
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-Q

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

For the quarterly period ended September 30, 2015

or

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

Commission File Number: 000-50768

ACADIA PHARMACEUTICALS INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State of Incorporation)

06-1376651
(I.R.S. Employer
Identification No.)

3611 Valley Centre Drive, Suite 300
San Diego, California
(Address of Principal Executive Offices)

92130
(Zip Code)

(858) 558-2871
(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 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 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 Securities Exchange Act of 1934.

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

Total shares of common stock outstanding as of the close of business on October 30, 2015:

<u>Class</u>	<u>Number of Shares Outstanding</u>
Common Stock, \$0.0001 par value	100,911,625

ACADIA PHARMACEUTICALS INC.

FORM 10-Q

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED).**ACADIA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)
(Unaudited)**

	September 30, 2015	December 31, 2014 (1)
Assets		
Cash and cash equivalents	\$ 70,799	\$ 61,854
Investment securities, available-for-sale	169,892	260,632
Interest and other receivables	206	964
Prepaid expenses and other current assets	1,950	1,168
Total current assets	242,847	324,618
Property and equipment, net	2,068	553
Other assets	405	287
Total assets	<u>\$ 245,320</u>	<u>\$ 325,458</u>
Liabilities and stockholders' equity		
Accounts payable	\$ 2,204	\$ 2,016
Accrued liabilities	15,531	13,818
Total current liabilities	17,735	15,834
Long-term liabilities	239	135
Total liabilities	17,974	15,969
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized at September 30, 2015 and December 31, 2014; no shares issued and outstanding at September 30, 2015 and December 31, 2014	—	—
Common stock, \$0.0001 par value; 225,000,000 shares and 150,000,000 shares authorized at September 30, 2015 and December 31, 2014, respectively; 100,896,200 shares and 100,047,331 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	10	10
Additional paid-in capital	844,093	807,631
Accumulated deficit	(616,802)	(498,143)
Accumulated other comprehensive income (loss)	45	(9)
Total stockholders' equity	227,346	309,489
Total liabilities and stockholders' equity	<u>\$ 245,320</u>	<u>\$ 325,458</u>

- (1) The condensed consolidated balance sheet at December 31, 2014 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

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

ACADIA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)
(Unaudited)

	<u>Three Months Ended</u> <u>September 30,</u>		<u>Nine Months Ended</u> <u>September 30,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Revenues				
Collaborative revenues	\$ 39	\$ 15	\$ 44	\$ 72
Operating expenses				
Research and development (includes stock-based compensation expense of \$3,938, \$1,358, \$9,139, and \$3,452, respectively)	18,729	16,952	53,403	42,420
General and administrative (includes stock-based compensation expense of \$5,327, \$2,544, \$22,153, and \$7,942, respectively)	20,308	8,057	65,688	22,328
Total operating expenses	<u>39,037</u>	<u>25,009</u>	<u>119,091</u>	<u>64,748</u>
Loss from operations	(38,998)	(24,994)	(119,047)	(64,676)
Interest income, net	92	208	388	567
Net loss	<u>\$ (38,906)</u>	<u>\$ (24,786)</u>	<u>\$ (118,659)</u>	<u>\$ (64,109)</u>
Net loss per common share, basic and diluted	<u>\$ (0.39)</u>	<u>\$ (0.25)</u>	<u>\$ (1.18)</u>	<u>\$ (0.66)</u>
Weighted average common shares outstanding, basic and diluted	<u>100,756</u>	<u>99,497</u>	<u>100,436</u>	<u>97,210</u>

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

ACADIA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)
(Unaudited)

	<u>Three Months Ended</u> <u>September 30,</u>		<u>Nine Months Ended</u> <u>September 30,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Net loss	<u>\$(38,906)</u>	<u>\$(24,786)</u>	<u>\$(118,659)</u>	<u>\$(64,109)</u>
Other comprehensive loss:				
Unrealized gain (loss) on investment securities	34	(17)	51	29
Foreign currency translation adjustments	—	—	3	—
Comprehensive loss	<u>\$(38,872)</u>	<u>\$(24,803)</u>	<u>\$(118,605)</u>	<u>\$(64,080)</u>

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

ACADIA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(Unaudited)

	Nine Months Ended	
	September 30,	
	2015	2014
Cash flows from operating activities		
Net loss	\$(118,659)	\$ (64,109)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	31,292	11,394
Amortization of premiums and accretion of discounts on investment securities, available for sale	(1,902)	345
Depreciation	519	145
Changes in operating assets and liabilities:		
Interest and other receivables	758	(389)
Prepaid expenses and other current assets	(782)	(307)
Other assets	(118)	1
Accounts payable	144	738
Accrued liabilities	1,571	3,576
Deferred revenue	—	(40)
Long-term liabilities	104	13
Net cash used in operating activities	<u>(87,073)</u>	<u>(48,633)</u>
Cash flows from investing activities		
Purchases of investment securities	(215,926)	(307,211)
Maturities of investment securities	308,619	179,548
Purchases of property and equipment	(1,848)	(86)
Net cash provided by (used in) investing activities	<u>90,845</u>	<u>(127,749)</u>
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	5,170	201,044
Net cash provided by financing activities	<u>5,170</u>	<u>201,044</u>
Effect of exchange rate changes on cash	3	—
Net increase in cash and cash equivalents	<u>8,945</u>	<u>24,662</u>
Cash and cash equivalents		
Beginning of period	61,854	11,707
End of period	<u>\$ 70,799</u>	<u>\$ 36,369</u>
Supplemental schedule of noncash investing activities		
Property and equipment purchases in accounts payable and accrued liabilities	<u>\$ 186</u>	<u>\$ —</u>

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

ACADIA PHARMACEUTICALS INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2015
(Unaudited)

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of ACADIA Pharmaceuticals Inc. should be read in conjunction with the audited financial statements and notes thereto as of and for the year ended December 31, 2014 included in the Company's Annual Report on Form 10-K ("Annual Report") filed with the Securities and Exchange Commission ("SEC"). The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying financial statements do not include all of the information and notes required by GAAP for complete financial statements. In the opinion of management, the accompanying financial statements reflect all adjustments (consisting of normal recurring adjustments) that are necessary for a fair statement of the financial position, results of operations and cash flows for the interim periods presented. Interim results are not necessarily indicative of results for a full year. The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the accompanying notes. Actual results could differ from those estimates.

The Company has incurred substantial operating losses since its inception due in large part to expenditures for its research and development activities. As of September 30, 2015, the Company had an accumulated deficit of \$616.8 million. The Company expects to continue to incur operating losses for at least the next few years as it advances its programs and incurs significant development and commercialization costs.

The Company may require significant additional financing in the future to fund its operations. Future capital requirements will depend on many factors, including the progress in, the outcome of and the costs of the Company's development, regulatory and potential commercialization activities, including the ability of the Company to obtain regulatory approval for its products, costs associated with establishing necessary sales and marketing capabilities, the amount of product sales, if any, the scope, prioritization and number of its research and development programs, the ability of its collaborators and the Company to reach milestones and other events or developments under its collaboration and license agreements, and the ability of the Company to enter into new, and to maintain existing, collaboration and license agreements. Unless and until the Company can generate significant cash from operations, it expects to fund its operations through its existing cash, cash equivalents and investment securities, payments from existing and potential future collaborations, proceeds from public or private sales of its equity securities, debt financing, grant funding, or by licensing all or a portion of its product candidates or technology. The Company cannot be certain that adequate additional funding will be available on acceptable terms, or at all. Conditions in the financial markets and other factors could have a material adverse effect on the Company's ability to access sufficient funding on acceptable terms, or at all. If the Company needs but cannot raise adequate additional capital, it will be required to delay, reduce the scope of, or eliminate one or more of its research or development programs or its commercialization efforts. In such circumstances, the Company may also be required to relinquish greater, or even all, rights to product candidates at earlier stages of development or commercialization or on less favorable terms than it would otherwise choose.

2. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares and common stock equivalents outstanding for the period determined using the treasury stock method. For purposes of this calculation, stock options and warrants are considered to be common stock equivalents but are not included in the calculations of diluted net loss per share for the periods presented as their effect would be antidilutive.

Shares used in calculating basic and diluted net loss per common share exclude the following potential common shares as their effect is antidilutive (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Antidilutive options to purchase common stock	10,386	7,787	9,638	7,733
Antidilutive warrants to purchase common stock	1,966	1,966	1,966	1,966
	<u>12,352</u>	<u>9,753</u>	<u>11,604</u>	<u>9,699</u>

3. Stock-Based Compensation

The fair value of each employee stock option and each employee stock purchase right granted is estimated on the grant date under the fair value method using the Black-Scholes valuation model. The estimated fair value of each stock option and purchase right, including the effect of estimated forfeitures, is then expensed over the requisite service period, which is generally the vesting period. During the first quarter of 2015, the Company entered into a transition agreement with Uli Hacksell, Ph.D., the Company's former Chief Executive Officer, in connection with his retirement from the Company in March 2015. Stock-based compensation expense for the first quarter of 2015 included a one-time \$9.0 million charge representing the fair value of the outstanding options expected to vest over the term of the transition agreement as valued on the retirement date. As of September 30, 2015, total unrecognized compensation cost related to stock options and purchase plan rights was approximately \$96.9 million, which is expected to be recognized over a weighted-average period of 3.0 years.

4. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2015	December 31, 2014
Accrued research and development services	\$ 5,877	\$ 7,814
Accrued compensation and benefits	4,984	4,167
Accrued consulting and professional fees	3,364	1,497
Other	1,306	340
	<u>\$ 15,531</u>	<u>\$ 13,818</u>

5. Investment Securities

Investment securities, all classified as available-for-sale, consisted of the following (in thousands):

	September 30, 2015			Estimated Fair Value
	Amortized Cost	Unrealized Gains	Unrealized Losses	
U.S. Treasury notes	\$ 8,999	\$ 5	\$ —	\$ 9,004
Government sponsored enterprise securities	160,857	31	—	160,888
	<u>\$169,856</u>	<u>\$ 36</u>	<u>\$ —</u>	<u>\$169,892</u>
	December 31, 2014			Estimated Fair Value
	Amortized Cost	Unrealized Gains	Unrealized Losses	
U.S. Treasury notes	\$ 2,748	\$ 2	\$ —	\$ 2,750
Government sponsored enterprise securities	97,237	8	(10)	97,235
Corporate debt securities	137,682	3	(37)	137,648
Commercial paper	22,980	19	—	22,999
	<u>\$260,647</u>	<u>\$ 32</u>	<u>\$ (47)</u>	<u>\$260,632</u>

At each reporting date, the Company performs an evaluation of impairment to determine if any unrealized losses are other-than-temporary. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition of the issuer, and the Company's intent and ability to hold the investment until recovery of its amortized cost basis. The Company intends, and has the ability, to hold its investments in unrealized loss positions until their amortized cost basis has been recovered. Based on its evaluation, the Company determined that its unrealized losses were not other-than-temporary at December 31, 2014. As of September 30, 2015 and December 31, 2014, all of the Company's available-for-sale investment securities had contractual maturity dates of less than one year.

6. Fair Value Measurements

As of September 30, 2015, the Company held \$240.2 million of cash equivalents and available-for-sale investment securities consisting of a money market fund, U.S. Treasury notes, and high quality, marketable debt instruments of government sponsored enterprises in accordance with the Company's investment policy. The Company's investment policy defines allowable investments and establishes guidelines relating to credit quality, diversification, and maturities of its investments to preserve principal and maintain liquidity. All investment securities have a credit rating of at least A3/A- or better, or P-1/A-1 or better, as determined by Moody's Investors Service or Standard & Poor's.

The Company's cash equivalents and available-for-sale investment securities are classified within the fair value hierarchy as defined by authoritative guidance. The Company's investment securities classified as Level 1 are valued using quoted market prices. The Company obtains the fair value of its Level 2 financial instruments from third party pricing services. The pricing services utilize industry standard valuation models whereby all significant inputs, including benchmark yields, reported trades, broker/dealer quotes, issuer spreads, bids, offers, or other market-related data, are observable. The Company validates the prices provided by the third-party pricing services by reviewing their pricing methods and matrices, and obtaining market values from other pricing sources. After completing the validation procedures, the Company did not adjust or override any fair value measurements provided by these pricing services as of September 30, 2015 and December 31, 2014, respectively.

The Company does not hold any securities classified as Level 3, which are securities valued using unobservable inputs. The Company has not transferred any investment securities between the classifications.

The fair value measurements of the Company's cash equivalents and available-for-sale investment securities are identified in the following tables (in thousands):

	Fair Value Measurements at Reporting Date Using			
	September 30, 2015	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market fund	\$ 48,024	\$ 48,024	\$ —	\$ —
U.S. Treasury notes	9,004	9,004	—	—
Government sponsored enterprise securities	183,187	—	183,187	—
	<u>\$ 240,215</u>	<u>\$ 57,028</u>	<u>\$ 183,187</u>	<u>\$ —</u>

	Fair Value Measurements at Reporting Date Using			
	December 31, 2014	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market fund	\$ 48,423	\$ 48,423	\$ —	\$ —
U.S. Treasury notes	2,750	2,750	—	—
Government sponsored enterprise securities	110,235	—	110,235	—
Corporate debt securities	137,648	—	137,648	—
Commercial paper	22,999	—	22,999	—
	<u>\$ 322,055</u>	<u>\$ 51,173</u>	<u>\$ 270,882</u>	<u>\$ —</u>

7. Stockholders' Equity

Authorized Shares

In June 2015, following approval by the Company's stockholders, the Company filed a Certificate of Amendment of its Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware, which increased the number of authorized shares of common stock of the Company from 150,000,000 to 225,000,000.

Equity Incentive Plan

In June 2015, the Company's stockholders approved an amendment to its 2010 Equity Incentive Plan, as amended, to, among other things, increase the aggregate number of shares of common stock authorized for issuance under the plan by 5,000,000 shares.

Public Offering

In March 2014, the Company raised net proceeds of \$196.8 million from the sale of 7,360,000 shares of its common stock in a public offering, including 960,000 shares sold pursuant to the exercise in full of the underwriters' over-allotment option.

8. Commitments and Contingencies

External Services

The Company has entered into agreements with contract research organizations and other external service providers primarily for services in connection with the development and planned commercialization of its product candidates. The Company was contractually obligated for up to approximately \$30.4 million of future services under these agreements as of September 30, 2015. The nature of the work being conducted under the Company's agreements with external service providers is such that, in most cases, the services may be stopped with short notice. In such event, the Company would not be liable for the full amount of the contract. The Company's actual contractual obligations may vary depending upon several factors, including the progress and results of the underlying studies.

Contingent Regulatory Milestone Payments

In connection with the Company's 2006 license agreement with the Ipsen Group, pursuant to which the Company licensed certain intellectual property rights that complement its patent portfolio for its serotonin platform, including NUPLAZID™ (pimavanserin), the Company may be obligated in future periods to make certain regulatory milestone payments. These milestone payments are contingent on the achievement of certain regulatory events. These one-time payments include \$2.5 million payable upon the successful filing of the first regulatory application with the U.S. Food and Drug Administration ("FDA") and \$8.0 million payable upon obtaining the first regulatory approval from the FDA. If NUPLAZID is approved, then the Company would make royalty payments to Ipsen of up to two percent on net product sales, if any.

Legal Proceedings

In March 2015, following the Company's announcement of the update to the timing of its planned New Drug Application ("NDA") submission to the FDA for NUPLAZID for the treatment of Parkinson's disease psychosis and the subsequent decline of the price of its common stock, two putative securities class action complaints (captioned Rihn v. ACADIA Pharmaceuticals Inc., Case No. 15-cv-0575-BTM-DHB and Wright v. ACADIA Pharmaceuticals Inc., Case No. 15-cv-0593-BTM-DHB) were filed in the U.S. District Court for the Southern District of California, or the Court, against the Company and certain of its current and former officers. The complaints generally allege that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by making materially false and misleading statements regarding the timing of the Company's planned NDA submission to the FDA for NUPLAZID, thereby artificially inflating the price of its common stock. The complaints seek unspecified monetary damages and other relief. On April 10 and June 1, 2015, the Court entered orders deferring the defendants' response to the Rihn and Wright complaints until after the Court appoints a lead plaintiff and assigns lead counsel. On May 12, 2015, several putative stockholders filed separate motions to consolidate the two actions and be appointed lead plaintiff. On September 8, 2015, the Court issued an order consolidating the actions and naming the lead plaintiff. The lead plaintiff must file a consolidated complaint on or before November 16, 2015. The Company has assessed such legal proceedings, and given the unpredictability inherent in litigation, the Company cannot predict the outcome of these matters. At this time, the Company is unable to estimate possible losses or ranges of losses that may result from such legal proceedings, and it has not accrued any amounts in connection with such legal proceedings other than ongoing attorneys' fees.

9. Recent Accounting Pronouncements

In April 2015, the Financial Accounting Standards Board (“FASB”) issued authoritative guidance related to accounting for fees paid in a cloud computing arrangement. This accounting update provides guidance to customers about whether a cloud computing arrangement includes a software license. If a cloud computing arrangement includes a software license, then the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. This guidance is effective for annual reporting periods beginning after December 15, 2015 and early adoption is permitted. The Company adopted this guidance in the first quarter of fiscal 2015 with no significant impact to its consolidated financial statements.

In May 2014, the FASB issued authoritative accounting guidance related to revenue from contracts with customers. This guidance is a comprehensive new revenue recognition model that requires a company to recognize revenue to depict the transfer of goods or services to a customer at an amount that reflects the consideration it expects to receive in exchange for those goods or services. The original guidance was effective for annual reporting periods beginning after December 15, 2016. However, in July 2015, the FASB agreed to delay the effective date by one year, with early adoption permitted, but not before the original effective date of the standard. In accordance with the agreed upon delay, the Company will adopt this guidance on January 1, 2018. Companies may use either a full retrospective or a modified retrospective approach to adopt this guidance. The Company is evaluating which transition approach to use and its impact, if any, on its consolidated financial statements.

10. Subsequent Event

In November 2015, the Company announced its NDA for NUPLAZID was accepted for review by the FDA and classified as a Priority Review filing. As discussed in Note 8, *Commitments and Contingencies*, the FDA’s acceptance of the filing for review triggered a \$2.5 million milestone which is payable to the Ipsen Group in the fourth quarter of 2015.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our consolidated financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included in this quarterly report on Form 10-Q, or this Quarterly Report, and the audited financial statements and notes thereto as of and for the year ended December 31, 2014 included with our Annual Report filed with the SEC. Past operating results are not necessarily indicative of results that may occur in future periods.

This Quarterly Report contains forward-looking statements. These forward-looking statements involve a number of risks and uncertainties. Such forward-looking statements include statements about our strategies, objectives, expectations, discoveries, collaborations, clinical trials, regulatory submissions, product candidates, proprietary and external programs, financial condition and resources, and other statements that are not historical facts, including statements which may be preceded by the words "believes," "expects," "hopes," "may," "will," "plans," "intends," "estimates," "could," "should," "would," "continue," "seeks," "aims," "projects," "predicts," "pro forma," "anticipates," "potential" or similar words. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Readers of this Quarterly Report are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date on which they were made. We undertake no obligation to update publicly or revise any forward-looking statements. Actual events or results may differ materially from our expectations. Important factors that could cause actual results to differ materially from those stated or implied by our forward-looking statements include, but are not limited to, the risk factors identified in our filings with the SEC, including this Quarterly Report.

Overview

Background

We are a biopharmaceutical company focused on the development and commercialization of innovative small molecule drugs that address unmet medical needs in central nervous system disorders. We have a portfolio of product opportunities led by our novel drug candidate, NUPLAZID™ (pimavanserin), for which we have reported positive Phase III pivotal trial results in Parkinson's disease psychosis, or PDP, and which has the potential to be the first drug approved in the United States for this disorder. In September 2015, we submitted a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, for NUPLAZID for the treatment of psychosis associated with Parkinson's disease, which was accepted for priority review by the FDA on October 30, 2015 with a Prescription Drug User Fee Act, or PDUFA, goal date of May 1, 2016. NUPLAZID is a selective serotonin inverse agonist, or SSIA, preferentially targeting 5-HT_{2A} receptors. Through this novel mechanism, NUPLAZID has demonstrated significant efficacy in Parkinson's disease psychosis in our Phase III pivotal trial and has the potential to avoid many of the debilitating side effects of existing antipsychotics, none of which are approved for use in PDP patients. We hold worldwide commercialization rights to pimavanserin.

In September 2014, we announced that the FDA granted Breakthrough Therapy designation for NUPLAZID for the treatment of Parkinson's disease psychosis. The Breakthrough Therapy designation was created by the FDA to expedite the development and review of drugs that are intended to treat serious or life-threatening conditions. If approved, we intend to commercialize NUPLAZID for Parkinson's disease psychosis in the United States by establishing a specialty sales force focused primarily on physicians who are high prescribers of antipsychotics for PDP patients, including neurologists, psychiatrists and health-care professionals treating patients in the long-term care setting. We are currently preparing for the planned future launch of NUPLAZID and plan to hire a commercial sales force to coincide approximately with a NUPLAZID approval, if any. In addition to building our commercial capabilities, we are expanding our existing infrastructure to support the planned launch and commercialization of NUPLAZID, including adding to our commercial level manufacturing, medical affairs, quality control, and compliance capabilities.

We believe that pimavanserin also has the potential to address important unmet medical needs in neurological and psychiatric disorders beyond PDP and we plan to continue to study the use of pimavanserin in multiple disease states. We believe Alzheimer's disease represents one of our most important opportunities for further exploration. We are currently conducting a Phase II study exploring the utility of pimavanserin for the treatment of Alzheimer's disease psychosis, or ADP, a disorder for which no drug is currently approved by the FDA, and expect to complete enrollment of this study in the first half of 2016. We believe schizophrenia also represents a disease with multiple unmet or ill-served needs and we are currently evaluating the most attractive development opportunities there. We have successfully completed a Phase II study of pimavanserin in the treatment of schizophrenia where we observed significant anti-psychotic effects when pimavanserin was co-administered with a low dose of risperidone, a generic drug currently approved for the treatment of schizophrenia. In the second quarter of this year we commenced a significant life cycle planning project to assess and prioritize medically important and attractive lifecycle development opportunities, including those within Alzheimer's disease, schizophrenia and other disease states. We expect to complete this planning exercise around the end of this year.

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Our active pharmaceutical ingredient, or API, for our NUPLAZID (pimavanserin) program has been manufactured in Switzerland for over 10 years and we anticipate continuing to manufacture our API in Switzerland as we transition to a commercial organization. During the first half of 2015, we licensed worldwide intellectual property rights related to pimavanserin in certain indications to ACADIA Pharmaceuticals GmbH, our wholly-owned Swiss subsidiary. ACADIA Pharmaceuticals GmbH will manage the worldwide supply chain of pimavanserin API. We believe the establishment of ACADIA Pharmaceuticals GmbH, as well as the licensing of worldwide intellectual property rights for pimavanserin, will allow us to build a platform for long-term operational and financial efficiencies.

We have incurred substantial operating losses since our inception due in large part to expenditures for our research and development activities. As of September 30, 2015, we had an accumulated deficit of \$616.8 million. We expect to continue to incur operating losses for at least the next few years as we advance our programs and incur significant development and commercialization costs.

We maintain a website at www.acadia-pharm.com to which we regularly post copies of our press releases as well as additional information about us. Our filings with the SEC are available free of charge through our website as soon as reasonably practicable after being electronically filed with or furnished to the SEC. Interested persons can subscribe on our website to email alerts that are sent automatically when we issue press releases, file our reports with the SEC or post certain other information to our website. Information contained in our website does not constitute a part of this Quarterly Report.

Revenues

We have not generated any revenues from product sales to date. Our revenues to date have been generated substantially from payments under our current and past collaboration agreements. In September 2015, Allergan provided notice of termination of our collaboration agreement focused on muscarinic product candidates for the treatment of glaucoma and we will not be receiving any further payments under that agreement, other than payments for a portion of patent costs incurred prior to the termination. Upon termination of this collaboration, we regained the rights to the muscarinic program. Our continuing collaboration agreement with Allergan involves the development of product candidates in the area of chronic pain. Under this continuing agreement, we are eligible to receive payments upon achievement of development and regulatory milestones, as well as royalties on future product sales, if any. We no longer receive research funding from this agreement and additional payments are dependent upon the advancement of an applicable product candidate. Our continuing collaboration agreement with Allergan in chronic pain is subject to termination upon notice by Allergan.

Research and Development Expenses

Our research and development expenses have consisted primarily of fees paid to external service providers, salaries and related personnel expenses, facilities and equipment expenses, and other costs. We charge all research and development expenses to operations as incurred. Our research and development activities are primarily focused on our most advanced product candidate, NUPLAZID (pimavanserin). We currently are responsible for all costs incurred in the development of pimavanserin.

We use external service providers to manufacture our product candidates and for the majority of the services performed in connection with the clinical development of our product candidates. Historically, we have used our internal research and development resources, including our employees and discovery infrastructure, across several projects and many of our costs have not been attributable to a specific project. Accordingly, we have not reported our internal research and development costs on a project basis. To the extent that external expenses are not attributable to a specific project, they are included in other programs. The following table summarizes our research and development expenses for the three and nine months ended September 30, 2015 and 2014 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Costs of external service providers:				
NUPLAZID (pimavanserin)	\$ 9,328	\$12,599	\$29,454	\$30,952
Other programs	236	156	607	348
Subtotal	9,564	12,755	30,061	31,300
Internal costs	5,227	2,839	14,203	7,668
Stock-based compensation	3,938	1,358	9,139	3,452
Total research and development	<u>\$18,729</u>	<u>\$16,952</u>	<u>\$53,403</u>	<u>\$42,420</u>

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Although our NDA for NUPLAZID has been accepted for filing by the FDA, at this time, due to the risks in the regulatory and approval processes, we are unable to estimate with any certainty the costs we will incur for the continued development of NUPLAZID for Parkinson's disease psychosis, including work necessary to support the review of the NDA. Due to the risks inherent in clinical development, we also are unable to estimate with certainty the costs we will incur for the development of pimavanserin for other indications, including those within Alzheimer's disease and schizophrenia. Due to these same factors, we are unable to determine with any certainty the anticipated completion dates for our current research and development programs. Clinical development and regulatory approval timelines, probability of success, and development costs vary widely. While our current focus is primarily on supporting a review of the NDA by the FDA and advancing the development of pimavanserin for other indications, we anticipate that we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success of each product candidate, as well as an ongoing assessment of the commercial potential of each opportunity and our financial position. We cannot forecast with any degree of certainty which product opportunities will be subject to future collaborative or licensing arrangements, when such arrangements will be secured, if at all, and to what degree any such arrangements would affect our development plans and capital requirements.

We expect our research and development expenses to increase and continue to be substantial as we pursue the development of pimavanserin, including supporting the FDA review of our NDA for NUPLAZID, our ongoing open-label safety extension study, our ongoing Phase II trial for Alzheimer's disease psychosis, and potential studies in other indications, including those within schizophrenia and other Alzheimer's disease indications. The lengthy process of completing clinical trials and supporting development activities and seeking regulatory approval for our product opportunities requires the expenditure of substantial resources. Any failure by us or delay in completing clinical trials, or in obtaining regulatory approvals, could cause our research and development expenses to increase and, in turn, have a material adverse effect on our results of operations.

General and Administrative Expenses

Our general and administrative expenses have consisted primarily of salaries and other costs for employees serving in executive, finance, business development, and business operations functions, as well as professional fees associated with legal and accounting services, and costs associated with patents and patent applications for our intellectual property. In addition, starting in the second half of 2013, we began to hire the senior leadership of our commercial organization that is helping us prepare for the planned future launch of NUPLAZID and we are currently expanding our commercial organization and preparing to build a specialty sales force in the United States that will focus on promoting NUPLAZID, if approved by the FDA. We expect our general and administrative expenses to increase in future periods to support activities associated with our preparation for, and planned launch of, NUPLAZID and our further development of pimavanserin in indications other than Parkinson's disease psychosis.

Critical Accounting Policies and Estimates

There have been no significant changes to our critical accounting policies since December 31, 2014. For a description of critical accounting policies that affect our significant judgments and estimates used in the preparation of our consolidated financial statements, refer to our Annual Report.

Results of Operations

Fluctuations in Operating Results

Our results of operations have fluctuated significantly from period to period in the past and are likely to continue to do so in the future. We anticipate that our quarterly and annual results of operations will be impacted for the foreseeable future by several factors, including the timing and amount of payments payable under our current license agreement, the timing and amount of payments received pursuant to our current and potential future collaborations, the progress and timing of expenditures related to our development and commercialization efforts, and the extent to which we generate revenues from product sales, if any. Due to these fluctuations, we believe that the period-to-period comparisons of our operating results are not a good indication of our future performance.

Comparison of the Three Months Ended September 30, 2015 and 2014

Research and Development Expenses

Research and development expenses increased to \$18.7 million for the three months ended September 30, 2015, including \$3.9 million in stock-based compensation expense, from \$17.0 million for the three months ended September 30, 2014, including \$1.4 million in stock-based compensation expense. This increase was primarily due to an increase of \$4.9 million in personnel and related costs and stock-based compensation expense associated with our expanded research and development organization, largely offset by pimavanserin manufacturing development costs incurred during the three months ended September 30, 2014 not incurred during the three months ended September 30, 2015. We expect our research and development expenses to increase in future periods as we continue to pursue the development of pimavanserin, including supporting the FDA review of our NDA for NUPLAZID, our ongoing open-label safety extension study, our ongoing Phase II trial for Alzheimer's disease psychosis, and potential studies in other indications, including those within schizophrenia and Alzheimer's disease, as well as the development of our other product candidates.

General and Administrative Expenses

General and administrative expenses increased to \$20.3 million for the three months ended September 30, 2015, including \$5.3 million in stock-based compensation expense, from \$8.1 million for the three months ended September 30, 2014, including \$2.5 million in stock-based compensation expense. This increase was due to increases in personnel and related costs of \$7.0 million and increases in external services costs of \$5.2 million, all largely related to our commercial preparations for the planned launch of NUPLAZID. We anticipate that these general and administrative expenses will increase in future periods to support our planned development and commercial activities for NUPLAZID.

Comparison of the Nine Months Ended September 30, 2015 and 2014

Research and Development Expenses

Research and development expenses increased to \$53.4 million for the nine months ended September 30, 2015, including \$9.1 million in stock-based compensation expense, from \$42.4 million for the nine months ended September 30, 2014, including \$3.5 million in stock-based compensation expense. This increase was primarily due to an increase of \$12.2 million in personnel and related costs and stock-based compensation expense associated with our expanded research and development organization. We expect our research and development expenses to increase in future periods as we continue to pursue the development of pimavanserin, including supporting the FDA review of our NDA for NUPLAZID, our ongoing open-label safety extension study, our ongoing Phase II trial for Alzheimer's disease psychosis, and potential studies in other indications, including those within schizophrenia and Alzheimer's disease, as well as the development of our other product candidates.

General and Administrative Expenses

General and administrative expenses increased to \$65.7 million for the nine months ended September 30, 2015, including \$22.2 million in stock-based compensation expense, from \$22.3 million for the nine months ended September 30, 2014, including \$7.9 million in stock-based compensation expense. This increase was due to increases in personnel and related costs of \$29.2 million and increases in external services costs of \$14.2 million. Contributing to the increase in personnel costs was \$9.6 million in expense incurred in connection with the transition agreement we entered into with our former Chief Executive Officer upon his retirement in March 2015. Included in this compensation expense of \$9.6 million was \$9.0 million in stock-based compensation expense representing the fair value of the outstanding options expected to vest over the term of the transition agreement as valued on his retirement date. Excluding the expense incurred in connection with the transition agreement with our former Chief Executive Officer, the increases in personnel costs and external services costs were largely related to our commercial preparations for the planned launch of NUPLAZID. We anticipate that these general and administrative expenses will increase in future periods to support our planned development and commercial activities for NUPLAZID.

Liquidity and Capital Resources

Since inception, we have funded our operations primarily through sales of our equity securities, payments received under our collaboration agreements, debt financings, and interest income. At September 30, 2015, we had \$240.7 million in cash, cash equivalents, and investment securities compared to \$322.5 million at December 31, 2014. We anticipate that the level of cash used in our operations will increase in future periods in order to fund our planned commercial activities for NUPLAZID and our ongoing and planned development activities for pimavanserin for other indications. We expect that our cash, cash equivalents, and investment securities will be sufficient to fund our planned operations at least into the second half of 2016.

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We may require significant additional financing in the future to fund our operations. Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

- the progress in, and the costs of, our ongoing and planned development activities for pimavanserin, planned commercialization activities for NUPLAZID, and other research and development programs;
- the costs of preparing applications for regulatory approvals for NUPLAZID and other product candidates, as well as the costs required to support review of such applications;
- the costs of establishing, or contracting for, sales and marketing capabilities for NUPLAZID or other product candidates;
- our ability to obtain regulatory approval for, and generate product sales from, NUPLAZID or other product candidates;
- the costs of acquiring additional product candidates or research and development programs;
- the scope, prioritization and number of our research and development programs;
- the ability of our collaborators and us to reach the milestones and other events or developments triggering payments under our collaboration or license agreements, or our collaborators' ability to make payments under these agreements;
- our ability to enter into new, and to maintain existing, collaboration and license agreements;
- the extent to which we are obligated to reimburse collaborators or collaborators are obligated to reimburse us for costs under collaboration agreements;
- the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights; and
- the costs of securing manufacturing arrangements for clinical or commercial production of NUPLAZID or other product candidates.

