (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.

May 8, 2014

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

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

May 8, 2014

/s/ James P. Kelly

James P. Kelly
Senior Vice President, Chief Financial Officer,
Secretary 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.