ACADIA PHARMACEUTICALS INC
Form 10-Q
November 05, 2015
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

x **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	**06-1376651**
(State of Incorporation)	**(I.R.S. Employer Identification No.)**

3611 Valley Centre Drive, Suite 300

San Diego, California	**92130**
(Address of Principal Executive Offices)	**(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 x 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 x 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 x	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 x

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

Class	**Number of Shares Outstanding**
Common Stock, $0.0001 par value	100,911,625

Table of Contents

ACADIA PHARMACEUTICALS INC.

FORM 10-Q

TABLE OF CONTENTS

Table of Contents

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	$ 245,320	$ 325,458
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	$	245,320	$	325,458

(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.

Table of Contents

ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
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	39,037	25,009	119,091	64,748
Loss from operations	(38,998)	(24,994)	(119,047)	(64,676)
Interest income, net	92	208	388	567
Net loss	$ (38,906)	$ (24,786)	$ (118,659)	$ (64,109)
Net loss per common share, basic and diluted	$ (0.39)	$ (0.25)	$ (1.18)	$ (0.66)
Weighted average common shares outstanding, basic and diluted	100,756	99,497	100,436	97,210

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

Table of Contents

ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

(Unaudited)

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

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

Table of Contents

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	(87,073)	(48,633)
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	90,845	(127,749)
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	5,170	201,044
Effect of exchange rate changes on cash	3	
Net increase in cash and cash equivalents	8,945	24,662
Cash and cash equivalents		
Beginning of period	61,854	11,707

End of period	$ 70,799	$ 36,369
Supplemental schedule of noncash investing activities		
Property and equipment purchases in accounts payable and accrued liabilities	$ 186	$

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

Table of Contents

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
	12,352	9,753	11,604	9,699

Table of Contents

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
	$ 15,531	$ 13,818

5. Investment Securities

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

	September 30, 2015			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury notes	$ 8,999	$ 5	$	$ 9,004
Government sponsored enterprise securities	160,857	31		160,888
	$ 169,856	$ 36	$	$ 169,892

	December 31, 2014			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value

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
	$ 260,647	$ 32	$ (47)	$ 260,632

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.

Table of Contents

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	
	$ 240,215	$ 57,028	$ 183,187	$

		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	
	$ 322,055	$ 51,173	$ 270,882	$

Table of Contents

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.

Table of Contents

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.

Table of Contents

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, estim should, would, continue, seeks, aims, projects, predicts, pro forma, anticipates, potential or simila 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-HT2A 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.

Table of Contents

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	$ 18,729	$ 16,952	$ 53,403	$ 42,420

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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):

	Total	Less than 1 Year	1-3 Years	4-5 Years	After 5 Years
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 .

15

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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

Table of Contents

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

Table of Contents

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 of 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,

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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

Table of Contents

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

Table of Contents

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.

Table of Contents

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

Table of Contents

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

Table of Contents

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.

Table of Contents

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.

Table of Contents

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

Table of Contents

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 under Section 404 of SOX with our Annual Report. In the future, if we are not able to issue 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.

Table of Contents

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

Table of Contents

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

Table of Contents

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

Table of Contents

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.

Table of Contents

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.

Table of Contents

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;

Table of Contents

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;

Table of Contents

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.

Table of Contents

ITEM 6. EXHIBITS

Exhibit Number	Description
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).
10.1[a]	Master Manufacturing Services Agreement and Product Agreement, dated August 3, 2015, by and between the Registrant and Patheon Pharmaceuticals Inc.
10.2[a]	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).
10.3[b]	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.

43

Table of Contents

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.

ACADIA Pharmaceuticals Inc.

Date: November 5, 2015

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)