Unless and until we can generate significant cash from our operations, we expect to satisfy our future cash needs through our existing cash, cash equivalents and investment securities, strategic collaborations, public or private sales of our securities, debt financings, grant funding, or by licensing all or a portion of our product candidates or technology. In the past, periods of turmoil and volatility in the financial markets have adversely affected the market capitalizations of many biotechnology companies, and generally made equity and debt financing more difficult to obtain. These events, coupled with other factors, may limit our access to additional financing in the future. This could have a material adverse effect on our ability to access sufficient funding. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. In particular, any unfavorable development in our NUPLAZID (pimavanserin) program could have a material adverse effect on our ability to raise additional capital.

If we need to but cannot raise adequate additional capital in the future, we will be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. We also may be required to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose.

We have invested a substantial portion of our available cash in a money market fund, U.S. Treasury notes, and high quality, marketable debt instruments of government sponsored enterprises in accordance with our investment policy. Our investment policy defines allowable investments and establishes guidelines relating to credit quality, diversification, and maturities of our investments to preserve principal and maintain liquidity. All investment securities have a credit rating of at least A3/A- or better, or P-1/A-1 or better, as determined by Moody's Investors Service or Standard & Poor's. Our investment portfolio has not been adversely impacted by the disruptions in the credit markets that have occurred in the past. However, if there are future disruptions in the credit markets, there can be no assurance that our investment portfolio will not be adversely affected.

Net cash used in operating activities increased to \$87.1 million for the nine months ended September 30, 2015 from \$48.6 million for the nine months ended September 30, 2014. This increase of \$38.5 million was primarily due to an increase in our net loss of \$54.6 million, offset by an increase of \$19.9 million in non-cash, stock-based compensation expense, together with changes in our operating assets and liabilities, including accounts payable and accrued liabilities. Accounts payable and accrued liabilities increased \$1.7 million for the nine months ended September 30, 2015 compared to an increase of \$4.3 million for the nine months ended September 30, 2014. The increase in accounts payable and accrued liabilities for the nine months ended September 30, 2015 was primarily due to an increase in external service costs related to our commercial preparations for the planned launch of NUPLAZID.

Net cash provided by investing activities totaled \$90.8 million for the nine months ended September 30, 2015 compared to net cash used in investing activities of \$127.7 million for the nine months ended September 30, 2014. The increase in net cash provided by investing activities for the nine months ended September 30, 2015 relative to the comparable period of 2014 was primarily due to the timing of maturities and purchases of investment securities.

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Net cash provided by financing activities decreased to \$5.2 million for the nine months ended September 30, 2015 compared to \$201.0 million for the nine months ended September 30, 2014. This decrease in net cash provided by financing activities for the nine months ended September 30, 2015 was primarily attributable to the March 2014 public offering that contributed \$196.8 million in net proceeds.

Contractual Obligations

The following table summarizes our contractual obligations at September 30, 2015 (in thousands):

	<u>Total</u>	<u>Less than 1 Year</u>	<u>1-3 Years</u>	<u>4-5 Years</u>	<u>After 5 Years</u>
Operating leases	\$6,546	\$ 2,443	\$ 4,103	\$ —	\$ —

We have also entered into agreements with contract research organizations and other external service providers for services, primarily in connection with the development and planned commercialization of our product candidates. We were contractually obligated for up to approximately \$30.4 million of future services under these agreements as of September 30, 2015. The nature of the work being conducted under our agreements with external service providers is such that, in most cases, the services may be stopped on short notice. In such event, we would not be liable for the full amount of the contract. Our actual contractual obligations will vary depending upon several factors, including the progress and results of the underlying services.

In addition, we have entered into an agreement with the Ipsen Group pursuant to which we licensed certain intellectual property rights that complement our patent portfolio for our serotonin platform, including NUPLAZID (pimavanserin). If certain conditions are met, we would be required to make future payments, including milestones, sublicensing fees, and royalties. A milestone payment obligation of \$2.5 million was triggered in the fourth quarter of 2015 upon the FDA's acceptance for filing of our NDA for NUPLAZID. A potential future milestone payment of \$8.0 million would be payable upon obtaining regulatory approval from the FDA. If NUPLAZID is approved, then we would also make royalty payments to Ipsen of up to two percent on future net product sales, if any. Because the remaining milestone payment would only be payable upon obtaining regulatory approval from the FDA and it is uncertain when, or if, such event will occur, we cannot forecast with any degree of certainty when, or if, we will be required to make this payment under this agreement. Similarly, royalty payments would be contingent upon any net product sales. Accordingly, none of these amounts are included in the above table.

Off-Balance Sheet Arrangements

To date, we have not had any relationships with unconsolidated entities or financial partnerships, such as entities referred to as structured finance or special purpose entities, which are established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

Recent Accounting Pronouncements

See Item 1 of Part I, "Notes to Condensed Consolidated Financial Statements — Note 9 — Recent Accounting Pronouncements".

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We invest our excess cash in investment-grade, interest-bearing securities. The primary objective of our investment activities is to preserve principal and liquidity. To achieve this objective, we invest in a money market fund, U.S. Treasury notes, and high quality marketable debt instruments of corporations, financial institutions and government sponsored enterprises with contractual maturity dates of generally less than two years. All investment securities have a credit rating of at least A3/A- or better, or P-1/A-1 or better, as determined by Moody's Investors Service or Standard & Poor's. We do not have any direct investments in auction-rate securities or securities that are collateralized by assets that include mortgages or subprime debt. If a 10 percent change in interest rates were to have occurred on September 30, 2015, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

ITEM 4. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer, who serves as our principal executive, financial and accounting officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, as of September 30, 2015. Based on this evaluation, our Chief Executive Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2015.

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

In March 2015, following our announcement of the update to the timing of our planned NDA submission to the FDA for NUPLAZID for the treatment of PDP and the subsequent decline of the price of our common stock, two putative securities class action complaints (captioned *Rihn v. ACADIA Pharmaceuticals Inc.*, Case No. 15-cv-0575-BTM-DHB and *Wright v. ACADIA Pharmaceuticals Inc.*, Case No. 15-cv-0593-BTM-DHB) were filed in the U.S. District Court for the Southern District of California, or the Court, against us and certain of our current and former officers. The complaints generally allege that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by making materially false and misleading statements regarding the timing of our planned NDA submission to the FDA for NUPLAZID, thereby artificially inflating the price of our common stock. The complaints seek unspecified monetary damages and other relief. On April 10 and June 1, 2015, the Court entered orders deferring the defendants' response to the Rihn and Wright complaints until after the Court appoints a lead plaintiff and assigns lead counsel. On May 12, 2015, several putative stockholders filed separate motions to consolidate the two actions and be appointed lead plaintiff. On September 8, 2015, the Court issued an order consolidating the actions and naming the lead plaintiff. The lead plaintiff must file a consolidated complaint on or before November 16, 2015. We plan to vigorously defend against the claims advanced.

ITEM 1A. RISK FACTORS

You should consider carefully the following information about the risks described below, together with the other information contained in this Quarterly Report and in our other public filings in evaluating our business. The risk factors set forth below that are marked with an asterisk () did not appear as separate risk factors in or contain changes to the similarly titled risk factors included in Item 1A to our Annual Report. If any of the following risks actually occurs, our business, financial condition, results of operations, and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.*

Risks Related to Our Business

Our prospects are highly dependent on the success of pimavanserin, our most advanced product candidate. To the extent regulatory approval of NUPLAZID (pimavanserin) is delayed or not granted or NUPLAZID is not commercially successful, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.*

We currently have no product candidates approved for sale, and we may never be able to develop marketable products. The research, testing, manufacturing, labeling, approval, sale, import, export, marketing, and distribution of pharmaceutical product candidates are subject to extensive regulation by the U.S. Food and Drug Administration, or FDA, and other regulatory authorities in the United States and other countries, whose regulations differ from country to country. We are focusing a significant portion of our activities and resources on pimavanserin, and we believe our prospects are highly dependent on, and a significant portion of the value of our company relates to, our ability to obtain regulatory approval for and successfully commercialize NUPLAZID (pimavanserin) in the United States and potentially in additional territories. The regulatory approval and successful commercialization of NUPLAZID is subject to many risks, including the risks discussed in other risk factors, and NUPLAZID may not receive marketing approval from any regulatory agency. If the results or timing of regulatory filings, the regulatory process, regulatory developments, commercialization, clinical trials or preclinical studies, or other activities, actions or decisions related to pimavanserin do not meet our or others' expectations, the market price of our common stock could decline significantly.

In April 2013, we announced that the FDA had agreed that the data from our -020 Study, together with supportive data from our other studies with NUPLAZID, are sufficient to support the filing of a New Drug Application, or NDA, for the treatment of Parkinson's disease psychosis, or PDP. In September 2015, we submitted our NDA for NUPLAZID for the treatment of PDP to the FDA, which was accepted for priority review by the FDA on October 30, 2015 with a Prescription Drug User Fee Act, or PDUFA, goal date of May 1, 2016. While the FDA has agreed to review our NDA for NUPLAZID on the basis of our positive pivotal -020 Study data, along with supportive efficacy and safety data from other NUPLAZID studies, the NDA will be subject to the FDA's substantive review of the entire NDA to assess whether it is adequate to support approval of NUPLAZID for PDP. Notwithstanding the guidance that we received in April 2013, the FDA retains complete discretion in deciding whether to approve an NDA for NUPLAZID and there are many components to an NDA filing beyond the efficacy and safety data provided to the FDA in 2013. For example, in addition to reviewing the safety and efficacy data for NUPLAZID, the FDA will review our internal systems and processes, as well as those of our vendors, related to our development of NUPLAZID, including those pertaining to our clinical trials and manufacturing processes. Further, we previously delayed the submission of our NDA for NUPLAZID to complete the preparation of manufacturing quality systems to support commercial manufacturing and supply of NUPLAZID, in order to support the FDA's review of the NDA, and we cannot be certain that our additional preparation of these quality systems will be sufficient to support the review of the NDA. Even though our NDA submission was accepted for filing, the FDA retains complete discretion in deciding whether or not to approve an NDA and there is no guarantee that NUPLAZID will be approved for the treatment of PDP or any other indication. There is no guarantee that the FDA will determine that our safety and efficacy data are sufficient to support approval for NUPLAZID for PDP. In addition, the FDA may determine that our manufacturing and quality systems, or those of our third-party suppliers, or that the clinical trials conducted with NUPLAZID are not sufficient to support approval of the NDA. Additionally, the FDA may convene an advisory committee of independent experts, including clinicians and other scientific experts, to review, evaluate and provide recommendations as to whether the NDA for NUPLAZID should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA may choose not to approve our NDA for NUPLAZID for any of a variety of reasons, including a decision related to the safety or efficacy data for NUPLAZID or for any other issues that they may identify related to our development of NUPLAZID for the treatment of PDP.

Thus, significant uncertainty remains regarding the regulatory approval process for NUPLAZID.

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Even if the FDA grants an approval for NUPLAZID for the treatment of PDP, the terms of the approval may limit its commercial potential. Additionally, even after receipt of FDA approval, NUPLAZID would be subject to substantial, ongoing regulatory requirements.*

The FDA has complete discretion over the approval of NUPLAZID for the treatment of PDP. If it grants approval, the scope of the approval may limit our ability to commercialize NUPLAZID and, therefore, our ability to generate substantial sales revenues. For example, the FDA may not approve the labeling claims for NUPLAZID that we believe are necessary or desirable for successful commercialization as a treatment for PDP, or may grant approval contingent on the performance of costly post-approval clinical trials or subject to warnings or contraindications. Additionally, even after granting approval, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for NUPLAZID will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing processes, good clinical practices, international conference on harmonization regulations and good laboratory practices, which are regulations and guidelines enforced by the FDA for all of our clinical development and for any clinical trials that we conduct post-approval. The FDA may decide to withdraw approval, add warnings or narrow the approved indications in the product label, or establish risk management programs that could restrict distribution. These actions could result from, among other things, safety concerns, including unexpected side effects or drug-drug interaction problems, or concerns over misuse or abuse of the product. If any of these actions were to occur following approval, we may have to discontinue the commercialization of NUPLAZID, limit our sales and marketing efforts, and/or conduct post-approval studies, which in turn could result in significant expense and delay or limit our ability to generate sales revenues.

Even if NUPLAZID is approved by the FDA for PDP, we may not be successful in its commercial launch.*

We currently have a small commercialization group but have never, as an organization, launched or commercialized a product. In connection with any potential approval by the FDA of NUPLAZID for the treatment of PDP, in addition to building a sales force, we will need to successfully coordinate the commercialization of NUPLAZID. Prior to commercialization, NUPLAZID could also be subject to review and potential scheduling by the Drug Enforcement Administration of the U.S. Department of Justice, or DEA, which could delay and adversely impact its marketing and commercialization. There are numerous examples of unsuccessful product launches and, since we have never launched a product, there is no guarantee that we will be able to do so if granted marketing approval for NUPLAZID for the treatment of PDP. If any product launch of NUPLAZID is unsuccessful or perceived as disappointing, our stock price could decline significantly and the long-term success of the product could be harmed.

We currently have no sales force and have no experience as a company in marketing or distributing pharmaceutical products. If we are unable to expand our marketing capabilities and establish our sales force or enter into agreements with third parties to distribute NUPLAZID, we may not be able to generate product revenues.

Our strategy is to build a fully-integrated biopharmaceutical company to successfully execute the commercial launch of NUPLAZID in the United States following regulatory approval. While we have established our core commercial team, we do not currently have a complete organization for the sales, marketing and distribution of NUPLAZID and, as an organization, we do not have any experience commercializing pharmaceutical products. In order to market any products that may be approved by the FDA, including NUPLAZID, we must build our sales, marketing, managerial, and related capabilities or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing, and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenues and may not become profitable.

Included in our strategy in the United States is a plan to establish a specialty sales force to commercialize NUPLAZID for the treatment of PDP. The establishment and development of our own sales force to market NUPLAZID will be expensive and time consuming and could delay any product launch, and we cannot be certain that we will be able to successfully develop this capability. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. To the extent we rely on third parties to commercialize NUPLAZID, we may receive less revenues than if we commercialized these products ourselves. In addition, we may have little or no control over the sales efforts of any third parties involved in commercializing our products. In the event we are unable to develop our own sales force or collaborate with a third-party marketing and sales organization, we would not be able to effectively commercialize NUPLAZID which would negatively impact our ability to generate product revenues.

If we are unable to effectively train and equip our sales force, our ability to successfully commercialize NUPLAZID will be harmed.*

If approved, NUPLAZID will be a newly-marketed drug and, therefore, none of the members of our sales force will have ever promoted NUPLAZID prior to its launch. As a result, we will be required to expend significant time and resources to train our sales force to be credible and persuasive in marketing NUPLAZID for the treatment of PDP to neurologists, select psychiatrists, and pharmacists and physicians in long-term care facilities. In addition, we must train our sales force to ensure that a consistent and appropriate message about NUPLAZID is being delivered to our potential customers. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits of NUPLAZID and its proper administration, our efforts to successfully commercialize NUPLAZID could be put in jeopardy, which would negatively impact our ability to generate product revenues.

NUPLAZID may not gain acceptance among physicians, patients, and the medical community, thereby limiting our potential to generate revenues.*

Even if a product is approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product candidate by physicians, healthcare professionals and third-party payors, and our profitability and growth will depend on a number of factors, including:

- the ability to provide acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- availability of alternative treatments;
- pricing and cost effectiveness, which may be subject to regulatory control;
- effectiveness of our or our collaborators' sales and marketing strategy; and
- our ability to obtain sufficient third-party insurance coverage or adequate reimbursement levels.

If a product does not provide a treatment regimen that is at least as beneficial as the current standard of care or otherwise does not provide patient benefit, that product will not achieve market acceptance and we will not generate sufficient revenues to achieve or maintain profitability.

With respect to NUPLAZID specifically, even if approved by the FDA for the treatment of PDP, successful commercialization will depend on whether and to what extent physicians, long-term care facilities and pharmacies, over whom we have no control, determine to utilize NUPLAZID. NUPLAZID, if approved by the FDA, would be made available to treat PDP, an indication for which the FDA has not approved a pharmaceutical treatment. Because of this, it is particularly difficult to estimate NUPLAZID's market potential. Industry sources and analysts have a divergence of estimates for the near- and long-term market potential of NUPLAZID, and a variety of assumptions directly impact the estimates for NUPLAZID's market potential, including assumptions regarding the prevalence of PDP, the rate of diagnosis of PDP, the rate of physician adoption of NUPLAZID, and patient adherence and compliance rates. Small differences in these assumptions can lead to widely divergent estimates of the market potential of NUPLAZID. For example, certain research suggests that patients with Parkinson's disease may be hesitant to report symptoms of PDP to their treating physicians for a variety of reasons, including apprehension about societal stigmas relating to mental illness. Research also suggests that physicians who typically treat patients with Parkinson's disease may not ask about or identify symptoms of PDP. For these reasons, even if PDP occurs in high rates among patients with Parkinson's disease, it may be underdiagnosed. Even if PDP is diagnosed, physicians may not prescribe treatment for it, and if they do prescribe treatment, they may prescribe other drugs to treat it, even though they are not approved for PDP, instead of NUPLAZID. In addition, even if NUPLAZID is prescribed for the treatment of PDP, issues may arise with respect to patient adherence and compliance rates. It is anticipated that the recommended dosing of NUPLAZID, if approved, will be two 17 mg tablets taken together once a day. Patients may elect, whether at the direction of their physician or otherwise, to take only one tablet a day instead of two, to take tablets at different times during the day, or to otherwise not adhere to the recommended dosing, any of which could result in far lower efficacy. If patients do not adhere to the recommended dosing of NUPLAZID, patients and physicians may believe that NUPLAZID is less effective, and as a result they may stop taking it and prescribing it. The commercial success of NUPLAZID depends on acceptance by patients and physicians, and there are a number

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of factors that could skew our or others' estimates about whether and to what extent NUPLAZID will be prescribed for the treatment of PDP.

Our ability to generate product revenues will be diminished if NUPLAZID does not receive coverage from payors or sells for inadequate prices, or if patients are unable to obtain adequate levels of reimbursement.

Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Even if we obtain coverage for NUPLAZID, or other products we may market, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients may not use NUPLAZID if coverage is not provided or reimbursement is inadequate to cover a significant portion of the cost of those products.

In addition, the market for NUPLAZID will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of any approved products to each payor separately, with no assurance that coverage will be obtained. If we are unable to obtain coverage of, and adequate payment levels for, NUPLAZID or any other products we may market to third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them and patients may decline to purchase them. This in turn could affect our ability to successfully commercialize NUPLAZID, or any other products we may market, and thereby adversely impact our profitability, results of operations, financial condition, and future success.

We are subject to federal, state and foreign healthcare laws and regulations and implementation or changes to such healthcare laws and regulations could adversely affect our business and results of operations.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals in recent years to change the healthcare system in ways that could impact our ability to sell our potential products, including NUPLAZID, as described in greater detail in the Government Regulation section of our Annual Report. If we are found to be in violation of any of these laws or any other federal or state regulations, we may be subject to administrative, civil and/or criminal penalties, damages, fines, individual imprisonment, exclusion from federal health care programs and the restructuring of our operations. Any of these could have a material adverse effect on our business and financial results. Since many of these laws have not been fully interpreted by the courts, there is an increased risk that we may be found in violation of one or more of their provisions. Any action against us for violation of these laws, even if we ultimately are successful in our defense, will cause us to incur significant legal expenses and divert our management's attention away from the operation of our business.

In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. We may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, there may be importation of foreign products that compete with any products we may market, including NUPLAZID, which could negatively impact our profitability.

We expect that the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved product, including NUPLAZID. An expansion in the government's role in the U.S. healthcare industry may cause general downward

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pressure on the prices of prescription drug products, lower reimbursements for providers using our products, reduce product utilization and adversely affect our business and results of operations. It is unclear whether and to what extent, if at all, other anticipated developments resulting from the federal healthcare reform legislation, such as an increase in the number of people with health insurance and an increased focus on preventive medicine, may provide us additional revenue to offset fees enacted under the ACA on certain drug product sales, subject to limited exceptions. It is possible that these fees, if applicable, would adversely affect our financial performance. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize any products for which we receive regulatory approval, including NUPLAZID.

If our operations are found to be in violation of any of the laws or regulations described above, comparable laws and regulations of non-U.S. jurisdictions or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, physician payment transparency laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.*

Although we do not currently have any products on the market, if we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be directly, or indirectly through our customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal False Claims Act, and physician sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing and education programs and constrain the business or financial arrangements with healthcare providers, physicians and other parties through which we market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business. Finally, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal civil and criminal false claims laws and civil monetary penalties laws, including the civil False Claims Act, which impose criminal and civil penalties, through civil whistleblower or qui tam actions, on individuals or entities for, among other things, knowingly presenting, or causing to be presented to the U.S. federal government, claims for payment or approval that are false or fraudulent or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statement, in connection with the delivery of, or payment for,

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healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, and as amended again by the Final HIPAA Omnibus Rule, Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information;
- the U.S. Federal Food, Drug and Cosmetic Act, or FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. federal physician payment transparency requirements, sometimes referred to as the “Physician Payments Sunshine Act”, which was enacted as part of the ACA and its implementing regulations and requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program to report annually to the Centers for Medicare and Medicaid Services, or CMS, information related to certain payments and other transfers of value made to physicians, other healthcare providers, and teaching hospitals, as well as ownership and investment interests held by physicians and other healthcare providers and their immediate family members;
- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits, and the curtailment or restructuring of our operations. Moreover, while we do not bill third-party payors directly and our customers make the ultimate decision on how to submit claims, from time-to-time, after approval of our product candidates, we may provide reimbursement guidance to patients and healthcare providers. If a government authority were to conclude that we provided improper advice and/or encouraged the submission of a false claim for reimbursement, we could face action against us by government authorities. If any of the physicians or other providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

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If we receive marketing approval from the FDA for NUPLAZID for the treatment of PDP, we could face liability if a regulatory authority determines that we are promoting the product for “off-label” uses.*

A company may not promote “off-label” uses for its drug products. An off-label use is the use of a product for an indication that is not described in the product’s FDA-approved label in the United States or for uses in other jurisdictions that differ from those approved by the applicable regulatory agencies. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician’s choice of drug treatment made in the physician’s independent medical judgment, they do restrict promotional communications from pharmaceutical companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. A company that is found to have promoted off-label use of its product may be subject to significant liability, including civil and criminal sanctions. If we begin marketing NUPLAZID, or any other product, we intend to comply with the requirements and restrictions of the FDA and other regulatory agencies with respect to our promotion of our products, but we cannot be sure that the FDA or other regulatory agencies will agree that we have not violated their restrictions. As a result, we may be subject to criminal and civil liability. In addition, our management’s attention could be diverted to handle any such alleged violations. A significant number of pharmaceutical companies have been the target of inquiries and investigations by various U.S. federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys’ Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission and various state Attorneys General offices. These investigations have alleged violations of various U.S. federal and state laws and regulations, including claims asserting antitrust violations, violations of the FDCA, the federal False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a *qui tam* suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects, and reputation.

We expect our net losses to continue for at least the next few years and are unable to predict the extent of future losses or when we will become profitable, if ever.*

We have experienced significant net losses since our inception. As of September 30, 2015, we had an accumulated deficit of approximately \$616.8 million. We expect to incur net losses over the next few years as we advance our programs and incur significant development and commercialization costs.

We have not received any revenues from the commercialization of our product candidates. In September 2015, we submitted our NDA for NUPLAZID for the treatment of PDP to the FDA, which was accepted for priority review by the FDA on October 30, 2015 with a PDUFA goal date of May 1, 2016. The regulatory approval process is time consuming and uncertain and there is no guarantee that our NDA for NUPLAZID will be approved for marketing. Even if our NDA for NUPLAZID is approved, we would still expect to incur significant expenses and net losses for at least the next few years as we begin our first ever commercialization efforts and pursue the development and commercialization of NUPLAZID and other product candidates. Substantially all of our revenues for the nine months ended September 30, 2015 were from reimbursement of patent costs under our agreements with third parties. The research term of our 2003 research collaboration with Allergan concluded in March 2013 and we no longer recognize revenues from this collaboration. In addition, in September 2015, Allergan provided notice of termination of our collaboration focused on muscarinic product candidates and we will not be receiving any further payments under that agreement. Thus, any payments from Allergan pursuant to our continuing collaboration in chronic pain are dependent upon the advancement of an applicable product candidate. Until such time as we may gain regulatory approval for, and generate revenues from, product sales, we anticipate that collaborations, which provide us with research funding and potential milestone payments and royalties, and grant funding will continue to be our primary sources of revenues.

We cannot be certain that the milestones required to trigger payments under our existing collaborations will be reached or that we will secure additional collaboration agreements. To obtain revenues from our product candidates, we must succeed, either alone or with others, in developing, obtaining regulatory approval for, manufacturing and marketing drugs with significant market potential. We may never succeed in these activities and may never generate revenues that are significant enough to achieve profitability.

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If we fail to obtain the capital necessary to fund our operations, we will be unable to successfully develop and commercialize NUPLAZID or any of our other product candidates.*

We have consumed substantial amounts of capital since our inception. Our cash, cash equivalents and investment securities totaled \$240.7 million at September 30, 2015. While we believe that our existing cash resources will be sufficient to fund our cash requirements at least into the second half of 2016, we may require significant additional financing in the future to continue to fund our operations. Our future capital requirements will depend on, and could increase significantly as a result of, many factors including:

- the progress in, and the costs of, our ongoing and planned development activities for pimavanserin, planned commercialization activities for NUPLAZID, and other research and development programs;
- the costs of preparing applications for regulatory approvals for NUPLAZID and other product candidates, as well as the costs required to support review of such applications;
- the costs of establishing, or contracting for, sales and marketing capabilities for NUPLAZID or other product candidates;
- our ability to obtain regulatory approval for, and generate product sales from, NUPLAZID or other product candidates;
- the costs of acquiring additional product candidates or research and development programs;
- the scope, prioritization and number of our research and development programs;
- the ability of our collaborators and us to reach the milestones and other events or developments triggering payments under our collaboration or license agreements, or our collaborators' ability to make payments under these agreements;
- our ability to enter into new, and to maintain existing, collaboration and license agreements;
- the extent to which we are obligated to reimburse collaborators or collaborators are obligated to reimburse us for costs under collaboration agreements;
- the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs of securing manufacturing arrangements for clinical or commercial production of NUPLAZID or other product candidates; and
- the costs associated with litigation, including the costs incurred in defending against claims made in the consolidated putative class action that was commenced following our announcement of the update to the timing of our planned NDA submission to the FDA for NUPLAZID and the subsequent decline of the price of our common stock in March 2015.

Unless and until we can generate significant cash from our operations, we expect to satisfy our future cash needs through our existing cash, cash equivalents and investment securities, strategic collaborations, public or private sales of our securities, debt financings, grant funding, or by licensing all or a portion of our product candidates or technology. In the past, periods of turmoil and volatility in the financial markets have adversely affected the market capitalizations of many biotechnology companies, and generally made equity and debt financing more difficult to obtain. These events, coupled with other factors, may limit our access to additional financing in the future. This could have a material adverse effect on our ability to access sufficient funding. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. If funds are not available, we will be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. We also may be required to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Additional funding, if obtained, may significantly dilute existing stockholders and could negatively impact the price of our stock.

If we do not obtain regulatory approval from foreign jurisdictions, we will not be able to market our products in those jurisdictions, which will limit our commercial revenues.*

In order to market our products in foreign jurisdictions, we must obtain foreign regulatory approval in each of those jurisdictions. We currently plan to submit our Marketing Authorization Application for NUPLAZID in Europe in the second quarter of 2016.

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Even if we obtain regulatory approval in the United States, approval by the FDA does not ensure that foreign jurisdictions will also approve our products for commercial distribution. The regulations in foreign jurisdictions vary. We will be required to comply with different regulations and policies of the jurisdictions where we seek approval for our product candidates, and we have not yet identified all of the requirements that we will need to satisfy to submit NUPLAZID for approval in foreign jurisdictions. This will require additional time, expertise and expense, including the potential need to conduct additional studies or development work beyond the work that we have conducted to support our NDA submission for PDP. Furthermore, we may not be able to obtain approval for foreign sales. This will restrict our ability to market our products and would limit their commercial potential and value, including that of NUPLAZID.

The pivotal Phase III study with NUPLAZID for PDP, the results of which were announced in November 2012, was our first successful pivotal Phase III trial and there is no guarantee that future studies with pimavanserin will be successful.*

The historical rate of failures for product candidates in clinical development is extremely high. In November 2012, we announced results from our successful pivotal -020 Phase III trial with NUPLAZID for the treatment of PDP. Even though we successfully completed the -020 Study, those results are not predictive of the results of any additional studies that we may undertake with pimavanserin, including any post-approval studies that we may undertake if NUPLAZID is approved for marketing by the FDA. We believe that pimavanserin also may have utility in indications other than PDP, such as Alzheimer's disease psychosis, or ADP, and schizophrenia and other indications related to Alzheimer's disease. However, prior to the first efficacy study that we commenced in late 2013, we had never tested pimavanserin in clinical studies for ADP or any Alzheimer's disease indication, and we have only conducted a Phase II trial for pimavanserin as a co-therapy treatment in schizophrenia. There is no guarantee that we will have the same level of success with pimavanserin in other indications that we had with the -020 Study or that we will be successful at all in future studies for additional indications or that future results of studies of NUPLAZID for the treatment of PDP will be consistent with those from the -020 Study.

If we do not successfully complete development of NUPLAZID, we will be unable to market and sell NUPLAZID or products derived from it, or to generate related product revenues.

We do not have a partner for the development of our lead product candidate, pimavanserin, and are solely responsible for the advancement of this program and, if approved for marketing, commercialization of the product.*

We have full responsibility for the pimavanserin program throughout the world. We expect our research and development costs for continued development of pimavanserin to be substantial. While we currently are undertaking the ongoing development work for pimavanserin, including clinical trials of pimavanserin for indications other than PDP, in the future we would need to add resources and raise additional funds in order to take this product candidate to market and to conduct the necessary sales and marketing activities, and to conduct further development activities, if we do not secure a partner. Following any potential approval by the FDA, our current strategy is to commercialize NUPLAZID for PDP in the United States by establishing a specialty sales force focused primarily on neurologists, a small group of psychiatrists and physicians in long-term care facilities who are high prescribers of antipsychotics for PDP patients. In addition, if we commercialize NUPLAZID in select markets outside of the United States, we will more than likely need to establish one or more strategic alliances in the future for that purpose. Without future collaboration partners in the United States and abroad, we might not be able to realize the full value of NUPLAZID.

We are currently conducting a significant life cycle planning project for pimavanserin that was initiated in the second quarter of 2015 and through which we expect to formulate a multi-year plan to develop pimavanserin in indications beyond PDP. Given the unique profile of pimavanserin, together with the list of potential indications we could pursue, this is a substantial and a very important undertaking. When we complete the project around the end of this year, we expect to have a long-term plan of which indications we intend to pursue for pimavanserin as we seek to maximize the opportunities for this compound. Pimavanserin has also shown significant benefits in nighttime sleep and daytime wakefulness in studies conducted in elderly patients with PDP and has shown sleep benefits in a proof-of-concept sleep-maintenance insomnia study in older volunteers. We had previously examined the possibility of following up these findings with a Phase II study to further explore the potential sleep benefits of pimavanserin in Parkinson's disease patients. However, as part of the life-cycle management process, we have concluded that we have sufficiently explored these findings and we have, therefore, elected not to pursue an additional sleep study at this time. If our life-cycle planning and execution is not conducted successfully, then we may not realize the full value from pimavanserin or may devote substantial resources to develop pimavanserin for indications that are ultimately not successful or do not yield adequate returns. Furthermore, even if NUPLAZID is approved for PDP, a failure in a subsequent study for another indication could harm our ability to successfully market NUPLAZID for PDP or could lead to it being withdrawn from the market.

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Our most advanced product candidates are in development, which is a long, expensive and unpredictable process, and there is a high risk of failure.*

Preclinical testing and clinical trials are long, expensive and unpredictable processes that can be subject to delays. It may take several years to complete the preclinical testing and clinical development necessary to commercialize a drug, and delays or failure can occur at any stage. Interim results of clinical trials do not necessarily predict final results, and success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials even after promising results in earlier trials.

Our drug development programs are at various stages of development and the historical rate of failures for product candidates is extremely high. In fact, we ended Phase I testing of AM-831 in 2012 and had previously had an unsuccessful Phase III trial with our most advanced product candidate, NUPLAZID. Following the reporting of successful results from the Phase III -020 Study with NUPLAZID in November 2012 and our meeting with the FDA in April 2013, we submitted our NDA for NUPLAZID for PDP in September 2015 that was accepted for priority review by the FDA on October 30, 2015 with a PDUFA goal date of May 1, 2016. An unfavorable outcome in any of the ongoing or future development efforts for NUPLAZID, including any unfavorable decisions related to our NDA, would be a major set-back for the program and for us, generally. In particular, an unfavorable outcome in our NUPLAZID program may require us to delay, devote additional substantial resources to, reduce the scope of, or eliminate this program and could have a material adverse effect on us and the value of our common stock. In addition to our PDP program, we commenced a Phase II study with pimavanserin for patients with ADP in November 2013 and we are planning additional studies in other indications, including those within schizophrenia and Alzheimer's disease. We have an ongoing clinical collaboration with Allergan with separate product candidates for the treatment of chronic pain that has reached Phase II development.

In connection with clinical trials, we face risks that:

- a product candidate may not prove to be efficacious or safe;
- patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested;
- the results may not be consistent with positive results of earlier trials; and
- the results may not meet the level of statistical significance required by the FDA or other regulatory agencies.

If we do not successfully complete preclinical and clinical development, we will be unable to market and sell products derived from our product candidates and to generate product revenues. Even if we do successfully complete clinical trials, those results are not necessarily predictive of results of additional trials that may be needed before an NDA may be submitted to the FDA. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are approved for commercialization.

Delays, suspensions and terminations in our clinical trials could result in increased costs to us and delay our ability to generate product revenues.

The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;
- manufacturing sufficient quantities of a product candidate;
- obtaining clearance from the FDA to commence clinical trials pursuant to an Investigational New Drug application;
- obtaining institutional review board approval to conduct a clinical trial at a prospective clinical trial site; and

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- patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical trial sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial.

Once a clinical trial has begun, it may be delayed, suspended or terminated due to a number of factors, including:

- ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials or requests by them for supplemental information with respect to our clinical trial results;
- imposition of clinical holds by regulatory authorities or institutional review boards;
- failure to conduct clinical trials in accordance with regulatory requirements;
- lower than anticipated screening or retention rates of patients in clinical trials;
- serious adverse events or side effects experienced by participants; and
- insufficient supply or deficient quality of product candidates or other materials necessary for the conduct of our clinical trials.

Many of these factors may also ultimately lead to denial of regulatory approval of a current or potential product candidate. If we experience delays, suspensions or terminations in a clinical trial, the commercial prospects for the related product candidate will be harmed, and our ability to generate product revenues will be delayed.

We depend on collaborations with third parties to develop and commercialize selected product candidates other than pimavanserin, and we have limited control over how those third parties conduct development and commercialization activities for such product candidates.*

One aspect of our strategy is to selectively enter into collaboration agreements with third parties. We currently rely, and will continue to rely, on our collaborators for financial resources and for development, regulatory, and commercialization expertise for selected product candidates, other than pimavanserin, and we have limited control over the amount and timing of resources that our collaborators may devote to our product candidates. We may choose to rely on collaborations in the future for certain portions of our pimavanserin program or for the commercialization of NUPLAZID in certain territories outside of the United States. Our 2003 research agreement with Allergan ended in March 2013 and Allergan provided notice of termination of our collaboration agreement focused on muscarinic product candidates in September 2015. Any additional payments from our ongoing collaboration agreement with Allergan in chronic pain are dependent upon further advancement of an applicable product candidate. Unless these milestones are met, we will not receive future revenues from our ongoing collaboration with Allergan.

Our collaborators may fail to develop or effectively commercialize products using our product candidates or technologies because they:

- do not have sufficient resources or decide not to devote the necessary resources due to internal constraints such as limited cash or human resources or a change in strategic focus;
- decide to pursue a competitive product developed outside of the collaboration; or
- cannot obtain the necessary regulatory approvals.

In July 2014, Allergan announced that it would be reducing its worldwide headcount by approximately 13% and that it would be restructuring its operations. In March 2015, Actavis plc acquired Allergan. Allergan also previously has announced that it was seeking a partner for further development and commercialization of drug candidates in our chronic pain program under our continuing collaboration. In connection with Actavis' acquisition of Allergan, and any related restructuring, Allergan has elected to terminate our collaboration focused on muscarinic product candidates, including the glaucoma program covered by such collaboration, and may choose to devote substantially less resources to the chronic pain program or could discontinue such program entirely. If Allergan is unable to successfully partner our chronic pain program, it may elect to not pursue further development. In addition, any partner that Allergan does identify may devote substantially less resources than Allergan has devoted to this program to date. In addition, Allergan

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can terminate our existing chronic pain collaboration upon prior notice to us, as it has done with the glaucoma collaboration. Allergan may be more likely to terminate, or decline to continue, our chronic pain collaboration in connection with Actavis' acquisition of Allergan.

If Allergan elects to devote substantially less resources to the chronic pain program, absent circumstances giving rise to our right to terminate, our remedies against Allergan are limited, and we may not be able to regain rights to such program. If Allergan elects to discontinue the chronic pain program and terminates our collaboration agreement, as is the case with the glaucoma program, the discontinued program may revert to us, in which case we would need to evaluate whether to continue advancing such program alone or with a new collaborator. Either advancing such program alone or seeking a new collaborator would divert our management's attention and involve expending additional resources that are currently devoted to our other programs, including our pimavanserin program. We have not yet made a determination with regard to any further development of the glaucoma program that will be returning to us under the collaboration focused on muscarinic product candidates.

We also face competition in our search for new collaborators, if we seek a new partner for our pimavanserin program or other programs, including any programs that may revert to us from Allergan. Given the current economic and industry environment, it is possible that competition for new collaborators may increase. If we are unable to find new collaborations, we may not be able to continue advancing our programs alone.

If conflicts arise with our collaborators, they may act in their self-interests, which may be adverse to our interests.*

Conflicts may arise in our collaborations due to one or more of the following:

- disputes or breaches with respect to payments that we believe are due under the applicable agreements, particularly in the current environment when companies, including large established ones, may be seeking to reduce external payments;
- disputes on strategy as to what development or commercialization activities should be pursued under the applicable agreements;
- disputes as to the responsibility for conducting development and commercialization activities pursuant to the applicable collaboration, including the payment of costs related thereto;
- disagreements with respect to ownership of intellectual property rights;
- unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities, or to permit public disclosure of these activities;
- delay or reduction of a collaborator's development or commercialization efforts with respect to our product candidates; or
- termination or non-renewal of the collaboration.

Conflicts arising with our collaborators could impair the progress of our product candidates, harm our reputation, result in a loss of revenues, reduce our cash position, and cause a decline in our stock price.

In addition, in our collaborations, we generally have agreed not to conduct independently, or with any third party, any research that is directly competitive with the research conducted under the applicable program. Our collaborations may have the effect of limiting the areas of research that we may pursue, either alone or with others. Our collaborators, however, may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by our collaborators or to which our collaborators have rights, may result in the allocation of resources by our collaborators to competing products and their withdrawal of support for our product candidates or may otherwise result in lower demand for our potential products.

We have an ongoing collaboration with Allergan for the development of product candidates related to chronic pain. Allergan may also pursue other research programs related to pain management that are independent from our collaboration in this therapeutic area. In March 2015, Actavis acquired Allergan. Actavis may have, or acquire rights to, additional programs related to chronic pain, which could impact the strategy with respect to the development of product candidates covered by our ongoing collaboration.

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We rely on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that prevent us from successfully commercializing product candidates.

Although we design and manage our current preclinical studies and clinical trials, we currently do not have the ability to conduct clinical trials for our product candidates on our own. In addition to our collaborators, we rely on contract research organizations, medical institutions, clinical investigators, and contract laboratories to perform data collection and analysis and other aspects of our clinical trials. In addition, we also rely on third parties to assist with our preclinical studies, including studies regarding biological activity, safety, absorption, metabolism, and excretion of product candidates.

Our preclinical activities or clinical trials may be delayed, suspended, or terminated if:

- these third parties do not successfully carry out their contractual duties or fail to meet regulatory obligations or expected deadlines;
- these third parties need to be replaced; or
- the quality or accuracy of the data obtained by these third parties is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons.

Failure to perform by these third parties may increase our development costs, delay our ability to obtain regulatory approval, and delay or prevent the commercialization of our product candidates. We currently use several contract research organizations to perform services for our preclinical studies and clinical trials. While we believe that there are numerous alternative sources to provide these services, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without delays or additional expenditures.

Even if we or our collaborators successfully complete the clinical trials of product candidates, the product candidates may fail for other reasons.

Of the large number of product candidates in development, only a small percentage result in the submission of an NDA to the FDA or comparable regulatory filing to regulatory authorities in other jurisdictions, and even fewer are approved for marketing. Even if we or our collaborators successfully complete the clinical trials of product candidates, the product candidates, such as pimavanserin, may fail for other reasons, including the possibility that the product candidates will:

- fail to receive the regulatory clearances required to market them as drugs;
- be subject to proprietary rights held by others requiring the negotiation of a license agreement prior to marketing;
- be difficult or expensive to manufacture on a commercial scale;
- have adverse side effects that make their use less desirable; or
- fail to compete with product candidates or other treatments commercialized by competitors.

We currently depend, and will in the future continue to depend, on third parties to manufacture NUPLAZID and our other product candidates. If these manufacturers fail to provide us and our collaborators with adequate supplies of clinical trial materials and commercial product or fail to comply with the requirements of regulatory authorities, we may be unable to develop or commercialize NUPLAZID or our other product candidates.*

We have no manufacturing facilities and only limited experience as an organization in the manufacturing of drugs or in designing drug-manufacturing processes. We have contracted with third-party manufacturers to produce, in collaboration with us, our product candidates, including NUPLAZID, for clinical trials. If any of our product candidates, including NUPLAZID, are approved by the FDA or other regulatory agencies for commercial sale, we will need to contract with a third party to manufacture them in larger quantities.

In August 2015, we contracted with Patheon Pharmaceuticals Inc., or Patheon, to manufacture NUPLAZID drug product for commercial use in the United States following any commercial launch of NUPLAZID, if approved by the FDA. Additionally, in

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August 2015 we contracted with BASF Pharma (Evionnaz) SA, which was subsequently acquired by Siegfried Pharma Evionnaz SA, or Siegfried, in October 2015, to manufacture active pharmaceutical ingredient, or API, to be used in the manufacture of NUPLAZID drug product for commercial use. However, we have not entered into any agreements with any alternate suppliers for NUPLAZID drug product or NUPLAZID API. Even if we are able to enter into other long-term agreements with manufacturers for commercial supply on reasonable terms, we may be unable to do so with sufficient time prior to launch of NUPLAZID, which would expose us to substantial supply risk and potentially jeopardize our launch.

Even though we entered into an agreement with Patheon for the manufacture of NUPLAZID drug product and with Siegfried for the manufacture of NUPLAZID API for commercial use, and even if we successfully enter into long-term agreements with other manufacturers, the FDA may not approve the facilities of such manufacturers, the manufacturers may not perform as agreed, or the manufacturers may terminate their agreements with us. Presently, we only have one supplier of API and one supplier of drug product for our NUPLAZID (pimavanserin) program. If any of the foregoing circumstances occur, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market NUPLAZID or any of our other product candidates. While we believe that there will be alternative sources available to manufacture our product candidates, including NUPLAZID, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without delays or additional expenditures. We cannot estimate these delays or costs with certainty but, if they were to occur, they could cause a delay in our development and commercialization efforts.

The manufacturers of our product candidates, including Patheon and Siegfried, are obliged to operate in accordance with FDA-mandated current good manufacturing practices, or cGMPs, and we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel to ensure compliance with cGMPs. In addition, the facilities used by our third-party manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted prior to any grant of regulatory approval by the FDA. If any of our third-party manufacturers are unable to successfully manufacture material that conforms to our specifications and the FDA's strict regulatory requirements, or pass regulatory inspection, they will not be able to secure or maintain approval for the manufacturing facilities. Additionally, a failure by any of our third-party manufacturers to establish and follow cGMPs or to document their adherence to such practices may lead to significant delays in clinical trials or in obtaining regulatory approval of product candidates, including NUPLAZID, or the ultimate launch of NUPLAZID or any other products based on our product candidates. Failure by our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of products, operating restrictions, and criminal prosecutions.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly-enforced federal, state and foreign regulations. We cannot assure you that any issues relating to the manufacture of any of our product candidates, including NUPLAZID, will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to commercialize NUPLAZID in the United States, or provide any product candidates to patients in clinical trials, would be jeopardized. Any delay or interruption in our ability to meet commercial demand for our products will result in the loss of potential revenues and could adversely affect our ability to gain market acceptance for these products. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

Failures or difficulties faced at any level of our supply chain could materially adversely affect our business and delay or impede the development and commercialization of any of our products or product candidates and could have a material adverse effect on our business, results of operations, financial condition and prospects.

If we are unable to attract, retain, and motivate key management, research and development, and sales and marketing personnel, our drug development programs, our research and discovery efforts, and our commercialization plans may be delayed and we may be unable to successfully develop or commercialize our product candidates, including NUPLAZID.

Our success depends on our ability to attract, retain, and motivate highly qualified management, scientific, and commercial personnel. In particular, our development programs depend on our ability to attract and retain highly skilled development personnel, especially in the fields of central nervous system disorders, including neuropsychiatric and related disorders. In the future, we expect

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to need to hire additional personnel as we expand our research and development efforts and commercial activities for pimavanserin from our current levels. We face competition for experienced scientists, clinical operations personnel, commercial and other personnel from numerous companies and academic and other research institutions. Competition for qualified personnel is particularly intense in the San Diego, California area. Many of the other biotechnology and pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than that which we have to offer. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize products and product candidates will be limited. If we are unable to attract and retain the necessary personnel, it will significantly impede the achievement of our research and development objectives, our commercialization efforts for NUPLAZID, and our ability to meet the demands of our collaborators in a timely fashion.

All of our employees are “at will” employees, which means that any employee may quit at any time and we may terminate any employee at any time. We do not carry “key person” insurance covering members of senior management.

We have recently increased the size of our organization, and will need to continue to increase the size of our organization. We may encounter difficulties with managing our growth, which could adversely affect our results of operations.*

As of September 30, 2015, we employed 151 employees. Although we have already added several capabilities, we will need to add additional qualified personnel and resources if the NDA for NUPLAZID is approved for marketing and we establish a commercial sales force. Our current infrastructure will be inadequate to support these future efforts and expected growth. In particular, we will have to develop internal sales, marketing, and distribution capabilities if we decide to market any drug that we may successfully develop, including NUPLAZID. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees, and may take time away from running other aspects of our business, including development and commercialization of our product candidates.

Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. In particular, as our commercialization plans and strategies develop, we will need to recruit and train a substantial number of sales and marketing personnel and expect to need to expand the size of our employee base for managerial, operational, financial and other resources. To that end, we must be able to:

- manage our development efforts effectively;
- integrate additional management, administrative and manufacturing personnel;
- build a marketing and sales organization; and
- maintain sufficient administrative, accounting and management information systems and controls.

We may not be able to accomplish these tasks or successfully manage our operations and, accordingly, may not achieve our research, development, and commercialization goals. Our failure to accomplish any of these goals could harm our financial results and prospects.

As we grow as an organization and expand from a development to a commercial-stage company, we may make certain changes to our organization in order to properly manage our growth, which may include changes to the composition of our board of directors and management. Any such changes may be disruptive to us as an organization, which could harm our business.*

As we continue to grow as an organization, including by expanding our development efforts and building out our commercial capabilities in anticipation of commercial launch of NUPLAZID, if approved, we will evaluate, and may implement, changes to our organization that may be appropriate in order to properly manage and direct our growth and transformation into a commercial-stage company. These changes may include changes to the size and composition of our management and/or board of directors, as appropriate, to include individuals with substantial experience in managing or serving on the boards of directors of commercial-stage pharmaceutical companies. We recently named Steve Davis, who had been serving as our Interim CEO since March 2015, to be our President and Chief Executive Officer and to be a member of our Board of Directors. We currently are recruiting for a new Chief Financial Officer and may decide to hire other executive level employees as we grow. Any such significant changes to the organization may distract management or otherwise be disruptive to us as a company, which could harm our business.

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If we fail to develop, acquire or in-license other product candidates or products, our business and prospects would be limited. Even if we obtain rights to other product candidates or products, we will incur a variety of costs and may never realize the anticipated benefits.

A key element of our strategy is to develop, acquire or in-license businesses, technologies, product candidates or products that we believe are a strategic fit with our business. The success of this strategy depends in large part on the combination of our regulatory, development and commercial capabilities and expertise and our ability to identify, select and acquire or in-license clinically-enabled product candidates for the treatment of neurological disorders, or for therapeutic indications that complement or augment our current product candidates, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. Identifying, selecting and acquiring or in-licensing promising product candidates requires substantial technical, financial and human resources expertise, and we have limited experience in identifying acquisition targets, successfully completing proposed acquisitions and integrating any acquired businesses, technologies, services or products into our current infrastructure. Efforts to do so may not result in the actual acquisition or in-license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. If we are unable to identify, select and acquire or license suitable product candidates from third parties on terms acceptable to us, our business and prospects will be limited. In particular, if NUPLAZID is approved for marketing and we are unable to add additional commercial products to our portfolio, we may not be able to successfully leverage our commercial organization.

The process of integrating any acquired business, technology, service, or product may result in unforeseen operating difficulties and expenditures and may divert significant management attention from our ongoing business operations. As a result, we will incur a variety of costs in connection with an acquisition and may never realize its anticipated benefits. Moreover, any product candidate we identify, select and acquire or license may require additional, time-consuming development or regulatory efforts prior to commercial sale, including preclinical studies, if applicable, and extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to the risk of failure that is inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective or desired than other commercially available alternatives.

In addition, if we fail to successfully commercialize and further develop NUPLAZID or our other product candidates, there is a greater likelihood that we will fail to successfully develop a pipeline of other product candidates, and our business and prospects would therefore be harmed.

We do not know whether our drug discovery platform will lead to the discovery or development of commercially viable product candidates.

Our drug discovery platform uses unproven methods to identify and develop product candidates, including NUPLAZID. We have never successfully completed clinical development of any of our product candidates, and there are no drugs on the market that have been discovered using our drug discovery platform.

Our research and development focuses on small molecule drugs for the treatment of central nervous system disorders. Due to our limited resources, we may have to forego potential opportunities with respect to discovering product candidates to treat diseases or conditions in other therapeutic areas. If we are not able to use our technologies to discover and develop product candidates that can be commercialized, we may not achieve profitability. In the future, as noted above, we will likely find it necessary to license the technology of others or acquire additional product candidates to augment the results of our internal discovery activities. If we are unable to identify new product candidates using our drug discovery platform, we may be unable to establish or maintain a clinical development pipeline or generate product revenues.

We may not be able to continue or fully exploit our collaborations with outside scientific and clinical advisors, which could impair the progress of our clinical trials and our research and development efforts.

We work with scientific and clinical advisors at academic and other institutions who are experts in the field of central nervous system disorders. They assist us in our research and development efforts and advise us with respect to our clinical trials. These advisors are not our employees and may have other commitments that would limit their future availability to us. Although our scientific and clinical advisors generally agree not to engage in competing work, if a conflict of interest arises between their work for us and their work for another entity, we may lose their services, which may impair our reputation in the industry and delay the development or commercialization of our product candidates.

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We expect that our results of operations will fluctuate, which may make it difficult to predict our future performance from period to period.*

Our operating results have fluctuated in the past and are likely to do so in future periods. Some of the factors that could cause our operating results to fluctuate from period to period include:

- whether and when we obtain FDA approval of NUPLAZID for the treatment of PDP;
- the success of our launch and commercialization of NUPLAZID, if approved, in the United States for the treatment of PDP;
- the status of development and commercialization of pimavanserin for indications other than PDP and in jurisdictions other than the United States;
- the status of development and commercialization of our other product candidates, including compounds being developed under our collaborations;
- whether we acquire or in-license additional product candidates or products, and the status of development and commercialization of such product candidates or products;
- whether we generate revenues or reimbursements by achieving specified research, development or commercialization milestones under any agreements or otherwise receive potential payments under these agreements;
- whether we are required to make payments due to achieving specified milestones under any licensing or similar agreements or otherwise make payments under these agreements;
- the incurrence of preclinical or clinical expenses that could fluctuate significantly from period to period, including reimbursement obligations pursuant to our collaboration agreements;
- the initiation, termination, or reduction in the scope of our collaborations or any disputes regarding these collaborations;
- the timing of our satisfaction of applicable regulatory requirements;
- the rate of expansion of our clinical development, other internal research and development efforts, and pre-commercial and commercial efforts;
- the effect of competing technologies and products and market developments;
- the costs associated with litigation, including the costs incurred in defending against claims made in the two putative class action complaints filed in March 2015 following our announcement of the update to the timing of our planned NDA submission to the FDA for NUPLAZID and the subsequent decline of the price of our common stock; and
- general and industry-specific economic conditions.

We believe that comparisons from period to period of our financial results are not necessarily meaningful and should not be relied upon as indications of our future performance.

Future changes to U.S. and non-U.S. tax laws could materially adversely affect us.*

During the first half of 2015, we licensed worldwide intellectual property rights related to pimavanserin in certain indications to ACADIA Pharmaceuticals GmbH, our wholly-owned Swiss subsidiary. Our goals for the establishment of ACADIA Pharmaceuticals GmbH, and the licensing of worldwide intellectual property rights for pimavanserin, include building a platform for long-term operational and financial efficiencies, including tax-related efficiencies. Future changes in U.S. and non-U.S. tax laws, including implementation of international tax reform relating to the tax treatment of multinational corporations, if enacted, may reduce or eliminate any potential financial efficiencies that we hope to achieve by establishing this operational structure. Additionally, taxing

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authorities, such as the U.S. Internal Revenue Service, may audit and otherwise challenge these types of arrangements, and have done so with other companies in the pharmaceutical industry. If any such changes in tax law are enacted, or our licensing of worldwide intellectual property rights for pimavanserin to our Swiss subsidiary is otherwise challenged, this could materially adversely affect our business.

Our management has broad discretion over the use of our cash and we may not use our cash effectively, which could adversely affect our results of operations.

Our management has significant flexibility in applying our cash resources and could use these resources for corporate purposes that do not increase our market value, or in ways with which our stockholders may not agree. We may use our cash resources for corporate purposes that do not yield a significant return or any return at all for our stockholders, which may cause our stock price to decline.

We have incurred, and expect to continue to incur, significant costs as a result of laws and regulations relating to corporate governance and other matters.

Laws and regulations affecting public companies, including provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act that was enacted in July 2010, the provisions of the Sarbanes-Oxley Act of 2002, or SOX, and rules adopted or proposed by the SEC and by The NASDAQ Stock Market, have resulted in, and will continue to result in, significant costs to us as we evaluate the implications of these rules and respond to their requirements. We issued an evaluation of our internal control over financial reporting as required or we or our independent registered public accounting firm determine that our internal control over financial reporting is not effective, this shortcoming could have an adverse effect on our business and financial results and the price of our common stock could be negatively affected. New rules could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the coverage that is the same or similar to our current coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors and board committees, and as our executive officers. We cannot predict or estimate the total amount of the costs we may incur or the timing of such costs to comply with these rules and regulations.

We will need to obtain final FDA approval of our proposed product name for pimavanserin, NUPLAZID, and the failure or any delay in receiving this approval may adversely impact the timing and success of our sales and marketing efforts.

The FDA will need to provide final approval of the NUPLAZID product name regardless of our trademark registration from the United States Patent and Trademark Office. Typically, the FDA conducts an extensive review of proposed product names, including an evaluation for possible confusion with other existing product names. If the FDA does not approve the name NUPLAZID, we will need to adopt an alternative name. As a result, we would lose the benefit of any existing trademark applications and may need to spend significant resources in an effort to select another product name that will meet FDA approval, qualify under existing trademark laws and not infringe on the existing rights of third parties. In addition, we will need to develop brand loyalty for any product name in order to commercialize pimavanserin effectively. If we fail to do this, it could negatively impact our future revenues from sales of pimavanserin.

Earthquake or fire damage to our facilities could delay our research and development efforts and adversely affect our business.

Our headquarters and research and development facilities in San Diego are located in a seismic zone, and there is the possibility of an earthquake, which could be disruptive to our operations and result in delays in our research and development efforts. In addition, while our facilities have not been adversely impacted by local wildfires, there is the possibility of future fires in the area. In the event of an earthquake or fire, if our facilities or the equipment in our facilities is significantly damaged or destroyed for any reason, we may not be able to rebuild or relocate our facilities or replace any damaged equipment in a timely manner and our business, financial condition, and results of operations could be materially and adversely affected. We do not have insurance for damages resulting from earthquakes. While we do have fire insurance for our property and equipment located in San Diego, any damage sustained in a fire could cause a delay in our research and development efforts and our results of operations could be materially and adversely affected.

Risks Related to Our Intellectual Property

Our ability to compete may decline if we do not adequately protect our proprietary rights.

Our commercial success depends on obtaining and maintaining intellectual property rights to our product candidates, including NUPLAZID, and technologies, as well as successfully defending these rights against third-party challenges. Any misappropriation of our intellectual property could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. To protect our intellectual property, we rely on a combination of patents, trade secret protection and confidentiality agreements.

With regard to patents, although we have filed numerous patent applications worldwide with respect to pimavanserin, not all of our patent applications resulted in an issued patent, or they resulted in an issued patent that is susceptible to challenge by a third party. Our ability to obtain, maintain, and/or defend our patents covering our product candidates and technologies is uncertain due to a number of factors, including:

- we may not have been the first to make the inventions covered by our pending patent applications or issued patents;
- we may not have been the first to file patent applications for our product candidates or the technologies we rely upon;
- others may develop similar or alternative technologies or design around our patent claims to produce competitive products that fall outside of the scope of our patents;
- our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- we may not seek or obtain patent protection in all countries that will eventually provide a significant business opportunity;
- any patents issued to us or our collaborators may not provide a basis for commercially viable products, may not provide us with any competitive advantages, or are easily susceptible to challenges by third parties;
- our proprietary technologies may not be patentable;
- changes to patent laws that limit the exclusivity rights of patent holders or make it easier to render a patent invalid;
- recent decisions by the United States Supreme Court limiting patent-eligible subject matter;
- the passage of the America Invents Act (2012) introduced new procedures for challenging pending patent applications and issued patents; and
- technology that we may in-license may become important to some aspects of our business, however, we generally would not control the patent prosecution, maintenance or enforcement of any such in-licensed technology.

Even if we have or obtain patents covering our product candidates or technologies, we may still be barred from making, using and selling our product candidates or technologies because of the patent rights of others. Others have or may have filed, and in the future are likely to file, patent applications covering compounds, assays, genes, gene products or therapeutic products that are similar or identical to ours. There are many issued U.S. and foreign patents relating to genes, nucleic acids, polypeptides, chemical compounds or therapeutic products, and some of these may encompass reagents utilized in the identification of candidate drug compounds or compounds that we desire to commercialize. Numerous U.S. and foreign issued patents and pending patent applications owned by others exist in the area of central nervous system disorders and the other fields in which we are developing products. These could materially affect our freedom to operate. Moreover, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, that may later result in issued patents that our product candidates or technologies may infringe. These patent applications may have priority over patent applications filed by us.

We regularly conduct searches to identify patents or patent applications that may prevent us from obtaining patent protection for our proprietary compounds or that could limit the rights we have claimed in our patents and patent applications. Disputes may arise regarding the ownership or inventorship of our inventions. For applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the United States Patent and Trademark

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Office, or United States PTO, to determine who was the first to invent the invention at issue. It is difficult to determine how such disputes would be resolved. Applications containing a claim not entitled to priority before March 16, 2013, are not subject to interference proceedings due the change brought by the America Invents Act (2012) to a “first to file” system. However, a derivation proceeding can be brought by a third-party alleging that the inventor derived the invention from another.

Periodic maintenance fees on any issued patent are due to be paid to the United States PTO and foreign patent agencies in several stages over the lifetime of the patent. The United States PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Some of our academic institutional licensors, research collaborators and scientific advisors have rights to publish data and information to which we have rights. We generally seek to prevent our collaborators from disclosing scientific discoveries until we have the opportunity to file patent applications on such discoveries, but in some cases, we are limited to relatively short periods to review a proposed publication and file a patent application. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations, then our ability to receive patent protection or protect our proprietary information will be impaired.

Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.

Because we operate in the highly technical field of drug discovery and development of small molecule drugs, we rely in part on trade secret protection in order to protect our proprietary technology and processes. However, trade secrets are difficult to protect. We enter into confidentiality and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party’s relationship with us. These agreements also generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. We also have not entered into any noncompete agreements with any of our employees. Although each of our employees is required to sign a confidentiality agreement with us at the time of hire, we cannot guarantee that the confidential nature of our proprietary information will be maintained in the course of future employment with any of our competitors. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time-consuming and costly, and an unfavorable outcome could harm our business.*

There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including post-issuance review proceedings before the United States PTO or oppositions and other comparable proceedings in foreign jurisdictions.

Central provisions of The Leahy-Smith America Invents Act, or the America Invents Act went into effect on September 16, 2012 and on March 16, 2013. The America Invents Act includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications are being filed, prosecuted and litigated. For example, the America Invents Act enacted proceedings involving post-issuance patent review procedures, such as inter partes review, or IPR, and post-grant review, that allow third parties to challenge the validity of an issued patent in front of the United States PTO Patent Trial and Appeal Board. Each proceeding has different eligibility criteria and different patentability challenges that can be raised. IPRs permit any person (except a party who has been litigating the patent for more than a year) to challenge the validity of the patent on the grounds that it was anticipated or made obvious by prior art. Patents covering pharmaceutical products have been subject to attack in IPRs from generic drug companies and from hedge funds. If it is within nine months of the issuance of the challenged patent, a third party can

petition the United States PTO for post-grant review, which can be based on any invalidity grounds and is not limited to prior art patents or printed publications.

In post-issuance proceedings, United States PTO rules and regulations generally tend to favor patent challengers over patent owners. For example, unlike in district court litigation, claims challenged in post-issuance proceedings are given their broadest reasonable meaning, which increases the chance a claim might be invalidated by prior art or lack support in the patent specification. And, unlike in district court litigation, there is no presumption of validity for an issued patent. As a result of these rules and others, statistics released by the United States PTO show a high percentage of claims being invalidated in post-issuance proceedings. Moreover, with few exceptions, there is no standing requirement to petition the United States PTO for inter partes review or post-grant review. In other words, companies that have not been charged with infringement or that lack commercial interest in the patented subject matter can still petition the United States PTO for review of an issued patent. Thus, even where we have issued patents, our rights under those patents may be challenged and ultimately not provide us with sufficient protection against competitive products or processes.

While we are not currently subject to any pending intellectual property litigation or patent challenges, and are not aware of any such threatened litigation or patent challenges, we may be exposed to future litigation by third parties based on claims that our product candidates, technologies or activities infringe the intellectual property rights of others. In particular, there are many patents relating to specific genes, nucleic acids, polypeptides or the uses thereof to identify product candidates. Some of these may encompass genes or polypeptides that we utilize in our drug development activities. If our drug development activities are found to infringe any such patents, and such patents are held to be valid and enforceable, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from using the patented genes or polypeptides for the identification or development of drug compounds. There are also many patents relating to chemical compounds and the uses thereof. If our compounds are found to infringe any such patents, and such patents are held to be valid and enforceable, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from making, using or selling the patented compounds.

We may need to resort to litigation to enforce a patent issued to us, protect our trade secrets or determine the scope and validity of third-party proprietary rights. From time to time, we may hire scientific personnel formerly employed by other companies involved in one or more areas similar to the activities conducted by us. Either we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of their prior affiliations. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. We may not be able to afford the costs of litigation. Any legal action against us or our collaborators could lead to:

- payment of damages, which could potentially be trebled if we are found to have willfully infringed a party's patent rights;
- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize, and sell products; or
- we or our collaborators having to enter into license arrangements that may not be available on commercially acceptable terms, or at all.

As a result, we could be prevented from commercializing current or future products.

Furthermore, because of the substantial amount of pre-trial document and witness discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the trading price of our common stock.

The patent applications of pharmaceutical and biotechnology companies involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position.

The strength of patents in the pharmaceutical and biotechnology field can be highly uncertain and involve complex legal and factual questions. For example, some of our patent applications may cover the uses of gene sequences. The patentability of gene sequences and the use of gene sequences has been seriously undermined by recent decisions of the United States Supreme Court. The United States PTO's interpretation of the Supreme Court's decisions and the standards for patentability it sets forth are uncertain and could change in the future. Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. U.S. patents and patent applications may also be subject to interference proceedings as

mentioned above, and U.S. patents may be subject to reexamination and post-issuance proceedings in the United States PTO (and foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent office), which proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. Similarly, opposition or invalidity proceedings could result in loss of rights or reduction in the scope of one or more claims of a patent in foreign jurisdictions. In addition, such interference, reexamination, post-issuance and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

In addition, changes in or different interpretations of patent laws in the United States and foreign countries may permit others to use our discoveries or to develop and commercialize our technology and products without providing any compensation to us or may limit the number of patents or claims we can obtain. In particular, there have been proposals to shorten the exclusivity periods available under U.S. patent law that, if adopted, could substantially harm our business. The product candidates that we are developing are protected by intellectual property rights, including patents and patent applications. If any of our product candidates becomes a marketable product, we will rely on our exclusivity under patents to sell the compound and recoup our investments in the research and development of the compound. If the exclusivity period for patents is shortened, then our ability to generate revenues without competition will be reduced and our business could be materially adversely impacted. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws and those countries may lack adequate rules and procedures for defending our intellectual property rights. For example, some countries, including many in Europe, do not grant patent claims directed to methods of treating humans and, in these countries, patent protection may not be available at all to protect our product candidates. In addition, U.S. patent laws may change which could prevent or limit us from filing patent applications or patent claims to protect our products and/or technologies or limit the exclusivity periods that are available to patent holders. For example, the America Invents Act (2012) included a number of significant changes to U.S. patent law. These included changes to transition from a “first-to-invent” system to a “first-to-file” system and to the way issued patents are challenged. These changes may favor larger and more established companies that have more resources to devote to patent application filing and prosecution. It is still not clear what, if any, impact the America Invents Act will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend our issued patents.

If we fail to obtain and maintain patent protection and trade secret protection of our product candidates, proprietary technologies and their uses, we could lose our competitive advantage and competition we face would increase, reducing our potential revenues and adversely affecting our ability to attain or maintain profitability.

Risks Related to Our Industry

We will be subject to stringent regulation in connection with the marketing of any products derived from our product candidates, including NUPLAZID, which could delay the development and commercialization of our products.

The pharmaceutical industry is subject to stringent regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Neither we nor our collaborators can market a pharmaceutical product, including NUPLAZID, in the United States until it has completed rigorous preclinical testing and clinical trials and an extensive regulatory clearance process implemented by the FDA. Satisfaction of regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product, and requires substantial resources. Even if regulatory approval is obtained, it may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, and/or marketing of such products, and requirements for post-approval studies, including additional research and development and clinical trials. These limitations may limit the size of the market for the product or result in the incurrence of additional costs. Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues from the particular product candidate.

Outside the United States, the ability to market a product is contingent upon receiving approval from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing, and reimbursement vary widely from country to country. Only after the appropriate regulatory authority is satisfied that adequate evidence of safety, quality, and efficacy has been presented will it grant a marketing authorization. Approval by the FDA does not automatically lead to the approval by regulatory authorities outside the United States and, similarly, approval by regulatory authorities outside the United States will not automatically lead to FDA approval.

In addition, U.S. and foreign government regulations control access to and use of some human or other tissue samples in our research and development efforts. U.S. and foreign government agencies may also impose restrictions on the use of data derived from human or other tissue samples. Accordingly, if we fail to comply with these regulations and restrictions, the commercialization of our product candidates may be delayed or suspended, which may delay or impede our ability to generate product revenues.

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If our competitors develop and market products that are more effective than our product candidates, including NUPLAZID, they may reduce or eliminate our commercial opportunity.

Competition in the pharmaceutical and biotechnology industries is intense and expected to increase. We face competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, both in the United States and abroad. Some of these competitors have products or are pursuing the development of drugs that target the same diseases and conditions that are the focus of our drug development programs.

For example, the use of NUPLAZID for the treatment of PDP would compete with off-label use of antipsychotic drugs, including Seroquel, marketed by Astra-Zeneca PLC, and with the generic drug clozapine. Our potential products for the treatment of schizophrenia would compete with Latuda, marketed by Sunovion Pharmaceuticals Inc., Zyprexa, marketed by Eli Lilly and Company, Risperdal, marketed by Johnson & Johnson, Abilify, marketed jointly by Bristol-Myers Squibb Company and Otsuka Pharmaceutical Co., Ltd., Seroquel, and clozapine. Our potential product for the treatment of ADP would compete with Risperdal and with off-label use of antipsychotic drugs and drugs indicated for the treatment of Alzheimer's disease and dementia in patients with Alzheimer's disease, including Aricept, marketed by Eisai Inc. and Pfizer Inc., and Namenda, marketed by Forest Laboratories, LLC, a wholly-owned subsidiary of Actavis. In the area of chronic pain, potential products would compete with Lyrica, marketed by Pfizer, and Cymbalta, marketed by Eli Lilly, as well as a variety of generic or proprietary opioids. Our potential products for the treatment of glaucoma would compete with Xalatan, marketed by Pfizer, and Lumigan and Alphagan, marketed by Allergan.

Many of our competitors and their collaborators have significantly greater experience than we do in the following:

- identifying and validating targets;
- screening compounds against targets;
- preclinical studies and clinical trials of potential pharmaceutical products; and
- obtaining FDA and other regulatory approvals.

In addition, many of our competitors and their collaborators have substantially greater capital and research and development resources, manufacturing, sales and marketing capabilities, and production facilities. Smaller companies also may prove to be significant competitors, particularly through proprietary research discoveries and collaboration arrangements with large pharmaceutical and established biotechnology companies. Many of our competitors have products that have been approved or are in advanced development and may develop superior technologies or methods to identify and validate drug targets and to discover novel small molecule drugs. Our competitors, either alone or with their collaborators, may succeed in developing drugs that are more effective, safer, more affordable, or more easily administered than ours and may achieve patent protection or commercialize drugs sooner than us. Our competitors may also develop alternative therapies that could further limit the market for any drugs that we may develop. Our failure to compete effectively could have a material adverse effect on our business.

Any claims relating to improper handling, storage, or disposal of biological, hazardous, and radioactive materials used in our business could be costly and delay our research and development efforts.

Our research and development activities involve the controlled use of potentially harmful hazardous materials, including volatile solvents, biological materials such as blood from patients that has the potential to transmit disease, chemicals that cause cancer, and various radioactive compounds. Our operations also produce hazardous waste products. We face the risk of contamination or injury from the use, storage, handling or disposal of these materials. We are subject to federal, state and local laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations could be significant, and current or future environmental regulations may impair our research, development, or production efforts. If one of our employees were accidentally injured from the use, storage, handling, or disposal of these materials, the medical costs related to his or her treatment would be covered by our workers' compensation insurance policy. However, we do not carry specific biological or hazardous waste insurance coverage and our general liability insurance policy specifically excludes coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be subject to criminal sanctions or fines or be held liable for damages, our operating licenses could be revoked, or we could be required to suspend or modify our operations and our research and development efforts.

Consumers may sue us for product liability, which could result in substantial liabilities that exceed our available resources and damage our reputation.

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Researching, developing, and commercializing drug products entails significant product liability risks. Liability claims may arise from our and our collaborators' use of products in clinical trials and the commercial sale of those products. Consumers may make these claims directly and our collaborators or others selling these products may seek contribution from us if they receive claims from consumers. Although we currently have product liability insurance that covers our clinical trials, we will need to increase and expand this coverage if we commence larger scale trials and if our product candidates are approved for commercial sale. This insurance may be prohibitively expensive or may not fully cover our potential liabilities. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of products that we or our collaborators develop. Product liability claims could have a material adverse effect on our business and results of operations. Our liability could exceed our total assets if we do not prevail in a lawsuit from any injury caused by our drug products.

Risks Related to Our Common Stock

Our stock price historically has been, and is likely to remain, highly volatile.*

The market prices for securities of biotechnology companies in general, and drug discovery and development companies in particular, have been highly volatile and may continue to be highly volatile in the future. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- the development status of our product candidates, including results of development and commercialization efforts in our pimavanserin development program;
- the timing, or developments regarding the timing, of submission and review of filings for our product candidates, including NUPLAZID, for approval by regulatory authorities in the United States and abroad and the results of any applications for marketing approval of product candidates;
- any other communications or guidance from the FDA or other regulatory authorities that pertain to our product candidates, including NUPLAZID;
- the initiation, termination, or reduction in the scope of our collaborations or any disputes or developments regarding our collaborations;
- market conditions or trends related to biotechnology and pharmaceutical industries, or the market in general;
- announcements of technological innovations, new products, or other material events by our competitors or us, including any new products that we may acquire or in-license;
- disputes or other developments concerning our proprietary and intellectual property rights;
- changes in, or failure to meet, securities analysts' or investors' expectations of our financial performance;
- our failure to meet applicable NASDAQ listing standards and the possible delisting of our common stock from the NASDAQ Stock Market;
- additions or departures of key personnel;
- discussions of our business, products, financial performance, prospects, or stock price by the financial and scientific press and online investor communities such as blogs and chat rooms;
- public concern as to, and legislative action with respect to, genetic testing or other research areas of biopharmaceutical companies, the pricing and availability of prescription drugs, or the safety of drugs and drug delivery techniques;
- regulatory developments in the United States and in foreign countries;

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- the announcement of, or developments in, any litigation matters; and
- economic and political factors, including but not limited to economic and financial crises, wars, terrorism, and political unrest.

In the past, following periods of volatility in the market price of a particular company's securities, securities class action litigation has often been brought against that company. For example, in March 2015, following our announcement of the update to the timing of our planned NDA submission to the FDA for NUPLAZID for the treatment of PDP and the subsequent decline of the price of our common stock, two putative securities class action complaints were filed against us and certain of our current and former officers. The complaints generally allege that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by making materially false and misleading statements regarding the timing of our planned NDA submission to the FDA for NUPLAZID, thereby artificially inflating the price of our common stock. If we are not successful in defense of these claims, we may have to make significant payments to, or other settlements with, our stockholders and their attorneys. Even if such claims are not successful, the litigation could result in substantial costs and divert our management's attention and resources, which could have a material adverse effect on our business, operating results or financial condition.

If we or our stockholders sell substantial amounts of our common stock, the market price of our common stock may decline.*

A significant number of shares of our common stock are held by a small number of stockholders. Sales of a significant number of shares of our common stock, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. We filed registration statements in connection with private financings that we concluded in January 2011 and December 2012, which registrations cover approximately 17.0 million shares and 19.5 million shares of our common stock, respectively. In addition, in connection with our March 2014 public offering of common stock, we agreed to provide resale registration rights for the shares of our common stock held by entities affiliated with one of our principal stockholders and one of our directors, Dr. Stephen R. Biggar. We also have an effective registration statement to sell shares of our common stock on our own behalf, and may elect to sell shares pursuant to such registration statement, or an indeterminate number of shares pursuant to a new registration statement or in a private placement, from time to time. Our stock price may decline as a result of the sale of the shares of our common stock included in any of these registration statements or future financings.

If our officers, directors, and largest stockholders choose to act together, they may be able to significantly influence our management and operations, acting in their best interests and not necessarily those of our other stockholders.

Our directors, executive officers and holders of five percent or more of our outstanding common stock and their affiliates beneficially own a substantial portion of our outstanding common stock. As a result, these stockholders, acting together, have the ability to significantly influence all matters requiring approval by our stockholders, including the election of all of our board members, amendments to our certificate of incorporation, going-private transactions, and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with the company's interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of our other stockholders.

Anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us more complicated and may make the removal and replacement of our directors and management more difficult.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may delay or prevent a change in control, discourage bids at a premium over the market price of our common stock and adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. These provisions may also make it difficult for stockholders to remove and replace our board of directors and management. These provisions:

- establish that members of the board of directors may be removed only for cause upon the affirmative vote of stockholders owning at least a majority of our capital stock;
- authorize the issuance of "blank check" preferred stock that could be issued by our board of directors to increase the number of outstanding shares and prevent or delay a takeover attempt;
- limit who may call a special meeting of stockholders;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings;

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- prohibit our stockholders from making certain changes to our amended and restated certificate of incorporation or amended and restated bylaws except with 66 ²/₃ percent stockholder approval; and
- provide for a board of directors with staggered terms.

We are also subject to provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15 percent or more of our common stock for three years unless the holder's acquisition of our stock was approved in advance by our board of directors. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders.

Adverse securities and credit market conditions may significantly affect our ability to raise capital.

Historically, turmoil and volatility in the financial markets have adversely affected the market capitalizations of many biotechnology companies, and generally made equity and debt financing more difficult to obtain. These events, coupled with other factors, may limit our access to financing in the future. This could have a material adverse effect on our ability to access funding on acceptable terms, or at all, and our stock price may suffer further as a result.

We do not intend to pay dividends on our common stock in the foreseeable future; as such, you must rely on stock appreciation for any return on your investment.

To date, we have not paid any cash dividends on our common stock, and we do not intend to pay any dividends in the foreseeable future. Instead, we intend to retain any future earnings to fund the development and growth of our business. For this reason, the success of an investment in our common stock, if any, will depend on the appreciation of our common stock, which may not occur. There is no guarantee that our common stock will appreciate, and therefore, a holder of our common stock may not realize a return on his or her investment.

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ITEM 6. EXHIBITS

<u>Exhibit Number</u>	<u>Description</u>
3.1	Amended and Restated Certificate of Incorporation, as amended (incorporated by reference to Exhibit 3.1 to Registrant's Quarterly Report on Form 10-Q, filed August 6, 2015).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed September 12, 2013).
4.1	Form of common stock certificate of the Registrant (incorporated by reference to Exhibit 4.1 to Registration Statement No. 333-52492).
4.2	Form of Warrant to Purchase Common Stock issued to purchasers in a private placement on January 12, 2011 (incorporated by reference to Exhibit 4.5 to Registration Statement No 333-171722).
4.3	Form of Warrant to Purchase Common Stock issued to purchasers in a private placement on December 17, 2012 (incorporated by reference to Exhibit 4.4 to Registration Statement No. 333-185639).
10.1a	Master Manufacturing Services Agreement and Product Agreement, dated August 3, 2015, by and between the Registrant and Patheon Pharmaceuticals Inc.
10.2a	Co-Operation Agreement and Product Schedule, dated August 17, 2015, by and between ACADIA Pharmaceuticals GmbH and BASF Pharma (Evionnaz) SA (now Siegfried Evionnaz SA).
10.3b	Executive Employment Agreement, dated September 1, 2015, by and between the Registrant and Stephen R. Davis (incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K, filed on September 3, 2015).
31.1	Certification of Stephen R. Davis, Chief Executive Officer, pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Stephen R. Davis, Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial statements from the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed on November 5, 2015, formatted in XBRL (Extensible Business Reporting Language), are filed herewith: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Comprehensive Loss, (iv) Consolidated Statements of Cash Flows, and (v) Notes to Condensed Consolidated Financial Statements.

a We have requested confidential treatment of certain portions of this agreement, which have been omitted and filed separately with the SEC pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

b Indicates management contract or compensatory plan or arrangement.

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.

Date: November 5, 2015

ACADIA Pharmaceuticals Inc.

By: /s/ Stephen R. Davis
Stephen R. Davis
Chief Executive Officer
(on behalf of the registrant and as the registrant's Principal Executive,
Financial and Accounting Officer)

*****Text Omitted and Filed Separately
with the Securities and Exchange Commission.
Confidential Treatment Requested
Under 17 C.F.R. Sections 200.80(b)(4)
and 240.24b-2.**

Master Manufacturing Services Agreement

Master Manufacturing Services Agreement

August 3, 2015

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MASTER MANUFACTURING SERVICES AGREEMENT

THIS MASTER MANUFACTURING SERVICES AGREEMENT (the “Agreement”) is made as of August 3, 2015 (the “Effective Date”)

B E T W E E N:

PATHEON PHARMACEUTICALS INC.,
a corporation existing under the laws of the State of Delaware

(“Patheon”),

- and -

ACADIA PHARMACEUTICALS INC.,
a corporation existing under the laws of the State of Delaware

(“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

STRUCTURE OF AGREEMENT AND INTERPRETATION

1.1 Master Agreement.

This Agreement establishes the general terms and conditions under which Patheon or any Affiliate of Patheon may perform Manufacturing Services for Client or any Affiliate of Client, at the manufacturing site where the Affiliate of Patheon resides. This “master” form of agreement is intended to allow the Parties, or any of their Affiliates, to contract for the manufacture of multiple Products through Patheon’s global network of manufacturing sites through the issuance of site specific Product Agreements without having to re-negotiate the basic terms and conditions contained herein.

1.2 Product Agreements.

This Agreement is structured so that a Product Agreement may be entered into by the Parties for the manufacture of a particular Product or multiple Products at a Patheon manufacturing site. Each Product Agreement will be governed by the terms and conditions of this Agreement unless the Parties to the Product Agreement expressly modify the terms and conditions of this Agreement in the Product Agreement. Unless otherwise agreed by the Parties, each Product Agreement will be in the general form and contain the information set forth in Appendix 1 hereto.

1.3 Definitions.

The following terms will have the respective meanings set out below and grammatical variations of these terms will have corresponding meanings:

“**Active Materials**”, “**Active Pharmaceutical Ingredients**” or “**API**” means the materials listed in a Product Agreement on Schedule D;

“**Active Materials Credit Value**” means the value of the Active Materials for certain purposes of this Agreement, as set forth in a Product Agreement 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; or
- (b) a business entity which is controlled by a Party to this Agreement, either directly or indirectly, by stock ownership or otherwise; or
- (c) a business entity, the controlling interest of which is directly or indirectly common to the controlling interest of a Party to this Agreement;

For this definition, “control” means the ownership of shares carrying at least a majority of the votes for the election of the directors of a corporation or other business entity (with corresponding meanings for “controlling interest” and “controlled by”);

“**Annual Minimum**” will have the meaning specified in Section 2.1;

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

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

“**Annual Volume**” means the minimum volume of Product to be manufactured in any Year of this Agreement as set forth in a Product Agreement on Schedule B;

“**Applicable Laws**” means the applicable provisions of any and all national, supranational, regional, state, provincial, county and local laws, statutes, treaties, ordinances, regulations, rules, administrative codes, guidance, ordinances, by-laws, judgments, decrees, directives, injunctions, permits (including marketing approvals) or orders of or from any Authority having jurisdiction over or related to the subject item;

“**Authority**” means any governmental or regulatory authority, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether national, supranational, regional, state, provincial, county or local;

“**Batch**” means a specific quantity of Product or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of Manufacturing Services;

“**Bill Back Items**” means the reasonable documented actual expenses in accordance with Section 2.1(g) 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 Product-specific items, in each case, as necessary for Patheon to perform the Manufacturing Services, and which are not included as Components;

“**Breach Notice**” will have the meaning specified in Section 8.2(a);

“**Business Day**” means a day other than a Saturday, Sunday or a day that is a statutory holiday in the jurisdiction where the Manufacturing Site is located or in the State of California;

“**Capital Equipment Agreement**” means a separate agreement that the Parties may enter into that will address responsibility for the purchase of capital equipment and facility modifications that may be required to perform the Manufacturing Services under a particular Product Agreement;

“**cGMPs**” means, as applicable, current good manufacturing practices 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;
- (c) EC Directive 2003/94/EC; and
- (d) ICH guidelines;

together with the latest Health Canada, FDA, and EMA and any other jurisdiction agreed to by the Parties guidance documents pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time, and any foreign equivalents to any such regulations which may apply to the Manufacturing Site or be applicable to Products sold outside of the United States, Canada or the European Union;

“**Certificate of Analysis**” means, with respect to a Batch, that document setting for the measured and observable characteristics of Product from the Batch, as required by the Specifications, as dated, executed and provided to Client by Patheon prior to delivery of the Product;

“**Certificate of Compliance**” means a statement signed by Patheon that certifies that all Manufacturing Services of a Batch of Product was performed or otherwise implemented, packaged, stored and tested in accordance with cGMP and all other regulatory requirements;

“**Claims**” has the meaning specified in Section 10.3;

“**Client Indemnitees**” has the meaning specified in Section 10.3;

“**Client Intellectual Property**” means Intellectual Property generated or derived by Client or any of its Affiliates before entering into this Agreement or independent of this Agreement, or by Patheon or any of its Affiliates while performing any Manufacturing Services or otherwise

generated or derived by Patheon or any of its Affiliates in its business, which Intellectual Property is directly related to, specific to, or dependent upon, Client's Active Materials or Product;

“**Client Property**” will have the meaning specified in Section 8.4(e);

“**Client-Supplied Components**” means those Components to be supplied by Client or that have been supplied by Client;

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

“**Components**” means, collectively, all packaging components, raw materials, ingredients, and other materials (including labels, product inserts and other labelling for the Products) required to manufacture the Products in accordance with the Specifications, other than the Active Materials;

“**Confidential Information**” has the meaning specified in Section 11.1;

“**DDP**” has the meaning as set forth in the 2010 edition of the International Commercial terms published by the International Chamber of Commerce, as may be amended or modified from time to time (**Incoterms 2010**);

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

“**Deficiency Notice**” has the meaning specified in Section 6.1(a);

“**Delivery Date**” means the date scheduled for shipment of Product under a Firm Order as set forth in Section 5.1(d);

“**Delivery Documentation**” has the meaning specified in Section 2.1(b);

“**Disclosing Party**” has the meaning specified in Section 11.1;

“**Deviation**” means a departure from an established quality standard, including, but not limited to, that set forth in any Product Agreement, any Quality Agreement, cGMP standard operating procedure, manufacturing work order, packaging order, raw material or product specification, analytical control procedure, water monitoring procedure, equipment maintenance schedule, or any unusual occurrence that could affect the Product. Deviations may be either anticipated or unanticipated departures from established quality standards and may have the potential to affect the safety, identity, strength, quality or purity of a Product;

“**EMA**” means the European Medicines Agency or any successor agency thereto which may regulate pharmaceutical products;

“**EXW**” has the meaning as set forth in Incoterms 2010;

“**FDA**” means the United States Food and Drug Administration or any successor agency thereto which may regulate pharmaceutical products;

“**Firm Order**” has the meaning specified in Section 5.1(c);

“**First Firm Order**” has the meaning specified in Section 5.1(b);

“For Cause Audit” means an audit of manufacturing records of Patheon or its subcontractors and supplies by Client following: (a) an unfavorable observation during regulatory inspections that is material to the quality of Product; or (b) a major or repeated quality excursion that may result in a failed manufacture Batch or Non-Conforming Product;

“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 or any successor agency thereto which may regulate pharmaceutical products;

“Initial Manufacturing Month” has the meaning specified in Section 5.1(b);

“Initial Manufacturing Period” has the meaning specified in Section 5.1(b);

“Initial Product Term” has the meaning specified in Section 8.1;

“Initial Set Exchange Rate” means as of the Effective Date of a Product Agreement, the initial exchange rate set forth in the Product Agreement to convert one unit of the Patheon Manufacturing Site local currency into one unit of the billing currency, calculated as the daily average interbank exchange rate for conversion of one unit of the Patheon Manufacturing Site local currency into one unit of the billing currency during the 90 day period immediately preceding the Effective Date as published by OANDA.com “The Currency Site” under the heading “FxHistory: historical currency exchange rates” at www.OANDA.com/convert/fxhistory;

“Initial Term” has the meaning specified in Section 8.1;

“Intellectual Property” means any and all rights in patents, patent applications, formulae, trademarks, trademark applications, trade-names, Inventions, copyrights, industrial designs, trade secrets, and know how;

“Invention” means any and all information, results, data, innovation, improvement, development, discovery, computer program, device, trade secret, 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;

“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;

“Late Delivery” will have the meaning specified in Section 5.5(b);

“Latent Defect” means a defect in any Batch of Product, the API or Materials that was not, and could not reasonably be expected to have been, found by exercise of ordinary care, following the approved specifications or in inspection at Delivery;

“Late Product” means Product ordered under a Firm Order that is not delivered on the Delivery Date;

“Losses” has the meaning specified in Section 10.3;

“**Manufacturing Services**” means the manufacturing, quality control, quality assurance, stability testing, packaging, labelling, storage and related services provided by Patheon to manufacture Product or Products using the Active Materials, Components, and Bill Back Items pursuant to this Agreement;

“**Manufacturing Site**” means the facility owned and operated by Patheon where the Manufacturing Services will be performed as identified in a Product Agreement;

“**Materials**” means all Components and Bill Back Items required to manufacture the Products in accordance with the Specifications, other than the Active Materials;

“**Maximum Credit Value**” means the maximum value of Active Materials that may be credited by Patheon under this Agreement, as set forth in a Product Agreement on Schedule D;

“**Minimum Order Quantity**” means the minimum number of Batches of a Product to be produced as set forth in a Product Agreement on Schedule B;

“**Non-Conforming Products**” will have the meaning specified in Section 6.1(a);

“**Out of Specification**” or “**OOS**” means a confirmed result that falls outside the Specifications.

“**Party**” or “**Parties**” means, as the context requires individually or collectively, Patheon and Client;

“**Patheon Competitor**” means a business that derives greater than 50% of its revenues from performing contract pharmaceutical development or commercial manufacturing services for Third Parties;

“**Patheon Indemnities**” has the meaning specified in Section 10.4;

“**Patheon Intellectual Property**” means Intellectual Property generated or derived by Patheon before performing any Manufacturing Services, or developed by Patheon while performing the Manufacturing Services or otherwise generated or derived by Patheon in its business which Intellectual Property is not Client Intellectual Property;

“**Price**” means the price measured in US Dollars to be charged by Patheon for performing the Manufacturing Services, and includes the cost of Components (other than Client-Supplied Components), certain cost items as set forth in a Product Agreement on Schedule B, and annual stability testing costs as set forth in a Product Agreement on Schedule C;

“**Product(s)**” means the product(s) listed in a Product Agreement on Schedule A;

“**Product Agreement**” means the agreement between Patheon and Client issued under this Agreement in the form set forth in Appendix 1 (including Schedules A to D) under which Patheon will perform Manufacturing Services at a particular Manufacturing Site as updated, amended and revised from time to time by the Parties in accordance with the terms of this Agreement;

“**Product Warranties**” will have the meaning specified in Section 9.3(a);

“**Quality Agreement**” means the agreement between the Parties entering into a Product Agreement that sets out the quality assurance standards and responsibilities for the

Manufacturing Services to be performed by Patheon for Client, as such agreement may be amended from time to time in accordance with its terms; the Parties anticipate that the Quality Agreement will be executed within 30 days after the Effective Date of the Product Agreement;

“**Quantity Converted**” as the meaning specified in Section 2.2(a);

“**Quantity Dispensed**” has the meaning specified in Section 2.2(a);

“**Quantity Received**” has the meaning specified in Section 2.2(a);

“**Quarter**” means each successive period of three calendar months commencing on January 1, April 1, July 1 and October 1;

“**Recall**” means any action (i) by Client or its Affiliates or licensees to recover title to or possession, or stop distribution, prescription or consumption, 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 will also include any action by Client or its Affiliates or licensees to refrain from selling or shipping quantities of the Products to Third Parties that would have been subject to a Recall if sold or shipped.

“**Recipient**” has the meaning specified in Section 11.1;

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

“**RFID**” means Radio Frequency Identification Devices which (at present or in the future) may be affixed to Products or Materials to assist in inventory control, tracking, and identification;

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

“**Set Exchange Rate**” means the exchange rate to convert one unit of the Patheon Manufacturing Site local currency into one unit of the billing currency for each Year, calculated as the average daily interbank exchange rate for conversion of the Patheon Manufacturing Site local currency into one unit of the billing currency during the full year period (October 1st [preceding year] to September 30th) as published by OANDA.com “The Currency Site” under the heading “FxHistory: historical currency exchange rates” at www.OANDA.com/convert/fxhistory;

“**Shortfall**” has the meaning specified in Section 2.2(b);

“**Significant Quality Event**” means any event occurring during the Manufacturing of the Product resulting in a Deviation that materially impacts the quality, performance, safety or reliability of the Product or intermediates thereof. A confirmed Out of Specification result is a Significant Quality Event;

“**Specifications**” means the requirements, for each Material, Component, Active Material or Product, which is given by Client to Patheon in accordance with the procedures listed in a Product Agreement on Schedule A and which contains documents or requirements relating to each 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 for each Product including material safety data sheets;
 - (e) the in-process specifications; and
 - (f) the finished Product specifications, packaging specifications and shipping requirements for each Product;
- all as updated, amended and revised from time to time by 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;

“**Technology Transfer**” means the transfer to Client or any Third Party designated by Client by Patheon of all information relating to the process of manufacturing Product, all documents, manufacturing instructions, specifications, and any other relevant documentation, all relevant manufacturing know-how, licenses and materials (including raw materials specifications) related to Product that Patheon or its Affiliates, as applicable, controls or has the right to license at any time during the Term and that is necessary to enable Client or its designee to manufacture Product in accordance with the Specifications, and to comply with applicable regulatory requirements (including obtaining any necessary regulatory approvals, conducting any required studies and developing any other regulatory documentation) and all Applicable Laws in connection with the transfer;

“**Territory**” means any geographic area described in a Product Agreement where Products manufactured by Patheon will be distributed by Client;

“**Third Party**” means any party other than Client, Patheon or their respective Affiliates;

“**Third Party Rights**” means any Intellectual Property of any party other than Client or Patheon or their respective Affiliates;

“**United States**” means the United States of America including its territories and possessions; and

“**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 will mean a calendar year.

1.4 Currency.

Unless otherwise agreed in a Product Agreement, all monetary amounts expressed in this Agreement are in United States Dollars (USD).

1.5 Sections and Headings.

The division of this Agreement into Articles, Sections, Subsections, an Appendix, Schedules and Exhibits and the insertion of headings are for convenience of reference only and will not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to a Section, Appendix, Schedule or Exhibit refers to the specified Section, Appendix, Schedule or Exhibit to this Agreement. In this Agreement, the terms “**this Agreement**”, “**hereof**”, “**herein**”, “**hereunder**” and similar expressions refer to this Agreement as a whole and not to any particular part, Section, Appendix, Schedule or Exhibit of this Agreement.

1.6 Singular Terms.

Except as otherwise expressly stated or unless the context otherwise requires, all references to the singular will include the plural and vice versa, and all references to “includes” or “including” will mean “includes without limitation” or “including without limitation.”

1.7 Appendix 1, Schedules and Exhibits.

Appendix 1 (including Schedules thereto) and the following Exhibits are attached to, incorporated in, and form part of this Agreement:

- Appendix 1 - Form of Product Agreement (Including Schedules A to D)
- Exhibit A - Technical Dispute Resolution
- Exhibit B - Monthly Active Materials Inventory Report
- Exhibit C - Report of Annual Active Materials Inventory Reconciliation and Calculation of Actual Annual Yield
- Exhibit D - Example of Price Adjustment Due to Currency Fluctuation

ARTICLE 2**PATHEON'S MANUFACTURING SERVICES****2.1 Manufacturing Services.**

Patheon will perform the Manufacturing Services for the Territory for the fees specified in a Product Agreement in Schedules B and C. Schedule B to a Product Agreement sets forth a list of cost items that are included or not included in the unit Price for Products; all cost items that are not included in the Price are subject to additional fees to be paid by the Client as agreed by the Parties. Patheon may amend the fees set out in Schedules B and C to a Product Agreement as set forth and in accordance with Article 4. Patheon will perform the Manufacturing Services in strict compliance with the established Specifications, cGMP and Applicable Laws. Patheon may not change the Specifications or the Manufacturing Site (including facility modifications) or any other aspect of the manufacturing process used to perform the Manufacturing Services with respect to the Products except with the prior written consent of Client, this consent not to be unreasonably withheld. Unless otherwise agreed in a Product

Agreement or in this Agreement, and for so long as Patheon remains in material compliance with its obligations under this Agreement and the applicable Product Agreement, Patheon will manufacture at least [...***...] % (“**Annual Minimum**”) of Products manufactured by or on Client’s behalf for sale by Client in the Territory in a particular Year. If Patheon does not remain in material compliance, the Annual Minimum will no longer apply in addition to any other remedies the Client may have under this Agreement. In performing the Manufacturing Services, Patheon and Client agree that:

(a) Use of Active Materials and Components. Patheon will use the Active Materials and Components to manufacture Products in accordance with this Agreement. Patheon will not use the Active Materials, any Client-Supplied Components or any other Components paid for by Client for any other use or purpose. Patheon will use all Active Materials and Components on a first-to-expire, first-to-use basis in manufacturing Products under this Agreement.

(b) Quality Control and Quality Assurance. Patheon will perform the quality control and quality assurance testing specified in the Quality Agreement. Batch review and release to Client will be the responsibility of Patheon’s quality assurance group, consistent with the Quality Agreement. Patheon will perform its Batch review and release responsibilities in accordance with Patheon’s standard operating procedures copies of which have been made available to Client and will not change in a material way related to Product without Client consent (not to be unreasonably withheld), and the Quality Agreement. Each time Patheon ships Products to Client or Client’s designee, it will give Client a Certificate of Analysis and Certificate of Compliance, and a list of all Deviations (“**Delivery Documentation**”). Client will have sole responsibility for the release of Products to the market. The Batch documents, including, but not limited to, Batch production records, lot packaging/labeling records, equipment set up control, operating parameters, investigation/non-conformances, and data printouts, raw material data, and laboratory notebooks will be the exclusive property of Client. But any intellectual property comprised of the form and style of those Batch documents are the exclusive property of Patheon and Patheon will not be obligated to disclose to Client confidential or proprietary information of Third Parties contained in any lab notebooks that is unrelated to the Manufacturing Services. Subject to the foregoing, Patheon will provide any information reasonably required by Client to perform, if required, a Technology Transfer or if requested by a Regulatory Authority in a redacted form at Client’s expense. Except for Patheon Intellectual Property, all information contained in the Batch documents, including, but not limited to specific Product related information, is Client property.

(c) Components. Patheon will purchase (with the exception of Client-Supplied Components) and test all Components at Patheon’s expense and as required by the Product Agreement in accordance with the Specifications and the Quality Agreement.

(d) Stability Testing. Patheon will conduct stability testing on the Products as part of the Manufacturing Services provided hereunder. Patheon will perform this testing in accordance with the protocols set out in the Quality Agreement and the Specifications for the separate fees and during the time periods set out in Schedule C to a Product Agreement, if applicable. Patheon will not make any changes to these testing protocols without prior written approval from Client. If a confirmed stability test failure occurs, Patheon will notify Client within one Business Day, after which Patheon and Client will jointly determine the proceedings and methods to be undertaken to investigate the cause of the failure in accordance with the Quality Agreement, including which Party will bear the cost of the investigation. Patheon will not be liable for these costs unless it has failed to perform the Manufacturing Services in accordance with the Quality Agreement, Specifications, cGMPs or Applicable Laws. Patheon will give Client all stability test data and results (including a final report) at Client’s request within [...***...] Business Days, upon completion of the testing.

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(e) **Packaging.** Patheon will package the Products as set out in the Specifications and the applicable master packaging records approved by Client. Client will be responsible for the cost of artwork development, as applicable. Patheon will determine and imprint the Batch numbers and expiration dates for each Product shipped. The expiration dates must be determined in accordance with the Specifications. The Batch numbers and expiration dates will be affixed on the Products and on the shipping carton of each Product as outlined in the Specifications and as required by the Quality Agreement, cGMPs and Applicable Laws. Client may, in its sole discretion, make changes to labels, product inserts, and other packaging for the Products. Those changes will be submitted by Client to all applicable Regulatory Authorities. Client will be responsible for the cost of labelling obsolescence when changes occur, as contemplated in Section 4.4. Patheon's name will not appear on the label or anywhere else on the Products unless: (i) required by any Applicable Laws; or (ii) Patheon consents in writing to the use of its name.

(f) **Active Materials and Client-Supplied Components.** At least [...***...] before the scheduled production date, Client will deliver the Active Materials and any Client-Supplied Components to the Manufacturing Site DDP, in sufficient quantity to enable Patheon to manufacture the desired quantities of Product and to ship Product on the Delivery Date. Upon receipt of the Active Materials, Patheon will test all Active Materials in accordance with the provisions of the Product Agreement and in accordance with the applicable Quality Agreement. If the Active Materials and/or Client-Supplied Components are not received [...***...] before the scheduled production date, Patheon may delay the shipment of Product by the same number of days as the delay in receipt of the Active Materials and/or Client-Supplied Components. But if Patheon is unable to manufacture Product to meet this new shipment date due to prior Third Party production commitments, Patheon may delay the shipment until a later date as agreed to by the Parties, but Patheon will make commercially reasonable efforts to make the shipment as soon as possible. All shipments of Active Material will be accompanied by Certificate(s) of Analysis provided by Client, confirming the identity and purity of the Active Materials and its compliance with the Active Material Specifications set forth in the Product Agreement.

(g) **Bill Back Items.** Bill Back Items purchased by Patheon will be charged to Client at Patheon's actual and reasonable cost plus a [...***...] handling fee for Bill Back Items that cost less than \$5,000 and a [...***...] handling fee for Bill Back Items that cost \$5,000 or more, but Client must give prior written approval for the purchase of all Bill Back items. Patheon will use commercially reasonable efforts to order Bill Back Items in amounts to minimize the handling fee.

(h) **Handling and Storage.** Patheon will store at no cost to Client inventory to support [...***...] months of production per the forecast of the Active Material and Client-Supplied Components in a controlled and monitored environment and at appropriate conditions in accordance with Specifications, the Quality Agreement, and Applicable Laws.

2.2 **Active Material Yield.**

(a) **Reporting.** Patheon will give Client a monthly inventory report of the Active Materials held by Patheon within five Business Days of the end of the most recent monthly using the inventory report form set out in Exhibit B, which will contain the following information for the month:

Quantity Received: The total quantity of Active Materials that complies with the Specifications and is received at the Manufacturing Site during the applicable month ("**Quantity Received**").

Quantity Dispensed: The total quantity of Active Materials dispensed at the Manufacturing Site during the applicable month ("**Quantity Dispensed**"). The Quantity

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Dispensed is calculated by adding the Quantity Received to the inventory of Active Materials that complies with the Specifications and is held by Patheon at the beginning of the applicable month, less the inventory of Active Materials that complies with the Specifications and is held by Patheon at the end of the month. The Quantity Dispensed will only include Active Materials received and dispensed in commercial manufacturing of Products and will not include any (i) Active Materials that must be retained by Patheon as samples, (ii) Active Materials contained in Product that must be retained as samples, (iii) Active Materials used in testing (if applicable), and (iv) Active Materials received or dispensed in 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, in each case of clauses (i) through (iv) in accordance with this Agreement.

Quantity Converted: The total amount of Active Materials contained in the Product manufactured with the Quantity Dispensed (including any additional Product produced in accordance with Section 6.3(a) or 6.3(b)), delivered by Patheon, and not rejected, recalled or returned in accordance with Section 6.1 or 6.2 because of Patheon's failure to perform the Manufacturing Services in accordance with Specifications, cGMPs, and Applicable Laws.

Client acknowledges that, if there is no change in this information from one month to the next month, the report will reflect that.

Within [...***...] days after the end of each Year, Patheon will prepare an annual reconciliation of Active Materials on the reconciliation report form set forth in Exhibit C including the calculation of the "**Actual Annual Yield**" or "**AA Y**" for the Product at each Manufacturing Site during the Year. AAY is the percentage of the Quantity Dispensed that was converted to Product and is calculated as follows:

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

After Patheon has produced a minimum of [...***...] successful commercial production Batches of Product and has produced commercial production Batches for at least [...***...] months at the Manufacturing Site (collectively, the "**Target Yield Determination Batches**"), the Parties will agree on the target yield for the Product at the Manufacturing Site (each, a "**Target Yield**"). The Target Yield will be revised annually to reflect the actual manufacturing experience as agreed to by the Parties.

Additionally, promptly following production of the validation Batches, but prior to production of the [...***...] Target Yield Determination Batches described above, the Parties will agree to an interim Target Yield that will apply before determination of the Target Yield set out above, based on data from production of the validation Batches. Promptly following production of the first [...***...] Target Yield Determination Batches described above, the Parties will agree to an updated interim Target Yield that will apply before determination of the Target Yield set out above, based on data from production of the first [...***...] Target Yield Determination Batches.

(b) Shortfall Calculation. If the Actual Annual Yield falls more than [...***...]% below the respective Target Yield in a Year, then the shortfall for the Year (the "**Shortfall**") will be calculated as follows:

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Shortfall = [(Target Yield – [...***...])% – AAY] * Active Materials Credit Value * Quantity Dispensed

(c) Credit for Shortfall. If there is a Shortfall for a Product in a Year, then Patheon will credit Client's account for the amount of the Shortfall not later than [...***...] days after the end of the Year.

Each credit under this Section 2.2(c) will be summarized on the reconciliation report form set forth in Exhibit C. Upon expiration or termination of a Product Agreement, any remaining credit owing under this Section 2.2 will be paid to Client within [...***...] days of the expiration or termination of the Product Agreement. The Annual Shortfall, if any, will be disclosed by Patheon on the reconciliation report form.

(d) Maximum Credit. Patheon's liability for Active Materials calculated in accordance with this Section 2.2 for any Product Agreement in a Year will not exceed, in the aggregate, the Maximum Credit Value set forth in Schedule D to the Product Agreement.

(e) No Material Breach. It will not be a material breach of this Agreement by Patheon under Section 8.2(a) if the Actual Annual Yield is less than the Target Yield unless the Actual Annual Yield is more than [...***...]% below the Target Yield.

ARTICLE 3

CLIENT'S OBLIGATIONS

3.1 Payment.

Client will pay Patheon for performing the Manufacturing Services in accordance with this Agreement according to the Prices specified in Schedules B and C in a Product Agreement. These Prices may be subject to adjustment under Sections 4.2 and 4.3 of this Agreement. Client will also pay Patheon for any Bill Back Items as provided in Section 2.1(g).

3.2 Active Materials and Qualification of Additional Sources of Supply.

Client will at its sole cost and expense, deliver the Active Materials to Patheon (in accordance with Section 2.1(f)). If applicable, Patheon and the Client will reasonably cooperate to permit the import of the Active Materials to the Manufacturing Site. 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 will be held by Patheon on behalf of Client as set forth in this Agreement. The Active Materials will at all times remain the property of Client. Patheon will ensure that the Active Materials will not become subject to any encumbrances, liens or other third-party claims while in Patheon's possession. Any Active Materials received by Patheon will only be used by Patheon to perform the Manufacturing Services.

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:

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- (a) laboratory testing to confirm the Active Material meets existing specifications;
- (b) manufacture of an experimental Batch of Product that will be placed on three months accelerated stability; and
- (c) manufacture of three full-scale validation Batches that will be placed on concurrent stability (one Batch may be the registration Batch if manufactured at full scale).

Section 6.3(c) 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 First Year Pricing.

The tiered Price and annual stability Price for the Products through December 31, 2015 are listed in Schedules B and C in a Product Agreement and are subject to the adjustments set forth in Sections 4.2 and 4.3.

4.2 Price Adjustments – Subsequent Years’ Pricing.

Beginning January 1, 2016, Patheon may adjust the Price effective January 1st of each Year as follows:

(a) Manufacturing and Stability Testing Costs. For Products manufactured in the United States or Puerto Rico, Patheon may adjust the conversion component of Price for inflation, based upon the preliminary number for any increase or decrease in the Producer Price Index pcu325412325412 for Pharmaceutical Preparation Manufacturing published by the United States Department of Labor, Bureau of Labor Statistics (“**PPI**”) in August of the preceding Year compared to the final number for the same month of the Year prior to that, unless the Parties otherwise agree in writing. On or before November 30th of each Year, Patheon will give Client a statement setting forth the calculation for the inflation adjustment to be applied in calculating the Price for the next Year. But Client will have the right to dispute the calculation in good faith and the existing Prices will continue to apply until the dispute is resolved. If necessary, the Price will be retroactively adjusted for the applicable period after the dispute is resolved. For Products manufactured outside the United States or Puerto Rico, Patheon may similarly adjust the Price for inflation using an equivalent inflation index to be agreed by the Parties in a Product Agreement.

(b) Component Costs. Patheon may increase or, if the average price of the Component costs decreases, Patheon will decrease the Price for the next Year to pass through the actual additional or reduced Component costs. In November of each Year, Patheon will give Client reasonably detailed information about the increase or decrease in Component costs which will be applied to the calculation of the Price for the next Year to reasonably demonstrate that the Price increase or decrease is justified. But Patheon will not be required to give information to Client that is subject to obligations of confidentiality between Patheon and its suppliers. But, at Client’s request, Patheon will allow an independent third party auditor to review the information supporting the increase or decrease in Component costs and confirm that the information reasonably demonstrates that the Price increase or decrease is justified and reasonable.

(c) Pricing Basis. Client acknowledges that the Price in any Year is quoted based upon the Minimum Order Quantity and the Annual Volume specified in Schedule B to a Product Agreement. The Price is subject to change if the specified Minimum Order Quantity changes or if the Annual Volume is not ordered in a Year. For greater clarity, if Patheon and Client agree that the Minimum Order Quantity will be reduced or the Annual Volume in the lowest tier will not be ordered in a Year whether as a result of a decrease in estimated Annual Volume or otherwise and, as a result of the reduction, Patheon demonstrates to Client's reasonable satisfaction that its costs to perform the Manufacturing Services or to acquire the Components for the Product will increase or decrease on a per unit basis (including the amount of the increase), then Patheon may increase or decrease the Price by an amount sufficient to absorb the documented increased or reduced costs. On or before November 1st of each Year, Patheon will give Client a statement setting forth the information to be applied in calculating those cost increases or decreases for the next Year. But Patheon will not be required to give information to Client that is subject to obligations of confidentiality between Patheon and its suppliers. But, at Client's request, Patheon will allow an independent third party auditor to review the information supporting the increase in Component costs and confirm that the information reasonably demonstrates that the Price increase is justified.

(d) Adjustments Due to Currency Fluctuations. If the Parties agree in a Product Agreement to invoice in a currency other than the local currency for the Manufacturing Site, Patheon will adjust the Price to reflect currency fluctuations in accordance with this Section 4.2(d). If the Set Exchange Rate for a given Year has changed, the adjustment will be calculated after all other annual Price adjustments under this Section 4.2 have been made. The adjustment will proportionately reflect the increase or decrease, if any, in the Set Exchange Rate compared to the Set Exchange Rate established for the prior Year or the Initial Set Exchange Rate, as the case may be. An example of the calculation of the price adjustment (for a Canadian Manufacturing Site invoiced in USD) is set forth in Exhibit D.

(e) Tier Pricing (if applicable). The pricing in Schedule B of a Product Agreement is set forth in Annual Volume tiers based upon the Client's volume forecasts under Section 5.1. The Client will be invoiced during the Year for the unit price set forth in the Annual Volume tier based on the [...] month forecast provided in September of the previous Year. Within 30 days of the end of each Year or of the termination of the Agreement, Patheon will send Client a reconciliation of the actual volume of Product ordered by the Client during the Year with the pricing tiers. If Client has overpaid during the Year, Patheon will issue a credit to the Client for the amount of the overpayment within 45 days of the end of the Year or will issue payment to the Client for the overpayment within 45 days of the termination of the Agreement. If Client has underpaid during the Year, Patheon will issue an invoice to the Client under Section 5.6 for the amount of the underpayment within 45 days of the end of the Year or termination of the Agreement. If Client disagrees with the reconciliation, the Parties will work in good faith to resolve the disagreement amicably. If the Parties are unable to resolve the disagreement within 30 days, the matter will be handled under Section 12.1.

For all Price adjustments under this Section 4.2, Patheon will deliver to Client on or before November 30th of each Year a revised Schedule B to the Product Agreement to be effective for Product delivered on or after the first day of the next Year, which revised Schedule B must be approved in writing by Client before it becomes binding on the Parties. Client's approval must not be unreasonably withheld.

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4.3 Price Adjustments – Current Year Pricing.

During any Year, the Prices set out in Schedule B of a Product Agreement will be adjusted as follows:

Extraordinary Increases or Decreases in Component Costs. If, at any time, market conditions result in Patheon's cost of Components being materially greater or less than the cost on which the current Price is based, then the Parties will adjust the Price for any affected Product that reflects the increased or decreased Component costs. Changes materially greater than normal forecasted increases or decreases will have occurred if: (i) the cost of a Component increases or decreases by [...***...] % of the cost for that Component upon which the most recent fee quote was based; or (ii) the aggregate cost for all Components required to manufacture a Product increases or decreases by [...***...] % of the total Component costs for the Product upon which the most recent fee quote was based. If Component costs have been previously adjusted to reflect an increase or decrease in the cost of one or more Components, the adjustments set out in (i) and (ii) above will operate based on the last cost adjustment for the Components.

For a Price adjustment under this Section 4.3, Patheon will deliver to Client a revised Schedule B to the Product Agreement and budgetary pricing information, adjusted Component costs or other documents reasonably sufficient to demonstrate that a Price adjustment is justified, to Client's reasonable satisfaction. Client will have the right to dispute any Price adjustment in good faith, and for the duration of the dispute, the existing Prices will continue to apply. If necessary, the Price will be retroactively adjusted for the applicable period after the dispute is resolved. At Client's request, Patheon will allow an independent Third Party auditor to review the information supporting the increase or decrease in Component costs and confirm that the information reasonably demonstrates that the Price increase or decrease is justified and reasonable. Patheon will have no obligation to deliver any supporting documents that are subject to obligations of confidentiality between Patheon and its suppliers. For an undisputed Price adjustment, the revised Price will be effective for any Product delivered on or after the first day of the month following Client's receipt of the revised Schedule B to the Product Agreement. If the Price is revised pursuant to this Section 4.3, it will not be revised subsequently pursuant to Section 4.2(b) with respect to the same increased Component costs.

4.4 Adjustments Due to Technical Changes.

Amendments to the Specifications or the Quality Agreement requested by Client will only be implemented following a technical and cost review that Patheon will perform at Client's cost, and are subject to Client and Patheon reaching agreement on any Price changes required because of the amendment. Amendments to the Specifications, the Quality Agreement, or the Manufacturing Site requested by Patheon will only be implemented following the written approval of Client. Upon receiving notice of a request by Client for any such amendments, Patheon will promptly advise Client in writing of any scheduling adjustments, any cost increases or decreases or other changes that may result from the change, and (a) will use its best efforts to make any change identified in the Client request that is in response to a regulatory or safety issue pertaining to the Product, and (b) will use commercially reasonable efforts to implement any other change identified in a Client request by the date requested by Client, or as soon thereafter as it is commercially reasonable. If Client accepts a proposed Price change, the proposed change in the Specifications will be implemented, and the Price change will become effective, only for those orders of Products that are manufactured under the revised Specifications. In addition, Client agrees to purchase, at Patheon's actual cost (including all reasonable costs incurred by Patheon for the purchase and handling of the Inventory), all Inventory used under the "old" Specifications and purchased or maintained by Patheon in order to fill Firm Orders or under Section 5.2, but only to the

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extent the Inventory can no longer be used under the revised Specifications. Open purchase orders for Components no longer required under any revised Specifications that were placed by Patheon with suppliers in order to fill Firm Orders or under Section 5.2 will be cancelled where possible, and if the orders may not be cancelled without penalty, will, at Client's sole discretion, be assigned to and satisfied by Client or cancelled by Patheon and Client will reimburse Patheon for any penalty it incurs due to the cancellation.

4.5 Multi-Country Packaging Requirements.

If Client decides to have Patheon perform Manufacturing Services for the Product for countries outside the Territory, then Client will inform Patheon of the packaging requirements for each such country and Patheon will prepare a quotation for consideration by Client of any additional costs for Components (other than Client-Supplied Components) and the change over fees for the Product destined for each such country. The agreed additional packaging requirements and related packaging costs and change over fees will be set out in a written amendment to this Agreement.

ARTICLE 5

ORDERS, SHIPMENT, INVOICING, PAYMENT

5.1 Orders and Forecasts.

(a) Rolling [...***...] Month Forecast. When each Product Agreement is executed, Client will give Patheon a non-binding [...***...] month forecast of the volume of Product that Client expects to order in the first [...***...] months of commercial manufacture of the Product. This forecast will then be updated by Client on or before the [...***...] day of each month on a rolling forward basis. Client will update the forecast forthwith if it determines that the volumes estimated in the most recent forecast have changed by more than [...***...]. The most recent [...***...] month forecast will prevail.

(b) Firm Orders for Initial Manufacturing Month. At least [...***...] months before the start of commercial manufacture of the Product, Client will update the rolling forecast for the first [...***...] months of manufacture of the Product (the "**Initial Manufacturing Period**"). Subject to the provisions of Section 5.1(c), the first month of this updated forecast ("**Initial Manufacturing Month**") will constitute a firm written order in the form of a purchase order or otherwise ("**First Firm Order**") by Client to purchase and, when accepted by Patheon, for Patheon to manufacture the quantity of the Product. If manufacturing has not started, Client may cancel any Batches from the First Firm Order at a cost of \$[...***...] per cancelled Batch per month until manufacturing starts, if notice of cancellation is received by Patheon [...***...] days or more before the scheduled Delivery Date under the First Firm Order. If manufacturing has not started, Client may cancel any Batches from the First Firm Order if notice of cancellation is received by Patheon more than [...***...] days but fewer than [...***...] days before the scheduled Delivery Date under the First Firm Order, but Client will pay Patheon \$[...***...] for each cancelled Batch. The Parties agree that this payment will be considered liquidated damages for Patheon's loss of manufacturing capacity due to the Client's cancellation of manufacturing and will not be considered a penalty. If the First Firm Order is changed or adjusted as described above, then the initial rolling [...***...] month forecast will also be adjusted as necessary.

(c) Firm Orders Thereafter. Before and during the Initial Manufacturing Period, and on a rolling basis during the term of the Product Agreement, Client will issue an updated [...***...] month forecast on

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or before the [...] day of each month. This forecast will start on the first day of the next month. The first [...] months of this updated forecast will be considered binding firm orders. But the initial order related to the launch of each Product will not be binding until the Client receives approval from the FDA to market the applicable Product. Concurrent with the delivery of the applicable forecast, Client will issue a firm written order for the first [...] months of the forecast in the form of a purchase order or otherwise (“**Firm Order**”) by Client to purchase and, when accepted by Patheon, for Patheon to manufacture and deliver the agreed quantity of the Products as set forth in the Firm Order. The Delivery Date specified in the Firm Order will not be less than [...] days following the date that the Firm Order is submitted. Firm Orders submitted to Patheon will specify Client’s purchase order number, quantities by Product type, monthly delivery schedule, and any other elements necessary to ensure the timely manufacture and shipment of the Products. Upon Patheon’s acceptance of a Firm Order, the quantities of Products ordered in the Firm Order will be firm and binding on the Parties and may only be reduced by written agreement of the Parties.

(d) [...] Year Forecast. On or before the [...] day of May of each Year, Client will give Patheon a written non-binding [...] -year forecast, broken down by Quarters [...], of the volume of each Product Client then anticipates will be required to be manufactured and delivered to Client during the [...] -year period.

(e) Acceptance of Firm Order. Patheon will accept Firm Orders by sending an acknowledgement to Client within [...] Business Days of its receipt of the Firm Order. The acknowledgement will include, subject to confirmation from the Client, the Delivery Date for the Product ordered. The Delivery Date may be amended by written agreement of the Parties or as set forth in Section 2.1(f) or 5.1(b). If Patheon fails to send an acknowledgement to Client within the applicable [...] Business Day period, then the Firm Order will be deemed to have been accepted by Patheon. Patheon will accept Firm Orders submitted in accordance with this Agreement. If Patheon rejects a Firm Order submitted in accordance with this Agreement, without limiting Client’s other rights and remedies hereunder, Client may obtain the Product from another supplier, and this Product will not be included for purposes of calculating the Annual Minimum under this Agreement, and the Annual Minimum will automatically be reduced by [...]. If Patheon rejects two or more Firm Orders in a [...] -month period, the Annual Minimum will no longer apply.

5.2 Reliance by Patheon

(a) Client understands and acknowledges that Patheon will rely on the Firm Orders and rolling forecasts submitted under Sections 5.1(a) and (b) in ordering the Components (other than Client-Supplied Components) required to meet the Firm Orders. In addition, Client understands that to ensure an orderly supply of the Components, Patheon may want to purchase the Components in reasonable volumes to meet the production requirements for Products during part or all 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 Client. Accordingly, Client authorizes Patheon to purchase Components in quantities reasonably needed to satisfy the Manufacturing Services requirements for Products for the first [...] months contemplated in the most recent forecast given by Client under Section 5.1(a). Patheon may make other purchases of Components to meet Manufacturing Services requirements for longer periods if agreed to in writing by the Parties. The Client will give Patheon written authorization to order Components for any launch quantities of Product requested by Client which will be considered a Firm Order when accepted by Patheon. If Components ordered by Patheon under Firm Orders or this Section 5.2(a) are not included in finished Products manufactured for Client within [...] months after the forecasted month for which the purchases have been made (or for a longer period as the Parties may agree) or if the Components have expired during the period, then Client will pay to Patheon its costs therefor (including all reasonable costs incurred by Patheon for the purchase and handling of the Components). But if these

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Components are used in Products subsequently manufactured for Client or in third party products manufactured by Patheon, Client will receive credit for any costs of those Components previously paid to Patheon by Client or, at Client's election, a refund in an amount equal to these costs. On a Quarterly basis, Patheon will provide a report summarizing the Inventory held by Patheon.

(b) If Client fails to take possession or arrange for the destruction of Components purchased by Patheon in accordance with Section 5.2(a) within 12 months of purchase or, in the case of finished Product that is not the subject of a Deficiency Notice, within three months of manufacture, Client will pay Patheon \$100.00 per pallet, per month thereafter for storing the Components or finished Product. Storage fees for Components or Product which contain controlled substances or require refrigeration will be charged at \$200.00 per pallet per month. Storage fees are subject to a one pallet minimum charge per month. Patheon may ship finished Product that is not the subject of a Deficiency Notice held by it longer than three months to the Client at Client's expense on 14 days' prior written notice to the Client in accordance with the Specifications.

5.3 Minimum Orders.

Client may only order Manufacturing Services for amounts of Products in multiples of the Minimum Order Quantities as set out in Schedule B to a Product Agreement.

5.4 Shipments.

Shipments of Products will be made EXW Patheon's shipping point unless otherwise agreed in a Product Agreement. Risk of loss or of damage to Products will remain with Patheon until Patheon loads the Products onto the carrier's vehicle for shipment at the shipping point at which time risk of loss or damage will transfer to Client. Patheon will, in accordance with Client's instructions and as agent for Client, at Client's risk, (i) arrange for shipping to be paid by Client and (ii) at Client's expense, obtain any export license or other official authorization necessary to export the Products. Client will arrange for insurance and will select the freight carrier used by Patheon to ship Products and may monitor Patheon's shipping and freight practices as they pertain to this Agreement. Products will be transported in accordance with the Specifications.

5.5 Late Delivery.

(a) Patheon will deliver Products ordered under a Firm Order on the applicable Delivery Date. The Parties agree that they will work together closely to expedite deliveries of Product, including, without limitation, any samples of Products and Products for initial launch, and manage the scheduling of the initial Product launch.

(b) If, after the Initial Manufacturing Period, Patheon is unable to deliver [...***...] % of the quantity of a particular Product ordered under a Firm Order within [...***...] days of the Delivery Date due to an act or omission by Patheon (a "**Late Delivery**"), Client will receive a credit from Patheon for the Late Delivery that will be applied against the purchase price under the next Firm Order. The credit will be [...***...] % of the Price of the quantities of Product not delivered by Patheon under the Firm Order (i.e., Client Credit = [Quantity Ordered in the Firm Order – Actual Delivery Quantities of Product] * Price [...***...] %). Patheon will make commercially reasonable efforts to replace the late Product within [...***...] days. If, after the Initial Manufacturing Period, Patheon makes two or more Late Deliveries for the same Product in the same calendar Quarter, Client will receive an additional credit of [...***...] % from Patheon for the Late Deliveries that will be applied against the purchase price under the next Firm Order. The total credit will be [...***...] % of the Price of the quantities of Product not delivered by Patheon under the Firm Order (i.e., Client Credit = [Quantity Ordered in the Firm Order – Actual Delivery Quantities of Product] Price [...***...] %). Without

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limiting Client's other rights or remedies in this Agreement, if Patheon makes two or more Late Deliveries within a [...***...]-month period, the Annual Minimum will be reduced to [...***...]. In such case, for the remainder of the term of this Agreement, the Parties agree that Patheon will manufacture at least [...***...] of the Products manufactured by or on Client's behalf for sale by Client in the Territory in a particular Year until Patheon has no Late Deliveries for a [...***...] month period in which case the Annual Minimum will increase by [...***...] and by [...***...] in each sequential [...***...] month period that there are no Late Deliveries up to a maximum of [...***...]. Notwithstanding the foregoing, if Patheon makes two or more Late Deliveries within a [...***...]-month period, the Parties will meet and agree on and implement a delivery improvement action plan within five Business Days. If, after the delivery improvement plan is in place, two additional Late Deliveries occur within a [...***...]-month period, these Late Deliveries may be considered a material breach of this Agreement by Patheon under Section 8.2(a) and Patheon will not be allowed any further opportunity to remedy the material breach.

(c) A Late Delivery will not include any delay in shipment of Product caused by events outside of Patheon's reasonable control, such as a Force Majeure Event, a delay in delivery of API or Materials, a delay in Product release approval from Client, inaccurate Client forecasts, or receipt of non-conforming API or Client-Supplied Components.

5.6 Invoices and Payment.

Invoices will be sent by fax or email to the fax number or email address given by Client to Patheon in writing. Invoices will be sent when the Product is manufactured and released by Patheon to the Client. Patheon will also submit to Client, with each shipment of Products, a duplicate copy of the invoice covering the shipment and the associated Delivery Documentation. Patheon will also give Client an invoice covering any Inventory or Components which are to be purchased by Client under Section 5.2 of this Agreement. All payments made that are associated with Inventory or Components will be credited against the Price of any Batch of Product that incorporates the Components and/or Inventory. Each invoice will also reflect any credit to Client under Section 5.2. Each invoice will, to the extent applicable, identify Client's Manufacturing Services purchase order number, Product numbers, names and quantities, unit price, freight charges, Delivery Documentation and the total amount to be paid by Client. Client will pay all invoices within [...***...] days of the date thereof. If any portion of an invoice is disputed, the Client will pay Patheon for the undisputed amount and the Parties will use good faith efforts to reconcile the disputed amount as soon as practicable, but in no case more than [...***...] days. Interest on undisputed past due accounts will accrue at [...***...] per month which is equal to an annual rate of [...***...]. The Late Delivery credits set forth in Section 5.5(b) are only available to Client if all outstanding undisputed invoices have been paid in full or are within [...***...] days outstanding from the invoice date when the Late Delivery arose. In the case of a Deficiency Notice, payments will be due within [...***...] days following receipt of a replacement Batch or Batches that are not subject to a Deficiency Notice. Batches that are determined to have a Latent Defect due to Patheon will be either credited against future Batches or refunded at the sole discretion of Client. No payments will be due for Non-Conforming Product and Patheon will use commercially reasonable efforts to replace the Non-Conforming Product within [...***...] days.

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ARTICLE 6

PRODUCT CLAIMS AND RECALLS**6.1 Product Claims.**

(a) **Product Claims.** Client has the right to reject any shipment of Products or any portion thereof that does not conform to the Product Warranties set forth in Section 9.3(a) (“**Non-Conforming Products**”), without invalidating any portion of the shipment of Products that conforms to the Product Warranties. Client will inspect the Products manufactured by Patheon upon receipt at the third-party site agreed to by Patheon and Client and will give Patheon written notice (a “**Deficiency Notice**”) of all claims for Non-Conforming Products within [...***...] days after Client’s receipt of the Product and the Delivery Documentation thereof (or, in the case of Latent Defect, within [...***...] days after confirmation by Client, its Affiliate or any licensee, distributor or other Third Party but not after the expiration date of the Product). If Client fails to give Patheon the Deficiency Notice within the applicable [...***...]- or [...***...]-day period, then the delivery will be deemed to have been accepted by Client on the [...***...] or [...***...] day after delivery or confirmation, as applicable. Except as set out in Section 6.3, Patheon will have no liability for any Deviations for which it has not received notice within the applicable [...***...]-day period except for a Latent Defect.

(b) **Determination of Deficiency.** Upon receipt of a Deficiency Notice, Patheon will have [...***...] days to advise Client by notice in writing that it disagrees with the contents of the Deficiency Notice. Should Patheon fail to provide such notice to Client within the [...***...] day period, then Patheon will be deemed to agree with the contents of the Deficiency Notice. If Client and Patheon fail to agree within [...***...] days after Patheon’s notice to Client as to whether any Products identified in the Deficiency Notice are Non-Conforming Products, then the Parties will mutually select an independent laboratory or expert to evaluate if the Products are Non-Conforming Products. This evaluation will be binding on the Parties. If the independent laboratory or expert determines that any Products are Non-Conforming Products, Client may reject those Products in the manner contemplated in this Section 6.1 and Patheon will be responsible for the cost of the evaluation. If the independent laboratory determines that the Products conform to the Product Warranties, then Client will be deemed to have accepted delivery of the Products on the [...***...] day after delivery (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, on the [...***...] day after confirmation thereof by Client, but not after the expiration date of the Product) and Client will be responsible for the cost of the evaluation.

(c) **Shortages.** Claims for shortages in the amount of Products shipped by Patheon will be dealt with by reasonable agreement of the Parties.

6.2 Product Recalls and Returns.

(a) **Records and Notice.** Patheon and Client will each maintain records necessary to permit a Recall of any Products delivered to Client or customers of Client. Each Party will promptly notify the other by telephone to the contacts designated in the Quality Agreement (to be confirmed in writing) of any information which might affect the marketability, safety or effectiveness of the Products or which might result in the Recall or seizure of the Products within one Business Day. Upon receiving this notice or upon this discovery, each Party will stop making any further shipments of any Products in either Party’s possession or control until Client has made a decision as to 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, will be made and implemented by Client.

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(b) Recalls. If (i) any Regulatory Authority issues a directive, order or, following the issuance of a safety warning or alert about a Product, a written request that any Product be Recalled, (ii) a court of competent jurisdiction orders a Recall, or (iii) Client determines that any Product should be Recalled or that a “Dear Doctor” letter is required relating the restrictions on the use of any Product, Patheon will co-operate as reasonably required by Client, having regard to all Applicable Laws.

(c) Product Returns. Client will have the responsibility for handling customer returns of the Products. Patheon will give Client any assistance that Client may reasonably require to handle the returns including, if requested by Client, appropriate investigations.

6.3 Patheon’s Responsibility for Non-Conforming and Recalled Products.

(a) Non-Conforming Product. If Client rejects Products under Section 6.1, Client will not be required to pay for the Product under Section 3.1. Patheon will promptly, at Client’s election, either: (i) refund the amount paid for the Non-Conforming Products if Client previously paid for the Products, and the cost incurred by Client for the Bill Back Items and Client-Supplied Components used in the Products; (ii) offset the amount paid for the Non-Conforming Products, if Client previously paid for the Products, and the cost incurred by Client for the Bill Back Items and Client-Supplied Components used in the Products, against other amounts due to Patheon hereunder; or (iii) at Patheon’s sole expense (excluding expense to incur replacement Active Materials, but including the replacement of Client-Supplied Components and Bill Back Items), replace the Products with conforming Products without Client being liable for payment therefor under Section 3.1, contingent upon the receipt from Client of all Active Materials and Client-Supplied Components required for the manufacture of the replacement Products. For greater certainty, Patheon’s responsibility for any loss of Active Materials in Non-Conforming Product will be captured and calculated in the Active Materials Yield under Section 2.2.

(b) Recalled Product. If a Recall or return of Products results from, or arises out of, a failure by Patheon to perform the Manufacturing Services in accordance with the terms of this Agreement, including the warranties set forth in Sections 9.3 and 9.4 or other negligence or willful misconduct of Patheon, Patheon will be responsible for the documented costs and out-of-pocket expenses of the Recall or return and will promptly, at the election of Client, either: (i) refund the amount paid for the Recalled or returned Products and the cost incurred by Client for the Bill Back Items and Client-Supplied Components used in the Products; (ii) offset the amount paid for the Recalled or returned Products and the cost incurred by Client for the Bill Back Items and Client-Supplied Components used in the Products, against other amounts due to Patheon hereunder; or (iii) replace the Recalled or returned Products with conforming Products, at Patheon’s sole expense (excluding expense to incur replacement Active Materials, but including the expense to obtain replacement Bill Back Items and Client-Supplied Components), as promptly as practical without Client being liable for payment therefor under Section 3.1, contingent upon the receipt from Client of all Active Materials and Client-Supplied Components required for the manufacture of the replacement Products. For greater certainty, Patheon’s responsibility for any loss of Active Materials in Recalled Product will be captured and calculated in the Active Materials Yield under Section 2.2. In all other circumstances, Recalls, returns, or other corrective actions will be made at Client’s cost and expense. For clarification, any refund of the amount paid by Client for the Recall or return of Products that is paid by Patheon subject to this Section 6.3(b) will not be considered a liability under, and therefore will not be subject to, Section 10.2(a).

(c) Product Rejection for Finished Product Specification Failure. Internal process specifications will be defined and agreed upon. If a Batch or portion of a Batch of Product does not meet a finished Product Specification despite Patheon’s assertion that it manufactured the Product in accordance with the agreed upon process specifications, the Batch production record, and Patheon’s standard operating procedures for manufacturing, the Parties agree that they will mutually select an

independent laboratory or expert to evaluate if such laboratory or expert can determine why the Products do not meet a finished Product Specification. The evaluation will be binding on the Parties. If the independent laboratory or expert determines that the Product is Non-Conforming due to an act or omission by Patheon or does not otherwise comply with the Terms of the Agreement, Client may reject those Products in the manner contemplated by Section 6.1 and Patheon will be responsible for the cost of the evaluation. If the independent laboratory determines that the Patheon complied with the agreed upon process specifications, the Batch production record, and Patheon's standard operating procedures and that the Product does not meet a finished Product specification, Client will be responsible for the cost of the evaluation and will pay Patheon the applicable fee per unit for the Non-Conforming Product. In which case, the API in the Non-Conforming Product will be included in the "Quantity Converted" for purposes of calculating the "Actual Annual Yield" under Section 2.2(a).

(d) Except as set forth in Sections 6.3(a) and (b) above, Patheon will not be liable to Client nor have any responsibility to Client for any deficiencies in, or other liabilities associated with, any Product manufactured by it (collectively, "**Product Claims**"). For greater clarity, Patheon will have no obligation for any Product Claims to the extent the Product Claim (i) is caused by deficiencies in the Specifications, the safety, efficacy, or marketability of the Products manufactured in accordance with this Agreement and conforming to the Specifications or any distribution thereof, (ii) results from a defect in a Component that is not reasonably discoverable by Patheon using the methods set forth in the Specifications or as otherwise provided in this Agreement, (iii) results from a defect in the Active Materials or Client-Supplied Components that is not reasonably discoverable by Patheon using the methods set forth in the Specifications or as otherwise provided in this Agreement, (iv) is caused by actions of Third Parties occurring after the Product is shipped by Patheon under Section 5.4, (v) is due to packaging design or labelling defects or omissions for which neither Patheon nor any of its Affiliates or its or their employees, agents or subcontractors has any responsibility, (vi) is due to any unascertainable reason despite Patheon having performed the Manufacturing Services in accordance with the Quality Agreement, Specifications, cGMPs, Applicable Laws, and the other terms of this Agreement, as determined by an independent laboratory or expert as set forth in Section 6.3(c) above; or (vii) is due to any other breach by Client of its obligations under this Agreement.

6.4 Disposition of Defective or Recalled Products.

Client will not dispose of any damaged, defective, returned, Non-Conforming or Recalled Products for which it intends to assert a claim against Patheon without Patheon's prior written authorization to do so, which will not be unreasonably withheld or delayed. Alternatively, Patheon may instruct Client to return the Products to Patheon. Patheon will bear the cost of disposition (including any applicable storage fees or the cost of destruction) for any damaged, defective, returned or Recalled Products for which it bears responsibility under Section 6.1 or 6.3. In all other circumstances, Client will bear the cost of disposition, including all applicable fees for Manufacturing Services, for any damaged, defective, returned, or Recalled Products.

6.5 Healthcare Provider or Patient Questions and Complaints.

Client will have the sole responsibility for responding to questions and complaints from its customers. Questions or complaints received by Patheon from Client's and its Affiliates' and licensees' customers, healthcare providers or patients will be promptly referred to Client. Patheon will co-operate as reasonably required to allow Client to determine the cause of and resolve any questions and complaints. This assistance will include follow-up investigations, including testing and any other assistance reasonably requested by Client. In addition, Patheon promptly (and in any event within the timelines specified in the Quality Agreement) will give Client all agreed upon information that will enable Client to respond properly to questions or complaints about the Products as set forth in the Quality Agreement.

Client will bear all costs incurred under this Section 6.5, except to the extent the complaint resulted from a failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMPs, Applicable Laws, and the other terms of this Agreement, in which case those costs incurred under this Section 6.5 will be borne by Patheon.

6.6 Sole Remedy.

Except for the indemnity set forth in Section 10.3 and subject to the limitations set forth in Sections 10.1 and 10.2, the remedies described in this Article 6 will be Client's sole remedy for any failure by Patheon to supply Products that conform to the Product Warranties.

ARTICLE 7

CO-OPERATION

7.1 Quarterly Review.

Each Party will 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 will meet not less than Quarterly to review the current status of the business relationship and manage any issues that have arisen.

7.2 Governmental Agencies.

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 the Products only if, in the opinion of Patheon's counsel, the communication is necessary to comply with the terms of this Agreement or the requirements of any Applicable Law and a representative of Client is present for a verbal communication or has reviewed and approved a written communication. Patheon will notify Client immediately upon and in any event within 24 hours after receiving any request from a Regulatory Authority for communication related to a Product.

7.3 Records and Accounting by Patheon.

Patheon will keep records of the manufacture, testing, and shipping of the Products (including evidence on the testing of raw materials, packaging and labeling materials as required by the Quality Agreement), and retain samples of the Products as are necessary to comply with applicable manufacturing regulatory requirements, as well as to assist with resolving Product complaints and other similar investigations. Copies of the records and samples will be retained for five years or one year following the date of Product expiry (whichever is longer), or longer if required by Applicable Laws, at which time Client will be contacted concerning the delivery and destruction of the documents and/or samples of Products at least 45 days prior to the destruction of the documents or samples. Patheon will not store these documents and/or samples beyond the time period set forth above.

7.4 Inspection of Financial Records.

Client or its designee may inspect Patheon reports and records relating to this Agreement during normal business hours and with reasonable advance notice of at least [...***...] Business Days, but a Patheon representative must be present during the inspection. In addition, as more fully set forth in Section 4.2, Client will have the right to allow an independent third party auditor to review the information supporting the price adjustments made under Sections 4.2, 4.3 and 4.4.

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7.5 Access.

Patheon will give Client reasonable access at agreed times to procedures and documentation relevant to the Product, and to the areas of the Manufacturing Site in which the Products are manufactured, stored, handled, or shipped, to permit Client to verify that the Manufacturing Services are being performed in accordance with the Specifications, cGMPs, Applicable Laws and the Quality Agreement. But, with the exception of "For-Cause" Audits, Client will be limited each Year to one cGMP-type audit, lasting no more than [...***...] days, and involving no more than [...***...] auditors. Client may request additional cGMP-type audits, additional audit days, or the participation of additional auditors subject to payment to Patheon of a fee of \$5,000 for each additional audit day and \$1,000 per audit day for each additional auditor. The right of access set forth in this Section 7.5 will not include a right to access or inspect Patheon's financial records. In addition, upon the request of any Regulatory Authority having jurisdiction over the manufacture of Products hereunder, the Regulatory Authority will have access to observe, audit and inspect any Manufacturing Site and Patheon's procedures used for the manufacture, release and stability testing, and/or warehousing of Products and to audit those facilities and procedures for compliance with cGMP and/or other regulatory requirements. Patheon specifically agrees to cooperate with any inspection by a Regulatory Authority, whether prior to or after Regulatory Approval of a Product, and to provide Client a copy of any inspection or audit report resulting from the inspection within three Business Days from receiving the report. Client may be present at the Facility for consultation during any such inspection.

7.6 Notification of Regulatory Inspections.

Patheon will notify Client within one Business Day of any inspection, receipt of notice of any inspection and/or any request for samples by any governmental agency specifically involving the Products. Patheon will also notify Client within three Business Days of receipt of any form 483's or warning letters or any other significant regulatory action or finding which could directly or indirectly impact the regulatory status of the Products or Patheon's ability to perform the Manufacturing Services. Within three Business Days of receipt, Patheon will provide Client with a reasonable description of the notifications and inspections and all supporting documentation, including, as applicable, all form 483's and warning letters or similar warning or objection, responses and all other correspondence and discussions of the applicable Regulatory Authority, which should be redacted to protect the confidential information of Third Parties. Patheon will discuss with Client and consider in good faith any comments provided by Client on the proposed response. Additionally, Patheon will obtain Client's prior approval of any such responses related to Product. Patheon will use commercially reasonable efforts to address and rectify any issues or problems in its manufacturing facility or procedures and any objections or warnings raised by the Regulatory Authority as soon as practicable and to continue to manufacture and supply to Client, in compliance with all Applicable Laws and the terms of this Agreement, the Products ordered by Client. After the filing of a response with the FDA or other Regulatory Authority, Patheon will notify Client of any further contacts with the Regulatory Authority relating to the subject matter of the response.

7.7 Reports.

Patheon will supply on an annual basis all Product data in its control, including release test results, complaint test results, and all investigations (in manufacturing, testing, and storage), that Client reasonably requires in order to complete any filing under any applicable regulatory regime, including any Annual Report that Client is required to file with the FDA or any other Regulatory Authority or other information related to the performance of the Manufacturing Services mandated by a Regulatory Authority. Patheon will promptly provide a copy of the Annual Product Review Report to the Client at no additional cost. Any additional report requested by Client beyond the scope of cGMPs and customary

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FDA or other Regulatory Authority requirements will be subject to an additional fee to be agreed upon between Patheon and the Client.

7.8 **Regulatory Filings.**

(a) **Regulatory Authority.** Client will have the sole right and 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 manufacture, import, export, distribution, marketing, sale, pricing and/or reimbursement of the Products. Patheon will assist Client, to the extent consistent with Patheon's obligations under this Agreement, to obtain Regulatory Authority approval for the commercial manufacture of all Products as quickly as reasonably possible. Client will provide copies of relevant sections of regulatory filings to Patheon that are necessary for Patheon to ensure compliance of the manufacturing processes to those submitted to Regulatory Authorities.

(b) **Verification of Data.** Prior to filing any documents with any Regulatory Authority that incorporate data generated by Patheon, Client will give Patheon a copy of the documents incorporating this data to give Patheon the opportunity to verify the accuracy and regulatory validity of those documents as they relate to Patheon generated data. Patheon requires [...***...] days to perform this review but the Parties may agree to a shorter time for the review as needed, including as mandated by a Regulatory Authority. These documents will be Confidential Information of Client.

(c) **Verification of CMC.** Prior to filing with any Regulatory Authority any documentation which is or is equivalent to the FDA's Chemistry and Manufacturing Controls (all such documentation herein referred to as "CMC") related to any Marketing Authorization, such as a New Drug Application or Abbreviated New Drug Application, Client will give Patheon a copy of the CMC as well as all supporting documents which have been relied upon to prepare the CMC that directly relate to the Manufacturing Services provided by Patheon. This disclosure will permit Patheon to verify that the CMC accurately describes the work that Patheon has performed and the manufacturing processes that Patheon will perform under this Agreement. Patheon requires [...***...] days to perform this review but the Parties may agree to a shorter time for the review as needed. Client will give Patheon copies of all FDA filings at the time of submission to the extent containing CMC information that directly relate to the Manufacturing Services provided by Patheon and may redact this information to protect the Confidential Information of any Third Party.

(d) **Deficiencies.** If, in Patheon's sole discretion, acting reasonably, Patheon determines that any of the information given by Client under clauses (b) and (c) above is inaccurate or deficient in any material respect (the "Deficiencies"), Patheon will notify Client in writing of the Deficiencies as promptly as practical and in any case within the time frame set forth in clause (b) or (c), as applicable. The Parties will work together to have the Deficiencies resolved prior to any pre-approval inspection.

(e) **Client Responsibility.** For clarity, the Parties agree that in reviewing the documents referred to in clause (b) above, Patheon's role will be limited to verifying the accuracy of the description of the work undertaken or to be undertaken by Patheon. 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 responsible 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 give Patheon the documents requested under clause (b) above within the time specified and if Patheon reasonably believes that Patheon's standing with a Regulatory Authority may be jeopardized, Patheon may, in its sole discretion, delay or postpone any inspection by the Regulatory Authority until Patheon has reviewed the requested

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documents that directly relate to the Manufacturing Services provided by Patheon and is satisfied with their contents.

7.9 Quality Agreement.

For clarification, if there is any conflict between the terms and conditions of this Agreement, including this Article 7, and the terms and conditions of the Quality Agreement, the terms and conditions of the Quality Agreement will control with regard to topics directly related to quality and compliance only.

ARTICLE 8

TERM AND TERMINATION

8.1 Initial Term.

This Agreement will become effective as of the Effective Date and will continue until **December 31, 2020** (the “**Initial Term**”), unless terminated earlier by one of the Parties in accordance herewith. This Agreement will automatically renew after the Initial Term for successive terms of two Years each if there is a Product Agreement in effect, unless either Party gives written notice to the other Party of its intention to terminate this Agreement at least 24 months prior to the end of the then current term, subject to earlier termination in accordance with the terms of this Agreement. In any event, the legal terms and conditions of this Agreement will continue to govern any Product Agreement in effect as provided in Section 1.2. Each Product Agreement will have an initial term of five Years from the start of commercial manufacture at the Manufacturing Site for the Product unless the Parties agree to a different number of Years in the applicable Product Agreement (each, an “**Initial Product Term**”), subject to earlier termination in accordance with the terms of this Agreement. Product Agreements will automatically renew after the Initial Product Term for successive terms of two Years each unless either Party gives written notice to the other Party of its intention to terminate the Product Agreement at least 24 months prior to the end of the then current term, subject to earlier termination in accordance with the terms of this Agreement.

8.2 Termination for Cause.

(a) Either Party at its sole option may terminate this Agreement or any Product Agreement upon written notice where the other Party has failed to remedy a material breach of any of its representations, warranties, or other obligations under this Agreement or any Product Agreement within 60 days following receipt of a written notice (the “**Remediation Period**”) of the breach that expressly states that it is a notice under this Section 8.2(a) (a “**Breach Notice**”). The aggrieved Party’s right to terminate this Agreement or a Product Agreement under this Section 8.2(a) may only be exercised for a period of 60 days following the expiry of the Remediation Period (where the breach has not been remedied) and if the termination right is not exercised during this period then the aggrieved Party will be deemed to have waived the breach of the representation, warranty, or obligation described in the Breach Notice.

(b) Either Party at its sole option may immediately terminate this Agreement or any Product Agreement upon written notice, but without prior advance notice, to the other Party if: (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 the other Party; or (iii) this Agreement or any Product Agreement is assigned by the other Party for the benefit of creditors.

(c) Client may terminate this Agreement as to any Product and the related Product Agreement upon at least 30 days' prior written notice, if any Authority takes any action, or raises any objection, that prevents Client from importing, exporting, purchasing, or selling the Product, or Client (or its Affiliate or licensee) determines that for safety or efficacy reasons Client is not going to continue to develop or commercialize the Product. But if this occurs, Client must still fulfill all of its obligations under Section 8.4 below and under any Capital Equipment Agreement regarding the Product.

(d) Client may terminate this Agreement or a Product Agreement at any time upon written notice to Patheon, without limiting Client's other rights or remedies under this Agreement, if any Authority takes any enforcement action regarding the Manufacturing Site that relates to the Product or could reasonably be expected to adversely affect the ability of Patheon to supply the Product.

(e) Patheon may terminate this Agreement or a Product Agreement upon 18 months' prior written notice if Client assigns under Section 13.6 any of its rights under this Agreement or a Product Agreement to an assignee that, in the opinion of Patheon acting reasonably is a Patheon Competitor. But this time period will automatically be extended by an additional three months if, at 18 months after the notice, Client is working in good-faith to secure, and/or obtain required approvals for, another supplier.

8.3 Product Discontinuation; Other Causes for Termination by Client.

(a) Client will give at least six months' advance notice if it intends to no longer order Manufacturing Services for a Product due to this Product's discontinuance in the market. Upon expiration of the applicable six-month notice period, this Agreement will terminate with respect to the Product or, if the Product is the only Product subject to this Agreement, this Agreement will terminate in its entirety.

(b) Except for terminations under the other termination provisions of this Agreement (including Sections 8.2, 8.3(a), 9.4 and 13.7), Client will give at least 36 months' advance notice if it intends to no longer order Manufacturing Services for a Product for any other reason. In such case, the Annual Minimum will be reduced by [...***...] beginning one year from the date of notice and each year thereafter. Upon expiration of the applicable 36 month period, at Client's option, this Agreement will terminate with respect to the Product or, if the Product is the only Product subject to this Agreement, the Agreement will terminate in its entirety. Upon receipt of notice, Patheon will provide assistance to Client in a Technology Transfer. Except for a material breach of this Agreement by Patheon, Client will be responsible for all costs associated with the Technology Transfer. If the Technology Transfer is a result of a material breach of the Agreement by Patheon, each Party will be responsible for its own costs associated with the Technology Transfer. In all circumstances, Patheon will use at least commercially reasonable efforts to meet the timeline requested by Client.

8.4 Obligations on Termination.

If a Product Agreement is completed, expires, or is terminated in whole or in part for any reason, then:

- (a) Client will take delivery of and pay for all undelivered Products that are manufactured and/or packaged under a Firm Order and in compliance with the terms of this Agreement, at the price in effect at the time the Firm Order was placed;
- (b) Client will purchase, at Patheon's actual cost (including all costs incurred by Patheon for the purchase and handling of the Inventory), the Inventory applicable to the Products which was purchased, produced and maintained by Patheon in contemplation of filling Firm Orders or in accordance with Section 5.2;

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- (c) Client will reimburse Patheon for the purchase price payable under Patheon's orders with suppliers of Components, if the orders were made by Patheon in reliance on Firm Orders or in accordance with Section 5.2;
- (d) Client acknowledges that no Patheon Competitor will be permitted access to the Manufacturing Site; and
- (e) Client will make commercially reasonable efforts, at its own expense, to remove from Patheon site(s), within 30 days, all unused Active Material and Client-Supplied Components, all applicable Inventory and Materials (whether current or obsolete), 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 30 days following the completion, termination, or expiration of the Product Agreement, Client will pay Patheon \$100.00 per pallet, per month, one pallet minimum (except that Client will pay \$200 per pallet, per month, one pallet minimum, for any of the Client Property that contains controlled substances, requires refrigeration or other special storage requirements) 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 5.5 of this Agreement.

Any termination or expiration of this Agreement or a Product Agreement will not affect any outstanding obligations or payments due prior to the termination or expiration, nor will it prejudice any other remedies that the Parties may have under this Agreement or a Product Agreement or any related Capital Equipment Agreement. For greater certainty, expiration or termination of this Agreement or of a Product Agreement for any reason will not affect the obligations and responsibilities of the Parties under Articles 10, 11 and 12 and Sections 5.4, 5.6, 6.3, 6.4, 6.5, 6.6, 7.3, 7.4, 8.4, 13.1, 13.2, 13.3, 13.11, 13.15 and 13.16, all of which survive any termination.

ARTICLE 9

REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 Authority.

Each Party covenants, represents, and warrants to the other Party, as of the Effective Date, that (a) 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 has taken all necessary action on its part to authorize the performance of the obligations; (b) the execution and delivery of this Agreement and the performance of the Party's obligations hereunder (i) do not conflict with or violate any requirement of Applicable Laws or regulations and (ii) do not conflict with, or constitute a default or require any consent under, any contractual obligation of the Party; (c) it is duly organized, validly existing and in good standing under the laws of the state or country in which it is organized; and (d) this Agreement has been duly executed and delivered on behalf of the Party, and constitutes a legal, valid, binding obligation, enforceable against the Party in accordance with its terms.

9.2 Client Warranties.

Client covenants, represents, and warrants that:

- (a) Non-Infringement.

- (i) the Specifications for each of the Products are its or its Affiliate's property and Client may lawfully disclose the Specifications to Patheon;
- (ii) any Client Intellectual Property provided by Client for use by Patheon in performing the Manufacturing Services according to the Specifications and the other terms of this Agreement (i) is owned or controlled by Client or its Affiliate, (ii) may be lawfully used by Patheon as directed by Client, and (iii) when used by Patheon according to the Specifications and the other terms of this Agreement does not infringe any Third Party Rights known to Client;
- (iii) subject to [...***...], the [...***...] or the [...***...];
- (iv) as of the Effective Date, there are no actions or other legal proceedings to which the Client is a party or of which Client is aware, concerning the infringement of Third Party Rights related to any of the Specifications, or any of the Active Materials and the Client-Supplied Components, or the sale, use, or other disposition of any Product made in accordance with the Specifications;

(b) Quality and Compliance.

- (i) the Specifications for all Products conform to all applicable cGMPs and Applicable Laws;
- (ii) once Client has received approval from the FDA to market the Products, the Products, if labelled and manufactured in accordance with the Specifications and in compliance with applicable cGMPs and Applicable Laws (i) may be lawfully sold and distributed in every jurisdiction in which Client markets the Products and (iii) will be safe for human consumption;
- (iii) on the date of shipment to the Manufacturing Site, the API will conform to the specifications for the API that Client has given to Patheon, subject to Patheon's obligation to test the API in accordance with the Quality Agreement before beginning manufacture of the Products using the API, and that the API will be adequately contained, packaged, and labelled and will conform to the affirmations of fact on the container.

9.3 Patheon Warranties.

Patheon covenants, represents, and warrants that:

- (a) (1) all Products delivered hereunder will (i) conform to the applicable Specifications; (ii) be free and clear of any and all encumbrances, liens, or other third party claims; (iii) be manufactured, packaged, labelled and delivered in compliance with the Quality Agreement and applicable cGMP, all regulatory approvals for the Product, and Applicable Laws and in accordance with manufacturing procedures described in the applicable master Batch records for the Product; (iv) not be adulterated or misbranded within the meaning of the

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United States Food, Drug and Cosmetic Act, as amended, and any regulations promulgated thereunder or comparable provisions under the laws and regulations of any other applicable jurisdiction (the “Act”); and (v) not be articles that, under the provisions of the Act, may not be introduced into interstate commerce; and (2) Patheon’s processes used to perform the Manufacturing Services will not infringe on any Third Party Rights (collectively, the “Product Warranties”);

- (b) it will perform the Manufacturing Services in accordance with the Quality Agreement, Specifications, cGMPs, and Applicable Laws;
- (c) the Components, Active Materials and the Bill Back Items will at all times be free and clear of any and all encumbrances, liens, or other third party claims; and
- (d) any Patheon Intellectual Property used by Patheon to perform the Manufacturing Services (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.

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 comparable provisions under the laws and regulations of any other applicable jurisdiction. Patheon represents that it does not currently have, and covenants that it will not hire, as an officer or an employee 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 Act. If Patheon or any officer, employee or agent of Patheon: (a) becomes debarred; or (b) receives notice of action or threat of action with respect to its debarment, during the term of this Agreement, Patheon agrees to notify Client immediately. If Patheon or any of its officers, employees or agents becomes debarred as set forth in clause (a) above or receives notice of action or threat of action as set forth in clause (b) above, Client will have the right to terminate this Agreement upon written notice to Patheon.

9.5 Permits.

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

Patheon will maintain at all relevant times all governmental permits, licenses, approval, and authorities required to enable it to lawfully and properly perform the Manufacturing Services.

9.6 No Warranty.

NEITHER PARTY MAKES ANY WARRANTY OR REPRESENTATION OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT. WITHOUT LIMITING THE FOREGOING, NEITHER PARTY MAKES ANY WARRANTY OR REPRESENTATION OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY WARRANTY OR REPRESENTATION OF MERCHANTABILITY FOR THE PRODUCTS.

ARTICLE 10

REMEDIES AND INDEMNITIES**10.1 Consequential Damages.**

Except for liability for breach by either Party of its obligations of Confidentiality under Article 11, under no circumstances whatsoever will either Party be liable to the other in contract, tort, negligence, breach of statutory duty, or otherwise for (i) any (direct or indirect) loss of profits, of production, of anticipated savings, of business, or goodwill or (ii) for any other liability, damage, costs, or expense of any kind incurred by the other Party of an indirect or consequential nature, regardless of any notice of the possibility of these damages. This Section 10.1 will not be deemed to limit either Party's indemnification obligations under this Article 10.

10.2 Limitation of Liability.

(a) Active Materials. Except as expressly set forth in Section 2.2 and Section 6, under no circumstances will Patheon be responsible for any loss or damage to the Active Materials. Patheon's maximum responsibility per Year for loss or damage to the Active Materials will not exceed the Maximum Credit Value set forth in Schedule D of a Product Agreement.

(b) Maximum Liability. Subject to Section 10.2(c) and excluding Patheon's indemnity obligations arising under Section 10.3, Patheon's maximum liability to Client per Year under this Agreement or the Product Agreement for a single Product for any reason whatsoever, including, without limitation, any liability arising under Article 6 hereof or resulting from any and all breaches of its representations, warranties, or any other obligations under this Agreement or the applicable Product Agreement will not exceed on a per Product basis [...***...].

(c) Nothing contained in this Agreement will exclude or limit either Party's liability for personal injury, death or fraudulent misrepresentation.

10.3 Patheon Indemnity.

(a) Patheon agrees to defend and indemnify Client, its Affiliates and licensees, and their respective directors, officers, employees, and agents ("**Client Indemnitees**") against all losses, damages, costs, judgments, liability, fees and expenses (including reasonable attorneys' fees) (collectively, "**Losses**") incurred by any Client Indemnitee due to any suit, claim, demand, judgment or action brought by any Third Parties (other than Affiliates) (each, a "**Claim**"), including, without limitation any Claim of personal injury or property damage, to the extent that the injury or damage is the result of (a) a failure by Patheon or any of its Affiliates to perform the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws, (b) Patheon's breach of any of its obligations, representations or warranties under this Agreement, or (c) the negligence or willful misconduct of any Patheon Indemnitee except to the extent that the losses, damages, costs, claims, demands, judgments, and liability are due to the negligence or willful misconduct of any Client Indemnitee.

(b) If a Claim occurs, Client will: (a) promptly notify Patheon of the Claim; (b) use commercially reasonable efforts to mitigate the effects of the Claim; (c) reasonably cooperate with Patheon in the defense of the claim; and (d) permit Patheon to control the defense and settlement of the claim, all at Patheon's cost and expense. Notwithstanding the foregoing, Patheon will not compromise or

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settle any Claim for which a Client Indemnitee is requesting indemnification for any damages other than monetary damages without Client's prior written consent, which will not be unreasonably withheld.

10.4 Client Indemnity.

(a) Client agrees to defend and indemnify Patheon and its Affiliates and their respective directors, officers, employees, and agents ("**Patheon Indemnitees**") against all Losses, incurred by any Patheon Indemnitee due to any Claim of infringement or alleged infringement of any Third Party Rights in the Products, or any Claim of personal injury or property damage, in each case, to the extent that the Losses are the result of a breach of this Agreement by Client, including, without limitation, any representation or warranty contained herein, or the negligence or willful misconduct of any Client Indemnitee, except to the extent that the Losses are due to the negligence or willful misconduct of any Patheon Indemnitee.

(b) If a Claim occurs, Patheon will: (a) promptly notify Client of the Claim; (b) use commercially reasonable efforts to mitigate the effects of the Claim; (c) reasonably cooperate with Client in the defense of the Claim; and (d) permit Client to control the defense and settlement of the Claim, all at Client's cost and expense. Notwithstanding the foregoing, Client will not compromise or settle any Claim for which a Patheon Indemnitee is requesting indemnification for any damages other than monetary damages without Patheon's prior written consent, which will not be unreasonably withheld.

ARTICLE 11

CONFIDENTIALITY

11.1 Confidential Information.

"**Confidential Information**" means any information disclosed by the Disclosing Party to the Recipient (whether disclosed in oral, written, electronic or visual form) that is non-public, confidential or proprietary including, without limitation, information relating to the Disclosing Party's patent and trademark applications, process designs, process models, drawings, plans, designs, data, databases and extracts therefrom, formulae, methods, know-how and other intellectual property, its clients or client confidential information, finances, marketing, products and processes and all price quotations, manufacturing or professional services proposals, information relating to composition, proprietary technology, and all other information relating to manufacturing capabilities and operations. In addition, all analyses, compilations, studies, reports or other documents prepared by any Party's Representatives containing the Confidential Information will be considered Confidential Information. Samples or materials provided hereunder as well as any and all information derived from the approved analysis of the samples or materials will also constitute Confidential Information. For the purposes of this ARTICLE 11, a Party or its Representative receiving Confidential Information under this Agreement is a "**Recipient**," and a Party or its Representative disclosing Confidential Information under this Agreement is the "**Disclosing Party**."

11.2 Use of Confidential Information.

The Recipient will use the Confidential Information solely for the purpose of meeting its obligations under this Agreement. The Recipient will keep the Confidential Information strictly confidential and will not disclose the Confidential Information in any manner whatsoever, in whole or in part, other than to those of its Representatives who (i) have a need to know the Confidential Information for the purpose of this Agreement; (ii) have been advised of the confidential nature of the Confidential Information and (iii) have obligations of confidentiality and non-use to the Recipient no less restrictive than those of this Agreement. Additionally, Client will have the right to disclose Confidential Information

to sublicensees and/or other strategic partners or in connection with financings or similar transactions provided that the parties to whom Client discloses this information are bound by obligations of confidentiality and non-use no less restrictive than those of this Agreement. Recipient will protect the Confidential Information disclosed to it by using all reasonable precautions to prevent the unauthorized disclosure, dissemination or use of the Confidential Information, which precautions will in no event be less than those exercised by Recipient with respect to its own confidential or proprietary Confidential Information of a similar nature. The obligations of confidentiality and non-use set forth in this Article 11 will remain in effect for a period of seven years following the termination of this Agreement.

11.3 Exclusions.

The obligations of confidentiality will not apply to the extent that the information:

(a) is or becomes publicly known through no breach of this Agreement or fault of the Recipient or its Representatives;

(b) is in the Recipient's possession at the time of disclosure by the Disclosing Party other than as a result of the Recipient's breach of any legal obligation;

(c) is or becomes known to the Recipient on a non-confidential basis through disclosure by sources, other than the Disclosing Party, having the legal right to disclose the Confidential Information, provided that the other source is not known by the Recipient to be bound by any obligations (contractual, legal, fiduciary, or otherwise) of confidentiality to the Disclosing Party with respect to the Confidential Information;

(d) is independently developed by the Recipient without use of or reference to the Disclosing Party's Confidential Information as evidenced by Recipient's written records; or

(e) is expressly authorized for release by the written authorization of the Disclosing Party.

Any combination of information which comprises part of the Confidential Information are not exempt from the obligations of confidentiality merely because individual parts of that Confidential Information were publicly known, in the Recipient's possession, or received by the Recipient, unless the combination itself was publicly known, in the Recipient's possession, or received by the Recipient.

11.4 Photographs and Recordings.

Neither Party will take any photographs or videos of the other Party's facilities, equipment or processes, nor use any other audio or visual recording equipment (such as camera phones) while at the other Party's facilities, without that Party's express written consent.

11.5 Permitted Disclosure.

Notwithstanding any other provision of this Agreement, the Recipient may disclose Confidential Information of the Disclosing Party to the extent required, as advised by counsel, in response to a valid order of a court or other governmental body or as required by law, regulation or stock exchange rule. But the Recipient will advise the Disclosing Party in advance of the disclosure to the extent practicable and permissible by the order, law, regulation or stock exchange rule and any other applicable law, will reasonably cooperate with the Disclosing Party, if required, in seeking an appropriate protective order or other remedy, and will otherwise continue to perform its obligations of confidentiality set out

herein. If any public disclosure is required by law, the Parties will consult concerning the form of announcement prior to the public disclosure being made.

11.6 Marking.

The Disclosing Party agrees to use reasonable efforts to summarize in writing the content of any oral disclosure or other non-tangible disclosure of Confidential Information within 30 days of the disclosure, but failure to provide this summary will not affect the nature of the Confidential Information disclosed if the Confidential Information was identified as confidential or proprietary when disclosed orally or in any other non-tangible form.

11.7 Return of Confidential Information.

Upon the written request of the Disclosing Party, the Recipient will promptly return the Confidential Information to the Disclosing Party or, if the Disclosing Party directs, destroy all Confidential Information disclosed in or reduced to tangible form including any copies thereof and any summaries, compilations, analyses or other notes derived from the Confidential Information except for one copy which may be maintained by the Recipient for its records. The retained copy will remain subject to all confidentiality provisions contained in this Agreement.

11.8 Remedies.

The Parties acknowledge that monetary damages may not be sufficient to remedy a breach by either Party of this Agreement and agree that the non-breaching Party will be entitled to seek specific performance, injunctive and/or other equitable relief to prevent breaches of this Agreement and to specifically enforce the provisions hereof in addition to any other remedies available at law or in equity. These remedies will not be the exclusive remedies for breach of this Agreement but will be in addition to any and all other remedies available at law or in equity.

ARTICLE 12

DISPUTE RESOLUTION

12.1 Commercial Disputes.

If any dispute arises out of this Agreement or any Product Agreement (other than a dispute under Section 6.1(b) or a Technical Dispute, as defined herein), the Parties will first try to resolve it amicably. In that regard, any Party may send a notice of dispute to the other, and each Party will appoint, within [...***...] Business Days from receipt of the notice of dispute, a single representative having full power and authority to resolve the dispute. The representatives will meet as necessary in order to resolve the dispute. If the representatives fail to resolve the matter within [...***...] from their appointment, or if a Party fails to appoint a representative within the [...***...] Business Day period set forth above, the dispute will immediately be referred to the Chief Operating Officer (or another officer as he/she may designate) of Patheon and the Chief Executive Officer of Client each Party who will meet and discuss as necessary to try to resolve the dispute amicably. Should the Parties fail to reach a resolution under this Section 12.1, the dispute will be referred to a court of competent jurisdiction in accordance with Section 13.16.

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12.2 Technical Dispute Resolution.

If a dispute arises (other than disputes under Sections 6.1(b) or 12.1) between the Parties that is exclusively related to technical aspects of the manufacturing, packaging, labelling, quality control testing, handling, storage, or other activities under this Agreement (a “**Technical Dispute**”), the Parties will make all reasonable efforts to resolve the dispute by amicable negotiations. In that regard, senior representatives of each Party will, as soon as possible and in any event no later than [...***...] Business Days after a written request from either Party to the other, meet in good faith to resolve any Technical Dispute. If, despite this meeting, the Parties are unable to resolve a Technical Dispute within a reasonable time, and in any event within [...***...] Business Days of the written request, the Technical Dispute will, at the request of either Party, be referred for determination to an expert in accordance with Exhibit A. If the Parties cannot agree that a dispute is a Technical Dispute, Section 12.1 will prevail. For greater clarity, the Parties agree that the release of the Products for sale or distribution under the applicable marketing approval for the Products will not by itself indicate compliance by Patheon with its obligations for the Manufacturing Services and further that nothing in this Agreement (including Exhibit A) will 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.

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-transferable license under Client’s Intellectual Property solely to the extent necessary for Patheon to perform the Manufacturing Services in accordance with this Agreement, and not for any other purpose.

(b) All Inventions generated or derived by Patheon while performing the Manufacturing Services, to the extent relating specifically to the development, manufacture, use or sale of any Product that is the subject of the Manufacturing Services, and all Client Intellectual Property, will be the exclusive property of Client. Patheon hereby assigns, and agrees to assign, all of its right, title and interest in and to all such Inventions and Client Intellectual Property to Client and agrees to take all further acts reasonably required to evidence and/or perfect such assignment to Client, at Client’s expense. Patheon will notify Client in writing, as promptly as practicable, of all Inventions and Client Intellectual Property made, created, discovered, generated or derived by Patheon in the course of performing the Manufacturing Services. Patheon may retain one copy of records relating to Client Intellectual Property to the extent required under Applicable Laws.

(c) All Patheon Intellectual Property will be the exclusive property of Patheon. Patheon hereby grants to Client a perpetual, irrevocable, non-exclusive, paid-up, royalty-free, transferable license, with the right to sublicense through multiple tiers, to use the Patheon Intellectual Property used by Patheon to perform the Manufacturing Services to enable Client to manufacture the Product(s).

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

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13.2 Intellectual Property.

All Client Intellectual Property will be owned by Client and all Patheon Intellectual Property will be owned by Patheon. Neither Party has, nor will it acquire, any interest in any of the other Party's Intellectual Property unless otherwise expressly agreed to in writing or expressly set forth in this Agreement. Neither Party will 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.

13.3 Insurance.

Each Party will 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 three years thereafter. This insurance will have policy limits of not less than (i) \$[...***...] for each occurrence for personal injury or property damage liability; and (ii) \$[...***...] in the aggregate per annum for product and completed operations liability. If requested each Party will give the other 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. Each Party will further provide the other Party a minimum of 30 days' written notice 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 of its own, then the Party will forthwith notify the other Party in writing and the Parties will in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.

13.4 Independent Contractors.

The Parties are independent contractors and this Agreement and any Product Agreement will not be construed to create between Patheon and 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.

13.5 No Waiver.

Either Party's failure to require the other Party to comply with any provision of this Agreement or any Product Agreement will not be deemed a waiver of the provision or any other provision of this Agreement or any Product Agreement.

13.6 Assignment.

(a) Patheon may not assign this Agreement or any Product Agreement or any of its associated rights or obligations, or subcontract any of its rights or obligations, hereunder without the written consent of Client, this consent not to be unreasonably withheld. But Patheon may arrange for subcontractors to perform specific testing services arising under any Product Agreement without the consent of Client to the extent the subcontractors are specifically named and agreed in the Quality Agreement, provided that Patheon remains primarily liable to the Client for performance by Patheon's subcontractors. Further it is specifically agreed that Patheon may subcontract any part of the Services under a Product Agreement to any of its Affiliates to the extent the Affiliates are specifically named and agreed in the applicable Product Agreement and in the Quality Agreement, provided that Patheon remains primarily liable to the Client for performance by Patheon's Affiliates.

(b) Subject to Section 8.2(e), Client may assign this Agreement or any Product Agreement or any of its associated rights or obligations without approval from Patheon. Client will give Patheon prior

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written notice of any assignment, any assignee will covenant in writing with Patheon to be bound by the terms of this Agreement or the Product Agreement and Client will remain liable hereunder. If Client only assigns a portion of this Agreement or a Product Agreement to a Third Party, the partial assignment will be subject to Patheon's cost review of the assigned Products and Patheon may terminate this Agreement or the Product Agreement or any assigned part thereof, on 18 months' prior written notice to Client and the assignee if good faith discussions do not lead to agreement on amended Manufacturing Service fees within a reasonable time. But this time period will automatically be extended by an additional three months if, at 18 months after the notice, Client is working in good-faith to secure, and/or obtain required approvals for, another supplier.

(c) Despite the foregoing provisions of this Section 13.6, either Party may assign this Agreement or any Product Agreement to any of its Affiliates or to a successor to or purchaser of all or substantially all of its business to which this Agreement relates, but the assignee must execute an agreement with the non-assigning Party whereby it agrees to be bound hereunder.

13.7 Force Majeure.

Neither Party will be liable for the failure to perform its obligations under this Agreement or any Product Agreement if the failure is caused by an event beyond that Party's reasonable control, including, but not limited to, strikes or other labor disturbances, lockouts, riots, quarantines, communicable disease outbreaks, wars, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, lack of or inability to obtain fuel, power 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 will immediately notify the other Party in writing of the extent of its inability to perform, which notice will specify the event beyond its reasonable control that prevents the performance. Neither Party will 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 or any Product Agreement. If the performance of any obligation under this Agreement is delayed due to a Force Majeure Event for a continuous period of more than 60 days, the other Party may terminate this Agreement without penalty upon written notice to the other Party under such event. All Annual Minimums will be suspended for the period of a Force Majeure Event but will be re-instated if the Force Majeure Event is cured. If this Agreement or any Product Agreement is terminated due to a Force Majeure Event lasting longer than 60 days as set forth above, Client may request Patheon to reasonably assist in the transfer of the technology required to manufacture the Product to a third party supplier designated by Client. If so requested, Patheon will promptly initiate and complete the technology transfer at Client's cost.

13.8 Additional Product.

Additional Products may be added to, or existing Products deleted from, any Product Agreement by amendments to the Product Agreement including Schedules A, B, C, and D as applicable.

13.9 Notices.

Unless otherwise agreed in a Product Agreement, any notice, approval, instruction or other written communication required or permitted hereunder will be sufficient if made or given to the other Party by personal delivery, by telecopy, facsimile communication, or confirmed receipt email or by sending the same by first class mail, postage prepaid to the respective addresses, telecopy or facsimile numbers or electronic mail addresses set forth below:

If to Client:

ACADIA Pharmaceuticals Inc.
3611 Valley Centre Drive, Suite 300
San Diego, CA 92130
Attention: [...***...]
Telecopier No.: [...***...]
Email address: [...***...]

With a copy to:

ACADIA Pharmaceuticals Inc.
3611 Valley Centre Drive, Suite 300
San Diego, CA 92130
Attention: [...***...]
Telecopier No.: [...***...]
Email address: [...***...]

If to Patheon:

Patheon Pharmaceuticals Inc.
2110 East Galbraith Road
Cincinnati, OH 45237-1625
Attention: [...***...]
Telecopier No.: [...***...]
Email address: [...***...]

With a copy to:

Patheon Inc.
Canterbury Place
4815 Emperor Boulevard
Research Triangle Park,
NC 27703
Attention: [...***...]
Telecopier No.: [...***...]

or to any other addresses, telecopy or facsimile numbers or electronic mail addresses given to the other Party in accordance with the terms of this Section 13.9. Notices or written communications made or given by personal delivery, telecopy, facsimile, or electronic mail will 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, Canada, or European Union mail, postage prepaid or upon receipt, whichever is sooner, or one Business Day after being sent by overnight courier.

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13.10 Severability.

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

13.11 Entire Agreement.

This Agreement, and all Schedules hereto, together with the applicable Product Agreement and Quality Agreement, constitutes the full, complete, final and integrated agreement between the Parties relating to the subject matter hereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions, or understandings concerning the subject matter hereof. Any modification, amendment, or supplement to this Agreement or any Product Agreement must be in writing and signed by authorized representatives of the Parties. In case of conflict, the prevailing order of documents will be this Agreement, the Product Agreement, and the Quality Agreement.

13.12 Other Terms.

No terms, provisions or conditions of any purchase order or other business form or written authorization used by Client or Patheon will have any effect on the rights, duties, or obligations of the Parties under or otherwise modify this Agreement or any Product Agreement, regardless of any failure of Client or Patheon to object to the terms, provisions, or conditions unless the document specifically refers to this Agreement or the applicable Product Agreement and is signed by the Parties.

13.13 No Third Party Benefit or Right.

For greater clarity, nothing in this Agreement or any Product Agreement will 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 or any Product Agreement.

13.14 Execution in Counterparts.

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

13.15 Use of Client Name.

Patheon will not make any use of Client's name, trademarks or logo or any variations thereof, alone or with any other word or words, without the prior written consent of Client, which consent will not be unreasonably withheld. Despite this, Client agrees that Patheon may include Client's name and logo in customer lists or related marketing and promotional material for the purpose of identifying users of Patheon's Manufacturing Services.

13.16 Governing Law.

This Agreement and any Product Agreement will be construed and enforced in accordance with the laws of the State of New York and the laws of the United States of America applicable therein and subject to the exclusive jurisdiction of the courts thereof. The UN Convention on Contracts for the International Sale of Goods will not apply to this Agreement or any Product Agreement.

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/ Francis P. McCune
Name: Francis P. McCune
Title: Secretary

ACADIA PHARMACEUTICALS INC.

By: /s/ Steve Davis
Name: Steve Davis
Title: Interim CEO

APPENDIX 1**FORM OF PRODUCT AGREEMENT****(Includes Schedules A to D)****PRODUCT AGREEMENT**

This Product Agreement (this “**Product Agreement**”) is issued under the Master Manufacturing Services Agreement dated August 3, 2015 between **Patheon Pharmaceuticals Inc.**, and **ACADIA Pharmaceuticals Inc.** (the “**Master Agreement**”), and is entered into [**insert effective date**] (the “**Effective Date**”), between Patheon Pharmaceuticals Inc., [**or applicable Patheon Affiliate**], a corporation existing under the laws of the State of Delaware [**or applicable founding jurisdiction for Patheon Affiliate**], having a principal place of business at 2110 East Galbraith Road, Cincinnati, OH 45237-1625 [**or Patheon Affiliate address**] (“**Patheon**”) and [**insert Client name, legal entity, founding jurisdiction and address**] (“**Client**”).

The terms and conditions of the Master Agreement are incorporated herein except to the extent this Product Agreement expressly references the specific provision in the Master Agreement to be modified by this Product Agreement. All capitalized terms that are used but not defined in this Product Agreement will have the respective meanings given to them in the Master Agreement.

The Schedules to this Product Agreement are incorporated into and will be construed in accordance with the terms of this Product Agreement.

1. **Product List and Specifications** (See Schedule A attached hereto)
2. **Minimum Order Quantity, Annual Volume, and Price** (See Schedule B attached hereto)
3. **Annual Stability Testing and Validation Activities (if applicable)** (See Schedule C attached hereto)
4. **Active Materials, Active Materials Credit Value, and Maximum Credit Value** (See Schedule D attached hereto)
5. **Yearly Forecasted Volume:** (insert for sterile products if applicable under Section 4.2.1 of the Master Agreement)
6. **Territory:** (insert the description of the Territory here)
7. **Manufacturing Site:** (insert address of Patheon Manufacturing Site where the Manufacturing Services will be performed)
8. **Governing Law:** (if applicable under Section 13.16 of the Master Agreement)
9. **Inflation Index:** (if applicable under Section 4.2(a) of the Master Agreement for Products manufactured outside of the Unites States or Puerto Rico)
10. **Currency:** (if applicable under Section 1.4 of the Master Agreement)

- 11. **Initial Set Exchange Rate:** (if applicable under Section 4.2(d) of the Master Agreement)
- 12. **Initial Product Term:** (if applicable under Section 8.1 of the Master Agreement)
- 13. **Notices:** (if applicable under Section 13.9 of the Master Agreement)
- 14. **Other Modifications to the Master Agreement:** (if applicable under Section 1.2 of the Master Agreement)

IN WITNESS WHEREOF, the duly authorized representatives of the Parties have executed this Product Agreement as of the Effective Date set forth above.

PATHEON PHARMACEUTICALS INC. [or applicable Patheon Affiliate]

By: _____
Name: _____
Title: _____

ACADIA PHARMACEUTICALS INC. [or applicable Client Affiliate]

By: _____
Name: _____
Title: _____

SCHEDULE A

PRODUCT LIST AND SPECIFICATIONS

Product List

[insert product list]

Specifications

Prior to the start of commercial manufacturing of Product under this Agreement Client will give Patheon the originally executed copies of the Specifications as approved by the applicable Regulatory Authority or as most recently filed with such Regulatory Authority. If the Specifications received are subsequently amended, then Client will give Patheon the revised and originally executed copies of the revised Specifications. Upon acceptance of the revised Specifications, Patheon will give Client a signed and dated receipt indicating Patheon's receipt of the revised Specifications.

SCHEDULE B

MINIMUM ORDER QUANTITY, ANNUAL VOLUME, AND PRICE

[Insert Price Table]

Manufacturing Assumptions:

Packaging Assumptions:

Testing Assumptions:

Costs Included in Unit Pricing

[...***...]

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Costs Not Included in Unit Pricing

[...***...]

*****Confidential Treatment Requested**

[...***...]

*****Confidential Treatment Requested**

SCHEDULE C

ANNUAL STABILITY TESTING

Patheon and Client will agree in writing on any stability testing to be performed by Patheon on the Products. This agreement will specify the commercial and Product stability protocols applicable to the stability testing and the fees payable by Client for this testing.

[NTD: Schedule C should clearly indicate when and/or under what conditions Patheon's responsibility to perform stability testing will end]

SCHEDULE D

ACTIVE MATERIALS

Active Materials	Supplier
•	•
•	•

ACTIVE MATERIALS CREDIT VALUE

The Active Materials Credit Value will be as follows:

PRODUCT	ACTIVE MATERIALS	ACTIVE MATERIALS CREDIT VALUE
		Client's actual cost for Active Materials not to exceed \$____ per kilogram

MAXIMUM CREDIT VALUE

Patheon's liability for Active Materials calculated in accordance with Section 2.2 of the Master Agreement [**for any Product**] in a Year will not exceed, in the aggregate, the maximum credit value set forth below:

PRODUCT	MAXIMUM CREDIT VALUE
	[...***...]

[End of Product Agreement]

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EXHIBIT A**TECHNICAL DISPUTE RESOLUTION**

Technical Disputes which cannot be resolved by negotiation as provided in Section 12.2 will be resolved in the following manner:

1. **Appointment of Expert.** Within [...***...] Business Days after a Party requests under Section 12.2 that an expert be appointed to resolve a Technical Dispute, the Parties will jointly appoint a mutually acceptable expert with experience and expertise in the subject matter of the dispute. If the Parties are unable to so agree within the [...***...] Business Day period, or in the event of disclosure of a conflict by an expert under Paragraph 2 hereof which results in the Parties not confirming the appointment of the expert, then an expert (willing to act in that capacity hereunder) will be appointed by an experienced arbitrator on the roster of the American Arbitration Association.
2. **Conflicts of Interest.** Any person appointed as an expert will be entitled to act and continue to act as an expert even if at the time of his appointment or at any time before he gives his determination, he has or may have some interest or duty which conflicts or may conflict with his appointment if before accepting the appointment (or as soon as practicable after he becomes aware of the conflict or potential conflict) he fully discloses the interest or duty and the Parties will, after the disclosure, have confirmed his appointment.
3. **Not Arbitrator.** No expert will be deemed to be an arbitrator and the provisions of the American Arbitration Act or of any other applicable statute (foreign or domestic) and the law relating to arbitration will not apply to the expert or the expert's determination or the procedure by which the expert reaches his determination under this Exhibit A.
4. **Procedure.** Where an expert is appointed:
 - (a) **Timing.** The expert will be so appointed on condition that (i) he promptly fixes a reasonable time and place for receiving representations, submissions or information from the Parties and that he issues the authorizations to the Parties and any relevant third party for the proper conduct of his determination and any hearing and (ii) he renders his decision (with full reasons) within [...***...] Business Days (or another other date as the Parties and the expert may agree) after receipt of all information requested by him under Paragraph 4(b) hereof.
 - (b) **Disclosure of Evidence.** The Parties undertake one to the other to give to any expert all the evidence and information within their respective possession or control as the expert may reasonably consider necessary for determining the matter before him which they will disclose promptly and in any event within [...***...] Business Days of a written request from the relevant expert to do so.
 - (c) **Advisors.** Each Party may appoint any counsel, consultants and advisors as it feels appropriate to assist the expert in his determination and so as to present their respective cases so that at all times the Parties will co-operate and seek to narrow and limit the issues to be determined.
 - (d) **Appointment of New Expert.** If within the time specified in Paragraph 4(a) above the expert will not have rendered a decision in accordance with his appointment, a new expert may (at the request of either Party) be appointed and the appointment of the existing expert will thereupon cease for the purposes of determining the matter at issue between the Parties save this if the existing expert renders his decision with full reasons

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prior to the appointment of the new expert, then this decision will have effect and the proposed appointment of the new expert will be withdrawn.

- (e) Final and Binding. The determination of the expert will, except for fraud or manifest error, be final and binding upon the Parties.
- (f) Costs. Each Party will bear its own costs for any matter referred to an expert hereunder and, in the absence of express provision in the Agreement to the contrary, the costs and expenses of the expert will be shared equally by the Parties.

For greater certainty, the release of the Products for sale or distribution under the applicable marketing approval for the Products will not by itself indicate compliance by Patheon with its obligations for the Manufacturing Services and further that nothing in this Agreement (including this Exhibit A) will 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.

EXHIBIT B

MONTHLY ACTIVE MATERIALS INVENTORY REPORT

TO: ACADIA PHARMACEUTICALS INC.
 FROM: PATHEON PHARMACEUTICALS INC. [or applicable Patheon Affiliate]
 RE: Active Materials monthly inventory report under Section 2.2(a) of the Master Manufacturing Services Agreement dated August 3, 2015 (the “**Agreement**”)

Reporting month: _____

Active Materials on hand at beginning of month: _____ kg (A)

Active Materials on hand at end of month: _____ kg (B)

Quantity Received during month: _____ kg (C)

Quantity Dispensed¹ during month:
 (A + C – B) _____ kg

Quantity Converted during month: _____ kg
 (total Active Materials in Products produced
 and not rejected, recalled or returned)

Capitalized terms used in this report have the meanings given to the terms in the Agreement.

PATHEON PHARMACEUTICALS INC.

DATE: _____

[or applicable Patheon Affiliate]

Per: _____
 Name:
 Title:

¹ Excludes any (i) Active Materials that must be retained by Patheon as samples, (ii) Active Materials contained in Product that must be retained as samples, (iii) Active Materials used in testing (if applicable), and (iv) Active Materials received or consumed in technical transfer activities or development activities, including, without limitation, any regulatory, stability, validation, or test Batches manufactured during the month.

EXHIBIT CREPORT OF ANNUAL ACTIVE MATERIALS INVENTORY RECONCILIATION
AND CALCULATION OF ACTUAL ANNUAL YIELD

TO: ACADIA PHARMACEUTICALS INC.
 FROM: PATHEON PHARMACEUTICALS INC. [or applicable Patheon Affiliate]
 RE: Active Materials annual inventory reconciliation report and calculation of Actual Annual Yield under Section 2.2(a) of the Master Manufacturing Services Agreement dated August 3, 2015 (the "**Agreement**")

Reporting Year ending:	_____		
Active Materials on hand at beginning of Year:	_____	kg	(A)
Active Materials on hand at end of Year:	_____	kg	(B)
Quantity Received during Year:	_____	kg	(C)
Quantity Dispensed ² during Year: (A + C - B)	_____	kg	(D)
Quantity Converted during Year: (total Active Materials in Products produced and not rejected, recalled or returned)	_____	kg	(E)
Active Materials Credit Value:	\$ _____	/ kg	(F)
Target Yield:	_____	%	(G)
Actual Annual Yield:	_____	%	(H)

² Excludes any (i) Active Materials that must be retained by Patheon as samples, (ii) Active Materials contained in Product that must be retained as samples, (iii) Active Materials used in testing (if applicable), and (iv) Active Materials received or consumed in technical transfer activities or development activities, including, without limitation, any regulatory, stability, validation, or test Batches manufactured during the Year.

$((E / D) * 100)$

Shortfall: $\$$ _____ (I)
 $((G - [...***...]) - H) / 100 * F * D$
(if a negative number, insert zero)

Based on the foregoing reimbursement calculation Patheon will reimburse Client the amount of \$_____.

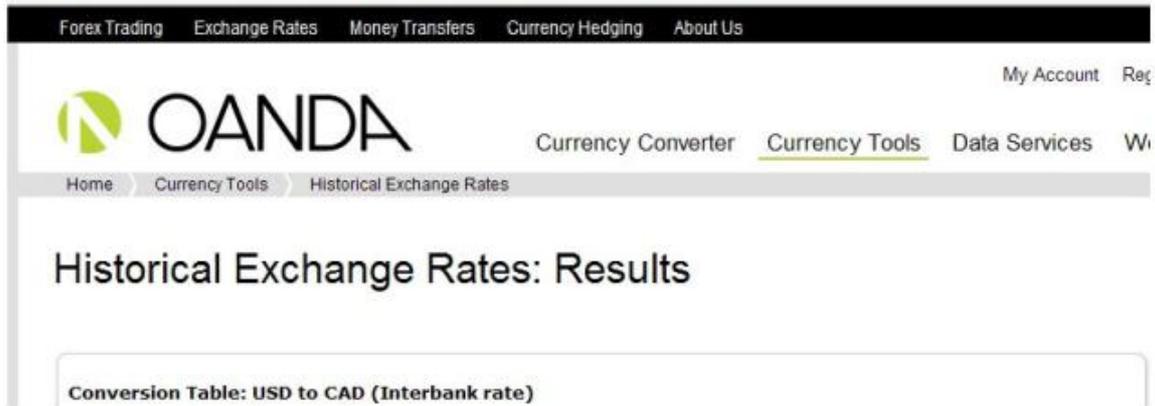
Capitalized terms used in this report have the meanings given to the terms in the Agreement.

DATE: _____

PATHEON PHARMACEUTICALS INC.
[or applicable Patheon Affiliate]

Per: _____
Name:
Title:

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EXHIBIT D**EXAMPLE OF PRICE ADJUSTMENT DUE TO CURRENCY FLUCTUATION****Section 4.2(d)**

Time period: 10/01/11 to 09/30/12.

Average (365 days): 0.998 – “Set Exchange Rate”

SAMPLE EXCHANGE CALCULATION

Initial Exchange Rate:	1.000	CAD/USD
Set Exchange Rate:	0.998	CAD/USD
Initial Price:	3.59	
Revised Price (FX):	3.70	(Material price and PPI adjustments)

Calculation:

$$\begin{aligned}
 [\text{Revised Price (After FX)}] &= [\text{Revised Price (Before FX)}] \times [\text{Initial Exchange Rate}] / [\text{Set Exchange Rate}] \\
 &= 3.70 \times [1.000 / 0.998] \\
 &= 3.71
 \end{aligned}$$

PRODUCT AGREEMENT

This Product Agreement (this “**Product Agreement**”) is issued under the Master Manufacturing Services Agreement dated August 3, 2015 between **Patheon Pharmaceuticals Inc.**, and **ACADIA Pharmaceuticals Inc.** (the “**Master Agreement**”), and is entered into as of August 3, 2015 (the “**Effective Date**”), between Patheon Pharmaceuticals Inc., a corporation existing under the laws of the State of Delaware, having a principal place of business at 2110 East Galbraith Road, Cincinnati, OH 45237-1625 (“**Patheon**”) and ACADIA Pharmaceuticals Inc., a corporation existing under the laws of the State of Delaware, having a principal place of business at 3611 Valley Centre Drive, Ste. 300, San Diego, CA 92130 (“**Client**”).

The terms and conditions of the Master Agreement are incorporated herein except to the extent this Product Agreement expressly references the specific provision in the Master Agreement to be modified by this Product Agreement. All capitalized terms that are used but not defined in this Product Agreement will have the respective meanings given to them in the Master Agreement.

The Schedules to this Product Agreement are incorporated into and will be construed in accordance with the terms of this Product Agreement.

1. **Product List and Specifications** (See Schedule A attached hereto)
2. **Minimum Order Quantity, Annual Volume, and Price** (See Schedule B attached hereto)
3. **Annual Stability Testing** (See Schedule C attached hereto)
4. **Active Materials, Active Materials Credit Value, and Maximum Credit Value** (See Schedule D attached hereto)
5. **Yearly Forecasted Volume:** Not applicable
6. **Territory:** The United States
7. **Manufacturing Site:** Patheon Pharmaceuticals Inc., 2110 East Galbraith Road, Cincinnati, OH 45237-1625.
8. **Governing Law:** Per Section 13.16 of the Master Agreement
9. **Inflation Index:** Per Section 4.2(a) of the Master Agreement
10. **Currency:** Per Section 1.4 of the Master Agreement
11. **Initial Set Exchange Rate:** Not applicable
12. **Initial Product Term:** From the Effective Date through December 31, 2020.
13. **Notices:** Per Section 13.9 of the Master Agreement
14. **Other Modifications to the Master Agreement:** Not applicable

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Product Agreement as of the Effective Date set forth above.

PATHEON PHARMACEUTICALS INC.

By: /s/ Francis P. McCune
Name: Francis P. McCune
Title: Secretary

ACADIA PHARMACEUTICALS INC.

By: /s/ Steve Davis
Name: Steve Davis
Title: Interim CEO

SCHEDULE A

PRODUCT LIST AND SPECIFICATIONS

Product List

Pimavanserin Tablets 17 mg strength (the “**Product**”)

Specifications

Prior to the start of commercial manufacturing of the Product under this Agreement Client will give Patheon the originally executed copies of the Specifications as approved by the applicable Regulatory Authority or as most recently filed with such Regulatory Authority. If the Specifications received are subsequently amended, then Client will give Patheon the revised and originally executed copies of the revised Specifications. Upon acceptance of the revised Specifications, Patheon will give Client a signed and dated receipt indicating Patheon’s acceptance of the revised Specifications.

SCHEDULE B

MINIMUM ORDER QUANTITY, ANNUAL VOLUME AND PRICE

Annual Volume Forecasts

Patheon is presenting pricing based on the following volume.

Product	# of Batches [...**...]
Pimavanserin Tablets	[...**...]

Pricing Table

Pricing includes the cost of labor, overhead, raw materials, packaging components and QC testing and such additional items noted as being included in the price as described below.

[...**...]

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[...***...]

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Costs Not Included in Unit Pricing

[...***...]

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Key Technical Assumptions

Below are listed the main assumptions that were utilized by Patheon for quoting this Product. Should any of the assumptions change, then the prices will be revised accordingly as agreed by the Parties.

Manufacturing Assumptions

- The manufacturing process at Patheon will follow the master Batch Product record approved by the Parties.
- The core tablet weights and manufacturing batch sizes for each strength are summarized in the following table.

[...***...]

- The following manufacturing equipment train is used for the Product.

[...***...]

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Packaging Assumptions

The Product will be packaged into the configurations listed in the tables below.

[...***...]

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Testing Assumptions

- Testing for raw materials, excipients, packaging components and finished Product are based on information provided by Client.
- Full release testing of API is included.
- It is assumed that QC test methods are fully validated and robust.
- Micro testing has been included on the finished Product.
- Testing labor may be subject to change after the final agreement on testing specifications and requirements.

Supply Chain Assumptions

- The quoted raw materials and packaging components (other than Client-Supplied Components) are assumed to be supplied from standard Patheon suppliers. This will need to be reviewed upon the detailed specifications of these materials. Patheon will procure components (raw materials and primary packaging materials) for the manufacture of the Product from Patheon qualified suppliers. Should Client require Patheon to source any materials from specified suppliers other than Patheon qualified suppliers or those otherwise agreed upon in the Master Agreement, as applicable, then these suppliers will remain under the quality audit control of Client unless it is agreed that Patheon will take on this responsibility. Components and excipients to be supplied by Patheon in accordance with Client's specifications. Patheon will issue formal Patheon specifications for each component following Client component requirements. Each lot of incoming components will be sampled and tested according to the agreed specifications. If different component specifications for primary packaging are required, these will be subject to a further evaluation and assessment by Patheon.

SCHEDULE C

ANNUAL STABILITY TESTING

Patheon and Client will agree in writing on any stability testing to be performed by Patheon on the Products. This agreement will specify the commercial and Product stability protocols applicable to the stability testing and the fees payable by Client for this testing. Release testing will be used for time zero testing as long as batches are placed on stability within [...***...] days of completion of release testing. Patheon will be responsible for retest of time zero if delay of placing batches are due to Patheon. Client will be responsible for \$[...***...] per sample for any batch delayed more than [...***...] days from release testing due to Client.

[...***...]

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SCHEDULE D

ACTIVE MATERIALS

Active Materials	Supplier
Pimavanserin tartrate	BASF Pharma (Evionnaz) SA and/or its affiliates

ACTIVE MATERIALS CREDIT VALUE

The Active Materials Credit Value will be as follows:

PRODUCT	ACTIVE MATERIALS	ACTIVE MATERIALS CREDIT VALUE
Pimavanserin tablets 17 mg strength	Pimavanserin tartrate	Client's actual cost for Active Materials not to exceed \$[...***...] per kilogram

MAXIMUM CREDIT VALUE

Patheon's liability for Active Materials calculated in accordance with Section 2.2 of the Master Agreement for Product in a Year will not exceed, in the aggregate, the maximum credit value set forth below:

PRODUCT	MAXIMUM CREDIT VALUE
Pimavanserin tablets 17 mg strength	[...***...]

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***Text Omitted and Filed Separately
with the Securities and Exchange Commission.
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Under 17 C.F.R. Sections 200.80(b)(4)
and 240.24b-2.

Co-operation Agreement

Between: ACADIA Pharmaceuticals GmbH
Pilatusstrasse 41
6003 Lucerne
Switzerland
(hereinafter called **ACADIA**)

And BASF Pharma (Evionnaz) SA
route du Simplon 1
1902 Evionnaz
Switzerland
(hereinafter called **BPE**)

Recitals:

Whereas, BPE sells and markets pharmaceutical products manufactured by it and its Affiliates (as defined below), e.g. BASF Pharma (Saint-Vulbas) SAS (“BPSV”), BASF PharmaChemikalien GmbH & Co. KG (“BPCG”) as well as BASF SE in Germany (“BASF”).

Whereas, BPE and/or one of its Affiliates have the ability and desire to manufacture and BPE has the desire to supply the PRODUCT (as defined in clause 1.1 herein). BPSV, BPCG, and BASF are referred to in this Agreement, collectively, as “Affiliates” of BPE and, individually, as an “Affiliate” of BPE.

Whereas, ACADIA is a biopharmaceutical company focused on the discovery, development and commercialization of small molecule drugs for the treatment of central nervous system disorders and is incorporated in Switzerland.

BPE and ACADIA are referred to herein, collectively, as the “Parties” and, individually, as a “Party”.

1. Preamble

1.1. The Parties wish to co-operate in the industrial scale manufacture of the products described in more detail in the PRODUCT schedules (essentially in the form as stipulated in Annex A hereto) hereto (hereinafter called **PRODUCTS**), and to establish the framework under which such co-operation is to be undertaken.

2. Co-operation scope:

2.1. The Parties agree to co-operate on the terms of this Agreement to manufacture **PRODUCTS** at BPE and/or its Affiliates, as indicated in more detail in the relevant PRODUCT schedule hereto, and to support the supply of the **PRODUCT** by **BPE** to **ACADIA**. ACADIA understands that the **PRODUCTS** are manufactured for ACADIA (including its affiliates and its

and their respective licensees and collaborators) only and that once the PRODUCTS have been manufactured in accordance with the terms of this Agreement and the relevant PRODUCT schedule, including but not limited to the forecasting and order procedures (and meet the warranties in Section 3.2), ACADIA shall purchase them on a first in first out basis as established in the relevant PRODUCT schedule; provided, however, that ACADIA shall not have any obligation to purchase PRODUCTS in quantities that exceed quantities reflected in a binding PRODUCT schedule.

- 2.2. The individual manufacturing program to be undertaken by BPE to manufacture a specific PRODUCT is set out in the respective PRODUCT schedule (hereinafter called the **Manufacturing Program**).
- 2.2.1. BPE hereby agrees to use commercially reasonable efforts and all due skills and care to conduct the **Manufacturing Program** and to provide or cause its Affiliates indicated in the PRODUCT schedule to provide adequate and appropriate resources required to complete the **Manufacturing Program**.
- 2.2.2. ACADIA hereby agrees to provide BPE and its Affiliates appropriate resources to the extent reasonably required by BPE, or its Affiliates, as provided in the relevant PRODUCT schedule. Upon reasonable advance notice during normal business hours, ACADIA will make available to BPE and its Affiliates ACADIA personnel to respond to queries and requests from BPE and its Affiliates.
- 2.3. The terms for lead times, forecasts and orders shall be individually agreed upon for each PRODUCT in the relevant PRODUCT schedule.

3. Obligations of BPE

- 3.1. BPE shall manufacture or have manufactured (by its Affiliates) and supply to ACADIA the PRODUCTS in accordance with current Good Manufacturing Practices as stipulated in the ICH Harmonized Tripartite Guideline Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients Q7 (“cGMP”), and the specifications mutually agreed upon in the respective PRODUCT schedule. Notwithstanding anything to the contrary in this Agreement, the PRODUCT schedule or the corresponding quality agreement entered into by the Parties (as may be amended by the Parties from time to time in accordance with its terms, the “Quality Agreement”), in no event may BPE initiate or perform any manufacturing or other activities under this Agreement through any Affiliates of BPE, or any subcontractor, without the prior written approval by ACADIA. BPE acknowledges that, prior to initiating any activities at an Affiliate of BPE or any subcontractor, such sites must be qualified by ACADIA.
- 3.2. BPE represents and warrants that PRODUCTS supplied under this Agreement shall: (i) be manufactured in accordance with applicable

regulatory approvals for such **PRODUCTS**, cGMP and all other applicable laws and regulations, (ii) conform to the specifications agreed upon in the respective **PRODUCT** schedule in effect at the time of delivery, (iii) not be adulterated or misbranded within the meaning of the U.S. Federal Food, Drug & Cosmetic Act, as amended from time to time, and/or any analogous regulations in any other applicable jurisdiction, (iv) not contain any defect in material or workmanship or any cross-contamination, and (v) at the time of delivery, be free and clear of any lien or encumbrance.

- 3.3. **BPE MAKES NO WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, BY FACT OR LAW, OTHER THAN (I) AS SET FORTH IN SECTION 3.2, AND (II) IMPLIED WARRANTIES OF TITLE, FREEDOM FROM ENCUMBRANCE, AND RIGHT TO TRANSFER SAME. BPE MAKES NO WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE, OR WARRANTY OF MERCHANTABILITY.**
- 3.4. **BPE** shall be responsible for obtaining all raw materials required for the manufacture of **PRODUCT** hereunder. **BPE** shall use its commercially reasonable efforts to deliver **PRODUCT** to **ACADIA** on the agreed upon delivery dates. **BPE** shall supply the **PRODUCTS** to **ACADIA** together with a certificate of analysis (“COA”) confirming that such **PRODUCT** meets the specifications set forth in the relevant **PRODUCT** schedule and was manufactured in accordance with cGMP and such additional documentation as detailed in the Quality Agreement. **ACADIA** shall inspect each delivery of **PRODUCT** to confirm that it meets the specifications. **ACADIA** may reject **PRODUCT** that does not conform to the warranties in Section 3.2. IN ORDER TO REJECT **PRODUCT**, **ACADIA** MUST GIVE WRITTEN NOTICE TO **BPE** OF SUCH REJECTION WITHIN [...***...] DAYS AFTER DELIVERY OF **PRODUCT** AND, IN THE EVENT OF DEFECTS WHICH CANNOT BE DETECTED UPON DILIGENT INSPECTION (“LATENT DEFECT”), WITHIN [...***...] DAYS AFTER DETECTION OF A LATENT DEFECT. **ACADIA**’S FAILURE TO GIVE SUCH NOTICE TO **BPE** OF ANY CLAIM WITHIN [...***...] DAYS AFTER THE DATE OF DELIVERY OR [...***...] DAYS AFTER DETECTION OF A LATENT DEFECT, AS APPLICABLE, SHALL CONSTITUTE ACCEPTANCE OF THE **PRODUCT**. If notice of rejection is given, **ACADIA** shall cooperate with **BPE** in determining whether rejection is necessary or justified. **BPE** will evaluate process issues and other reasons for such non-compliance. If **BPE** in good faith disagrees with **ACADIA**’s determination that **PRODUCT** does not meet the warranties in Section 3.2, it shall provide written notice to **ACADIA** within [...***...] days after notice of rejection from **ACADIA** (and **BPE** shall be deemed to accept such rejection if it does not provide notice within such period). If the Parties fail to reach agreement on the matter within [...***...] days after **BPE**’s notice to **ACADIA** of disagreement with the notice of rejection, then as promptly as practicable, and in any event within [...***...] days after **ACADIA** receives **BPE**’s notice of disagreement, such **PRODUCT** and the applicable COA shall (i) with respect to a dispute regarding compliance with specifications, be submitted to a mutually acceptable third party laboratory which shall determine whether such **PRODUCT** meets the specifications and (ii) with respect to a dispute regarding cGMP compliance, be submitted to a mutually acceptable third party quality/regulatory consultant. The Parties

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shall cooperate with the third party's reasonable requests for assistance in connection with its analysis and agree that such applicable third party's determination shall be final and binding on each of the Parties. The Party against whom the third party rules shall bear all costs of the third party testing/services. Whether or not **BPE** accepts **ACADIA's** rejection of **PRODUCT**, **BPE** shall endeavour to replace any **PRODUCT** for which **ACADIA** has provided a notice of rejection with **PRODUCT** that complies with the warranties set forth in Section 3.2 as promptly as practicable, but in any event, within [...***...] days from the date the notice of rejection is provided. If **ACADIA's** rejection of **PRODUCT** is accepted or deemed accepted by **BPE** or confirmed by the determination of the third party, then **BPE** shall bear the cost of the replacement **PRODUCT**. If the third party determination does not confirm **ACADIA's** rejection of **PRODUCT**, then **ACADIA** shall bear the cost of any replacement **PRODUCT** along with the cost of rejected **PRODUCT** if **ACADIA** has not previously paid for such **PRODUCT**. If the **PRODUCT** is not replaced within such [...***...] day period described above, and **ACADIA's** rejection of **PRODUCT** is accepted or deemed accepted by **BPE** or confirmed by the determination of the third party, **BPE** shall refund the amount paid by **ACADIA**, on a pro rata basis, for the portion of the **PRODUCT** that is not replaced. For clarity, the foregoing sentence shall not limit **BPE's** obligations to replace such **PRODUCT**. The rights and obligations in this Section 3.4 with respect to any **PRODUCT** shall continue during the term of the Agreement.

- 3.5. Any modification of the production process of the **PRODUCT**, or materials, equipment, or procedures used to manufacture **PRODUCT** [...***...] may only be carried out by **BPE** or its Affiliates with prior written consent of **ACADIA** and in accordance with the quality agreement between the Parties.
- 3.6. **BPE** shall keep and shall ensure that its Affiliates keep complete, accurate, up-to-date, and authentic accounts, notes, data and records of the work performed under this Agreement. Upon **ACADIA's** written request, **BPE** shall allow **ACADIA** to review such records for the purposes of assuring **PRODUCT** quality and compliance with cGMP. **ACADIA** acknowledges that all manufacturing records shall be protected under the confidentiality provisions of Section 7. **BPE** shall have and maintain, or shall procure that its Affiliates have and maintain, during the term of this Agreement all government permits and licenses, including without limitation health, safety and environmental permits, necessary for the conduct of the activities that it undertakes pursuant to this Agreement. **BPE** shall use commercially reasonable efforts to assist **ACADIA** in obtaining regulatory approval of any pharmaceutical product containing **PRODUCT**. **BPE** shall, and shall ensure that its Affiliates, as applicable, agree to reasonably cooperate with any inspection by any regulatory authority. **ACADIA** will reimburse **BPE** for its (or its Affiliates) out-of-pocket costs incurred in connection with any such assistance and cooperation provided under this Section 3.6.

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4. Price and Payment terms

- 4.1 The price is agreed for each PRODUCT in the relevant PRODUCT schedule.
- 4.2 The delivery terms for each **PRODUCT** are agreed upon in the relevant PRODUCT schedule. Risk of loss of, and title to, PRODUCT transfers to ACADIA when the PRODUCT has been delivered in accordance with the agreed upon INCOTERM.
- 4.3 Payment for the amount of PRODUCT actually delivered has to be made after delivery of the applicable PRODUCT and delivery of all documentation to be delivered with respect to the applicable PRODUCT under the Quality Agreement and within [...***...] days net from the date of the written invoice to **ACADIA** (which invoice will be provided on or after delivery of the applicable PRODUCT and documentation), unless the PRODUCT is rejected by ACADIA in good faith within [...***...] days from the date of delivery, provided that, if BPE disagrees in good faith with ACADIA's rejection, payment shall still be required by ACADIA within [...***...] days after ACADIA's receipt of BPE's notice of disagreement. If the applicable COA is not provided with (or prior to the delivery of) the PRODUCT, ACADIA will promptly notify BPE and BPE will send ACADIA the COA.

5. Termination / Cancellations

- 5.1 This Agreement or any of the PRODUCT schedules may be terminated in accordance with the stipulations set forth in Sections 5.2 and 5.3. If **ACADIA** wishes to terminate this Agreement or a PRODUCT schedule, **ACADIA** agrees to pay **BPE** all amounts owing to **BPE** to the date of termination in accordance with the other provisions of this Agreement and the PRODUCT schedules [...***...].
- 5.2 This Agreement or any of the PRODUCT schedules may be terminated immediately by a Party upon written notice to the other Party:
 - 5.2.1. in the event of a material breach of this Agreement by the other Party where such breach is capable of cure and such breach remains uncured [...***...] days after notice of such breach; or
 - 5.2.2. if the other Party shall dissolve or liquidate, or if the other Party shall make an assignment for the benefit of its creditors.
- 5.3 If **ACADIA**, including its affiliates, ceases the development, marketing and sales of the end product processed from a **PRODUCT**, the relevant PRODUCT schedule may be terminated promptly upon written notice from **ACADIA**. In addition, **ACADIA** may terminate this Agreement or any **PRODUCT** schedule upon at least 3 months' prior written notice to **BPE**. In case of termination under this Section 5.3, [...***...].

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5.4. All notices required or permitted hereunder, including notices of termination, shall be in writing and shall be deemed effectively given: (a) upon personal delivery to the Party to be notified, (b) when sent by confirmed email, telex or facsimile if sent during normal business hours of the recipient, if not, then on the next business day, (c) five days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one business day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. The addresses for such communications are:

If to **ACADIA**:

ACADIA Pharmaceuticals GmbH
Pilatusstrasse 41
6003 Lucerne
Switzerland
Facsimile: [...***...]
E-mail: [...***...]
Attn: [...***...]

cc:

ACADIA Pharmaceuticals Inc.
3611 Valley Centre Drive, Suite 300
San Diego, CA 92130
Facsimile: [...***...]
E-mail: [...***...]
Attn: [...***...]

If to **BPE**:

BASF Pharma (Evionnaz) SA
CH- 1902 Evionnaz (VS)
1, Route du Simplon
Facsimile: [...***...]
Attn: [...***...]
E-mail: [...***...]

cc: BASF SE

ZRR – D 100
Carl-Bosch-Str. 38
67056 Ludwigshafen, Germany
Attn: [...***...]
Facsimile: [...***...]

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6. Liability: Allocation and Force Majeure

6.1 Liability

- 6.1.1. **BPE** shall indemnify **ACADIA** and its affiliates and its and their respective directors, officers and employees from and against any and all liabilities, expenses and/or losses, including reasonable legal expenses and reasonable attorneys' fees ("Losses"), incurred by any such indemnified party as a result of any third party claim, demand, action or other proceeding ("Claim") resulting from or arising out of (i) the [...***...] of [...***...], (ii) a [...***...] of [...***...], or (iii) the [...***...] of [...***...], except, in each case, to the extent that a Claim results from or arises out of (a) the negligence or willful misconduct of **ACADIA**, or (b) a breach of **ACADIA**'s obligations, representations, or warranties.
- 6.1.2. **ACADIA** shall indemnify **BPE** and its Affiliates and its and their respective directors, officers and employees from and against any and all Losses incurred by any such indemnified party as a result of any Claim resulting from or arising out of (i) the [...***...] of [...***...], (ii) a [...***...] of [...***...], or (iii) the [...***...] of [...***...], except, in each case, to the extent that a Claim results from or arises out of (a) the negligence or willful misconduct of **BPE**, or (b) a breach of **BPE**'s obligations, representations, or warranties.
- 6.1.3. A party entitled to indemnification under this Section 6 shall give written notice to the indemnifying party of any Claim that may be subject to indemnification promptly after learning of such Claim, and the indemnifying party shall assume the defense of such Claim with counsel reasonably satisfactory to the indemnified party. If such defense is assumed by the indemnifying party with counsel so selected, the indemnifying party will not be subject to any liability for any settlement of such Claim made by the indemnified party without the indemnifying party's consent (but such consent will not be unreasonably withheld or delayed), and will not be obligated to pay the fees and expenses of any separate counsel retained by the indemnified party with respect to such Claim.
- 6.1.4. NOTWITHSTANDING ANY OTHER LANGUAGE HEREIN, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR INCIDENTAL, PUNITIVE, SPECIAL OR CONSEQUENTIAL DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY RIGHTS OR OBLIGATIONS HEREUNDER; provided, however, that this Section 6.1.4 shall not be construed to limit either party's indemnification obligations under Section 6.1.1 or 6.1.2 or liability for breach of Section 7.

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- 6.1.5. Except for any liability arising from gross negligence or wilful misconduct, to the fullest extent permitted by law, and notwithstanding any other provision of this Agreement, BPE's total liability, in the aggregate, for any and all claims and losses occurring in a particular calendar year, including without limitation, attorneys' fees and costs of any nature whatsoever or expenses, resulting from or in any way related to this Agreement from any cause or causes shall not exceed [...***...]. Notwithstanding the foregoing, (a) in no event shall this Section 6.1.5 apply to liability for breach of Section 7; and (b) with respect to BPE's indemnification obligations under 6.1.1, BPE's total liability, in the aggregate, for any and all claims and losses occurring in a particular calendar year shall not exceed [...***...]or [...***...], whichever is greater.
- 6.1.6. Liability for non-conforming Product.
- a) THE LIABILITY OF BPE FOR THE DELIVERY OF PRODUCT NOT COMPLIANT WITH THE WARRANTIES IN SECTION 3.2 (HEREINAFTER "NON-CONFORMING PRODUCT") SHALL BE LIMITED TO THE REPLACEMENT OF THE NON-CONFORMING PRODUCT WITH PRODUCT THAT COMPLIES WITH THE WARRANTIES IN SECTION 3.2 IN ACCORDANCE WITH SECTION 3.4.
 - b) BPE shall bear full manufacturing cost of such replacement, including (i) the purchasing cost of raw materials and (ii) the cost of destruction of any Non-Conforming Product.
 - c) IN THE EVENT THAT BPE IS NOT ABLE TO REPLACE NON-CONFORMING PRODUCT IN ACCORDANCE WITH SECTION 3.4, THEN BPE'S LIABILITY FOR NON-CONFORMING PRODUCTS SHALL BE LIMITED TO REFUNDING THE CONSIDERATION RECEIVED FOR THE NON-CONFORMING PRODUCT DELIVERED IN ACCORDANCE WITH SECTION 3.4.

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- 6.2 Force Majeure
- 6.2.1 Any events and circumstances whose occurrence is beyond the reasonable control of the Parties, such as acts of nature, war, labour disputes, industry-wide shortages of raw materials (that affect suppliers generally and not just BPE) or shortages of power, unavoidable transport and plant stoppages, fire or explosion, order of authority – including where such events make performance of the affected business uneconomical for the foreseeable future –shall discharge the affected Party from liability for failure or delay in performance under this Agreement for the period of interruption and to the extent of their effects from its obligations under this Agreement. Such discharge shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the Party has not caused such event(s) to occur. In a case of force majeure, BPE is not obliged to buy in PRODUCT for delivery from third parties.
- 6.2.2 The affected Party shall promptly notify the other Party of the anticipated duration and extent of the interruption and shall take all reasonable measures to forthwith remedy the interruption. The affected Party shall make reasonable efforts to make good non-performed services within its capacity.
- 6.2.3 Notwithstanding the foregoing, in the event a force majeure event results in a delay or failure in performance by **BPE** of any of its obligations under this Agreement for a period of [...***...] days or more, **ACADIA** shall have the right to terminate this Agreement immediately upon written notice to **BPE** [...***...].

7. Confidentiality

- 7.1 The Parties agree that a Party (hereinafter the **receiving party**) receiving Confidential Information (defined below) of the other Party (hereinafter the **disclosing party**) will (i) maintain in confidence such Confidential Information to the same extent the **receiving party** maintains its own proprietary information of similar kind and value (but at a minimum the **receiving party** shall use commercially reasonable efforts to maintain Confidential Information of the **disclosing party** in confidence), (ii) not disclose such Confidential Information to any third party without prior written consent of the **disclosing party**, except in the case of ACADIA for disclosures made in confidence to any permitted sub licensees or other strategic partners or in connection with financings and (iii) not use Confidential Information of the **disclosing party** for any purpose except those permitted by this Agreement. However, **ACADIA** may disclose Confidential Information received from **BPE** to the appropriate regulatory authorities in connection with obtaining regulatory approval of products containing or based on **PRODUCT**. Each Party may disclose the Confidential Information to its affiliates and its permitted subcontractors who have a need to know such information for purposes of this Agreement, provided that such affiliates and permitted subcontractors are bound by obligations of confidentiality and non-use consistent with those set forth in this Agreement. Each Party shall remain liable to the other

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Party for compliance of its affiliates and permitted subcontractors with the provisions of this Section 7.

Confidential Information of a disclosing party shall mean all confidential or proprietary information of such Party, whether in written form or disclosed orally, visually and/or in other form, disclosed by such Party or any of its affiliates or its or its affiliates' representatives to the receiving party or any of its affiliates. For purposes of clarification, all material and information disclosed by **ACADIA** to **BPE** that directly and specifically relates to **PRODUCT** and all data generated as a result of the manufacture of the **PRODUCT** to the extent they exclusively relate to **PRODUCT** (including, without limitation, all non-severable improvements, as defined below), shall be included within the Confidential Information of **ACADIA**. The **receiving party** shall have no obligation under this Section 7 with respect to any Confidential Information of the other party which the **receiving party** can demonstrate by competent proof:

- a) is in the public domain at the time of disclosure;
- b) is published or otherwise becomes part of the public domain through no fault of the **receiving party**;
- c) is known to the **receiving party**, before receipt thereof under this Agreement;
- d) is disclosed to the **receiving party** without restriction by a third party who has the right to disclose it to the receiving party; or
- e) has been developed independently by the receiving party, without the use of the disclosing party's Confidential Information.

Disclosure of Confidential Information of the **disclosing party** shall not be precluded to the extent such disclosure is in response to a valid order of a court or other governmental body or is required by law or regulation; *provided, however*, that the **receiving party** shall first give reasonable prior notice to the **disclosing party** and thereafter shall cooperate with the **disclosing party's** efforts, if applicable, to obtain a protective order limiting the extent of such disclosure and requiring that the Confidential Information so disclosed be used only for the purposes for which such order was issued or as required by such law or regulation. Any Confidential Information so disclosed shall still remain subject to the obligations of this Section 7.

7.2. This confidentiality obligation will continue for a period of [...***...] years after the termination or expiration date of this Agreement. Neither of the Parties shall be required to disclose to the other Party any information known to be property of, or obtained under obligations of secrecy from a third party.

7.3. The Confidential Information shall be deemed the property of the disclosing party and, upon request, the receiving party will, at the disclosing party's option, either return all Confidential Information in tangible form or destroy all such Confidential Information and certify such destruction in writing to the

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disclosing party. The receiving party is entitled to keep one set of copies of the disclosing party's Confidential Information for archival purposes in its legal department. The receiving party shall not obtain, and shall not attempt to obtain, patent coverage or any other sort of proprietary right on the received Confidential Information or on any invention, substance, or process that could not have been made but for knowledge of the received Confidential Information. Neither Party shall be deemed by this Agreement to have granted to the other Party any right or license under any patent application, issued patent, know-how or other proprietary information of such Party.

7.4 Except as otherwise provided in this Article 7, each Party agrees not to disclose to any third party the existence of this Agreement or the terms of this Agreement without the prior written consent of the other Party hereto, except that each Party may disclose the terms of this Agreement that are not otherwise made public as contemplated by this Section 7.4 as permitted under Section 7.1. Additionally, ACADIA shall have the right, upon consultation with BPE, to issue press releases relating to future events occurring in connection with this Agreement as reasonable determined by ACADIA; subject to ACADIA's confidentiality obligations with respect to BPE's Confidential Information as set forth above. Each Party shall have the right to disclose the terms of this Agreement and any PRODUCT schedules as required by applicable laws and regulations including disclosure requirements of the U.S. Securities and Exchange Commission ("SEC") or any stock exchange on which securities issued by ACADIA or its affiliates are traded. The Parties will coordinate in advance with each other in connection with the filing of this Agreement (including redaction of certain provisions of this Agreement) with the SEC or any stock exchange on which securities issued by a Party or its affiliate are traded, and each Party will use reasonable efforts to seek confidential treatment for the terms proposed to be redacted; provided that each Party will ultimately retain control over what information to disclose to the SEC or any stock exchange as the case may be.

For the avoidance of doubt, ACADIA shall at all times remain the sole and exclusive owner of all right, title and interest in and to the **PRODUCT** (including, without limitation, all intellectual property rights claiming the **PRODUCT** or its manufacture, use or sale). The Parties agree that ACADIA shall be the sole and exclusive owner of any ideas, discoveries, inventions, improvements, innovations and the like (whether or not patentable) developed by BPE or any of its Affiliates during the term of this Agreement to the extent relating to the **PRODUCT** [...***...] ("**non-severable improvements**") and BPE hereby transfers and assigns to ACADIA all right, title and interest in and to the **non-severable improvements**. ACADIA may obtain patent, copyright, and/or other proprietary protection respecting the same **non-severable improvements**, subject to the terms and conditions of this Agreement. At the reasonable request and expense of ACADIA, BPE shall, and shall procure that its Affiliates, at ACADIA's cost, take all actions and execute all documents necessary to transfer, effect, confirm, perfect, record, preserve, protect and enforce ACADIA's rights in all rights, title and interests transferred hereunder. BPE hereby grants, and shall procure that its Affiliates

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grant, ACADIA a non-exclusive, worldwide, perpetual, irrevocable, royalty free license, without the right to sublicense, to use ideas, discoveries, inventions, improvements, innovations and the like (whether or not patentable) developed during the term of this Agreement to the extent relating to the PRODUCT [...***...] (“severable improvements”) developed by BPE or its Affiliates during the term of this Agreement for the purpose of the manufacture of PRODUCT. Additionally, ACADIA has the right to allow a third party manufacturer to make the PRODUCT using those severable improvements developed by BPE or its Affiliates, provided ACADIA notifies BPE of any such manufacturer.

8. Duration of the Agreement

- 8.1 This Agreement shall commence on August 17, 2015 (the “Effective Date”) and shall continue in full force and effect until the end of the fifth full calendar year following the Effective Date (the “Initial Term”). After the Initial Term, the Agreement shall automatically be renewed for successive terms of one (1) year each (the “Renewed Term”). This Agreement may be terminated at the end of the Initial Term or any Renewed Term by the provision of notice in writing from one Party to the other, without having to assign any reasons therefore, which notice shall not be given less than twelve (12) months prior to the end of the Initial Term or the relevant Renewed Term. Each Party may terminate this Agreement or a PRODUCT schedule early as provided in Section 5.
- 8.2 Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. The provisions of Sections 3.3, 3.6, 5, 6, 7, 8 and 9 shall survive any termination or expiration of this Agreement.

9. Applicable Law; Miscellaneous

- 9.1 This Agreement shall be governed by the substantive laws of Switzerland excluding (i) its renvoi provisions on the conflict of laws and (ii) the United Nations Convention on Contracts for International Sale of Goods. Any dispute, controversy or claim, arising out of or in relation to this Agreement, including the validity, invalidity, breach or termination thereof, shall be resolved by arbitration in accordance with the Swiss Rules of International Arbitration of the Swiss Chambers of Commerce in force on the date when the Notice of Arbitration is submitted in accordance with these Rules. The number of arbitrators shall be one. The seat of arbitration shall be [...***...]. The arbitral proceedings shall be conducted in English.
- 9.2 This Agreement shall not be assignable by either Party without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed, except that either Party may make such an assignment without the other Party’s consent to an affiliate or to a successor to

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substantially all of its business to which this Agreement relates, whether in merger, sale of stock, sale of assets or other transaction; provided that with regard to any such transfer to an affiliate, the transferring party will continue to remain liable under this Agreement. This Agreement shall be binding upon and inure to the benefit of the Parties' successors, legal representatives and permitted assigns.

- 9.3 No amendment, modification or waiver of any terms or conditions hereof shall be effective unless made in writing and signed by a duly authorized representative of each Party. In the event of any conflict between this Agreement or the PRODUCT schedule and the Quality Agreement, the Quality Agreement shall control with respect to quality-related matters, and this Agreement and the PRODUCT schedule, as applicable, shall control with respect to all other matters.
- 9.4 The failure of a Party in any one or more instances to insist upon strict performance of any of the terms and conditions of this Agreement shall not constitute a waiver or relinquishment, to any extent, of the right to assert or rely upon any such terms or conditions on any future occasion.
- 9.5 This Agreement (including all exhibits and schedules hereto) embodies the entire, final and complete agreement and understanding between the Parties and replaces and supersedes all prior discussions and agreements between them with respect to the specific subject matter covered hereby.
- 9.6 ACADIA acknowledges that BPE has no control over ACADIA's use or disposition of, or its subsequent processing or admixing of any PRODUCT with other chemicals or materials subsequent to delivery of PRODUCT, and ACADIA assumes the liability and responsibility therefor.
- 9.7 BPE shall remain responsible for the performance by its Affiliates of any of its obligations under this Agreement.
- 9.8 This Agreement may be executed in counterparts, including by transmission of facsimile or PDF copies of signature pages to the Parties or their representative legal counsel, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument. The Parties additionally agree to exchange hard copy signature pages of the Agreement promptly following execution.
- 9.9 BPE represents and warrants that it shall not employ, contract with, or retain any person directly or indirectly to perform any services under this Agreement if such a person (a) is under investigation by the U.S. Food and Drug Administration ("FDA") for debarment or is presently debarred by the FDA pursuant to 21 U.S.C. § 335a or its successor provisions, or (b) has a disqualification hearing pending or has been disqualified by the FDA pursuant to 21 C.F.R. § 312.70 or its successor provisions. In addition, BPE represents and warrants that it has not engaged in any conduct or activity which could lead to any of the above-mentioned disqualification or debarment actions. If, during the term of this Agreement, BPE or any person employed or retained by it to perform under this Agreement (i) comes under investigation by the FDA

for a debarment action or disqualification, (ii) is debarred or disqualified, or (iii) engages in any conduct or activity that could lead to any of the above-mentioned disqualification or debarment actions, BPE shall immediately notify ACADIA of same.

IN WITNESS WHEREOF, the Parties sign, through their authorized representatives, have executed this Agreement in three original sets as of the dates set forth below.

ACADIA Pharmaceuticals GmbH

BASF Pharma (Evionnaz) SA

By: /s/ Glenn F. Baity
Name: Glenn F. Baity
Title: Director

By: /s/ Daniel Lasanow
Name: Daniel Lasanow
Title: Managing Director

Date: 17 August 2015

Date: 17 August 2015

PRODUCT SCHEDULE No 1.

(FOR SUPPLY OF Pimavanserin)

to the Co-operation Agreement with effective date August 17, 2015 entered into between:

- (1) ACADIA Pharmaceuticals GmbH, (“ACADIA”); and
- (2) BASF Pharma (Evionnaz) SA, (“BPE”)

(the “Agreement”)

This Product Schedule is made pursuant to, and is subject to all of the terms and conditions contained in the Agreement. Together, this Product Schedule and the Agreement form a binding agreement between the Parties in relation to the details set out in this Product Schedule.

This Product Schedule consists of the following parts:

1. PART A: Product, Specifications and Manufacturing Program	2
2. PART B: Delivery, Forecasting, Orders and Lead Times	2
3. PART C: Pricing and Payment	3
4. PART D: Special Conditions in addition to the Agreement	4
5. PART E: Term of Product Schedule	5

1. PART A: Product, Specifications and Manufacturing Program

1.1 Product: Pimavanserin

Product Specifications: The PRODUCT specifications have been separately provided by ACADIA to BPE. The PRODUCT specifications may be updated from time to time as agreed by the Parties.

Production Site: BASF Pharma (Evionnaz) SA

Manufacturing Program: Commercial

2. PART B: Delivery, Forecasting, Minimum Orders, Orders and Lead Times

2.1 Delivery Terms (Incoterms 2010): FCA BASF Pharma (Evionnaz) SA facility

2.1.1 Deliverables required to be included with PRODUCT supplied by BPE are described in the quality agreement executed by the Parties.

2.2 Forecasting:

By the [...***...] day of the last month in a given calendar quarter (or by the immediately preceding business day if the [...***...] day of the month is not a business day), ACADIA shall provide BPE with a rolling forecast which will state: (1) the required amounts and delivery dates of the PRODUCT in each month for the immediately subsequent [...***...] month period (the "Initial [...***...] Month Period") and (2) a quarterly estimate of the required amounts for each of the [...***...] quarters following the Initial [...***...] Month Period (such quarterly estimate shall be updated only every [...***...] months) ("Rolling Forecast"). The amount of the PRODUCT stated for the first [...***...] months of each Rolling Forecast ("Binding Part") shall be binding upon both ACADIA and BPE, and the subsequent quarterly estimates of each Rolling Forecast shall be non-binding and for the purpose of reference only.

ACADIA is aware that in case of orders in a [...***...] month period over [...***...], a new batch size shall have to be revalidated.

2.3 Minimum Orders

There will be no minimum quantity of PRODUCT to be ordered yearly. Each Firm PO (as defined below) shall however provide a minimum quantity equal to no less than [...***...] of the validated batch size of the final process step ([...***...]). The current batch size is approximately [...***...].

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2.5 Lead Times:

In accordance with the Binding Part set forth on the applicable Rolling Forecast, ACADIA shall deliver firm purchase orders for the PRODUCT to BPE at least [...***...] prior to the requested delivery date(s) of the PRODUCT to ACADIA (the "Firm POs"). Such Firm POs shall specify at a minimum: (i) the quantity of required PRODUCTS, (ii) the requested delivery dates for such specified quantities, and, (iii) the place of delivery. Upon receipt of such Firm POs, BPE shall promptly acknowledge such receipt in writing. BPE shall supply all PRODUCTS ordered in Firm POs in accordance with this Agreement and the Firm PO. Should ACADIA order a quantity in excess of the forecasted amount in the Binding Part of a Rolling Forecast, BPE shall use its commercially reasonable efforts to meet ACADIA's demand that exceeds the forecasted amount. ACADIA shall not have any recourse to BPE, and BPE shall not be liable to ACADIA in the event the demand above the forecasted quantity in the Binding Part of a Rolling Forecast cannot be produced in the time requested.

3. PART C: Pricing and Payment

3.1 Price

[...***...]

All PRODUCT prices as set forth in the table above ("Prices") are calculated based on volume of PRODUCT ordered in each Firm PO.

All Prices shall be [...***...], and any [...***...].

At either Party's request, BPE and ACADIA will jointly review cost saving factors at the end of each calendar year, in relation to BPE's or ACADIA's investments and

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make any necessary adjustments to the price with regard to the benefits coming from such cost savings. In principle, any cost saving arising out of any investment made by a Party shall be passed along to the Party responsible for cost savings.

In the event of any substantial increase [...***...] in the manufacturing cost of the PRODUCT, such as prices of raw materials, energy or utilities, the Parties shall [...***...] forthwith meet and negotiate in good faith to mutually agree on a revision to the Price consistent with the substantial increase in manufacturing cost of the PRODUCT. BPE agrees to provide supporting information and documentation as reasonably requested by ACADIA to evidence such substantial increase in manufacturing costs. BPE shall have the right to request negotiations as described in this paragraph no more than once per calendar year during the term of this PRODUCT Schedule. The parties will both use commercially reasonable efforts to reach agreement on the revision to the Price within [...***...] after receipt by ACADIA of the request and such information and documentation.

3.2 Invoice Currency

CHF

Bank account:

Payment shall be made to account stated on the invoice. Invoices shall be paid in accordance with the terms set forth in the Agreement, notwithstanding anything to the contrary indicated on the invoice provided.

4. PART D: [...***...] Special Conditions in addition to the Agreement

If ACADIA terminates the Agreement or this Product Schedule other than in accordance with Section 5.2 or Section 6.2.3 of the Agreement, then ACADIA shall pay [...***...] the out-of-pocket cost of all purchased and non-returnable or refundable raw-materials purchased before BPE's receipt of ACADIA's notice of termination [...***...]

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[...***...]

If ACADIA is [...***...], BPE shall [...***...] in accordance with this PRODUCT schedule and the Agreement [...***...].

5. PART E: Term of Product Schedule

This Product Schedule shall commence on August 17, 2015 (the "Effective Date") and shall continue in full force and effect until the end of the fifth full calendar year following the Effective Date (the "Initial Term"). After the Initial Term, the Product Schedule shall automatically be renewed for successive terms of one (1) year each (the "Renewed Term"). This Product Schedule may be terminated at the end of the Initial Term or any Renewed Term by the provision of notice in writing from one Party to the other, without having to assign any reasons therefore, which notice shall not be given less than six (6) months prior to the end of the Initial Term or the relevant Renewed Term. The Product Schedule may be terminated earlier subject to and in accordance with the terms and conditions contained in the Agreement.

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Execution

THIS PRODUCT SCHEDULE IS EXECUTED by the authorised representatives of the Parties as of the date last written below.

SIGNED for and on behalf of
ACADIA Pharmaceuticals GmbH

SIGNED for and on behalf of
BASF Pharma (Evionnaz) SA

/s/ Glenn F. Baity

/s/ Daniel Lasanow

Signature

Signature

Name: Glenn F. Baity
Title: Director

Name: Daniel Lasanow
Title: Managing Director

Date: 17 August 2015

Date: 17 August 2015

CERTIFICATION
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Stephen R. Davis, certify that:

1. I have reviewed this quarterly report on Form 10-Q of ACADIA 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. I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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 my 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 that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on my 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.

Date: November 5, 2015

/s/ STEPHEN R. DAVIS

Stephen R. Davis
Chief Executive Officer
(Registrant's Principal Executive,
Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the quarterly report of ACADIA Pharmaceuticals Inc. (the "Company") on Form 10-Q for the period ended September 30, 2015, as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, Stephen R. Davis, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"); and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Date: November 5, 2015

/s/ STEPHEN R. DAVIS

Stephen R. Davis
Chief Executive Officer
(Registrant's Principal Executive,
Financial and Accounting Officer)

This certification shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of Section 18 of the Exchange Act. Such certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.