ACADIA PHARMACEUTICALS INC
Form 10-Q
May 06, 2014
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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 March 31, 2014

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	**(I.R.S. Employer**
Incorporation)	**Identification No.)**

11085 Torreyana Road, Suite 100

San Diego, California	**92121**
(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 April 30, 2014:

Class	**Number of Shares Outstanding**
Common Stock, $0.0001 par value	98,976,326

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ACADIA PHARMACEUTICALS INC.

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except for par value and share data)

(Unaudited)

	March 31, 2014	December 31, 2013 (1)
Assets		
Cash and cash equivalents	$ 96,455	$ 11,707
Investment securities, available-for-sale	272,830	174,083
Interest and other receivables	1,642	750
Prepaid expenses	1,893	1,820
Total current assets	372,820	188,360
Property and equipment, net	543	579
Other assets	143	179
Total assets	$ 373,506	$ 189,118
Liabilities and stockholders equity		
Accounts payable	$ 1,562	$ 372
Accrued expenses	6,429	6,552
Deferred revenue	42	55
Total current liabilities	8,033	6,979
Long-term liabilities	13	8
Total liabilities	8,046	6,987
Commitments and contingencies (Note 9)		
Stockholders equity		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized at March 31, 2014 and December 31, 2013; no shares issued and outstanding at March 31, 2014 and December 31, 2013		
Common stock, $0.0001 par value; 150,000,000 shares authorized at March 31, 2014 and December 31, 2013; 98,835,635 shares and 91,102,618 shares issued and outstanding at March 31, 2014 and December 31, 2013, respectively	10	9

Additional paid-in capital	788,946	587,742
Accumulated deficit	(423,496)	(405,668)
Accumulated other comprehensive income		48
Total stockholders equity	365,460	182,131
Total liabilities and stockholders equity	$ 373,506	$ 189,118

(1) The condensed consolidated balance sheet at December 31, 2013 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.

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ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(Unaudited)

	Three Months Ended March 31,	
	2014	**2013**
Revenues		
Collaborative revenues	$ 30	$ 417
Operating expenses		
Research and development (includes stock-based compensation of $1,006 and $254, respectively)	11,668	4,430
General and administrative (includes stock-based compensation of $2,156 and $328, respectively)	6,320	2,151
Total operating expenses	17,988	6,581
Loss from operations	(17,958)	(6,164)
Interest income, net	130	41
Net loss	$ (17,828)	$ (6,123)
Net loss per common share, basic and diluted	$ (0.19)	$ (0.08)
Weighted average common shares outstanding, basic and diluted	92,968	78,748

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

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ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

(Unaudited)

	Three Months Ended March 31,	
	2014	**2013**
Net loss	$ (17,828)	$ (6,123)
Other comprehensive loss:		
Unrealized gain (loss) on investment securities	(48)	11
Comprehensive loss	$ (17,876)	$ (6,112)

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

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ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(Unaudited)

	Three Months Ended March 31,	
	2014	**2013**
Cash flows from operating activities		
Net loss	$ (17,828)	$ (6,123)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	3,162	582
Amortization of premiums on investment securities	311	145
Depreciation	43	12
Other		(7)
Changes in operating assets and liabilities:		
Interest and other receivables	(892)	(180)
Prepaid expenses	(73)	(761)
Other assets	36	
Accounts payable	1,190	21
Accrued expenses	(123)	20
Deferred revenue	(13)	(294)
Long-term liabilities	5	
Net cash used in operating activities	(14,182)	(6,585)
Cash flows from investing activities		
Purchases of investment securities	(150,921)	(54,867)
Maturities of investment securities	51,815	21,773
Purchases of property and equipment	(6)	
Proceeds from sales of property and equipment		8
Net cash used in investing activities	(99,112)	(33,086)
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	198,042	208
Net cash provided by financing activities	198,042	208
Net increase (decrease) in cash and cash equivalents	84,748	(39,463)
Cash and cash equivalents		
Beginning of period	11,707	57,899

End of period	$ 96,455	$ 18,436

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

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ACADIA PHARMACEUTICALS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2014

(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, 2013 included in the Company s Annual Report on Form 10-K (Annual Report) filed with the Securities and Exchange Commission (the 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 March 31, 2014, the Company had an accumulated deficit of $423.5 million. The Company expects to continue to incur operating losses for at least the next several years as it pursues the development and commercialization of its product candidates.

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 and regulatory 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. Until the Company can generate significant continuing revenues, 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 on less favorable terms than it would otherwise choose.

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2. Earnings (Loss) Per Share

Basic earnings (loss) per common share is computed by dividing net income (loss) by the weighted average number of common shares outstanding for the period. Diluted earnings (loss) per common share is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period, increased to include potential dilutive common shares that were outstanding during the period. The effect of outstanding stock options and warrants is reflected, when dilutive, in diluted earnings per common share by application of the treasury stock method. The Company has excluded all outstanding stock options and warrants from the calculation of diluted net loss per common share because all such securities are antidilutive for all periods presented.

Shares used in calculating basic and diluted net loss per common share exclude these potential common shares (in thousands):

	Three Months Ended March 31,	
	2014	2013
	(unaudited)	
Antidilutive options to purchase common stock	7,679	6,993
Antidilutive warrants to purchase common stock	1,966	3,725
	9,645	10,718

3. Stock-Based Compensation

The fair value of each stock option and each employee stock purchase plan right granted is estimated on the grant date under the fair value method using the Black-Scholes valuation model. The estimated fair values of the stock option or purchase plan rights, including the effect of estimated forfeitures, are then expensed over the vesting period. The Company recognized stock-based compensation expense of $3.2 million and $582,000 during the three months ended March 31, 2014 and 2013, respectively. In January 2014, the Company announced that its Chief Financial Officer intended to retire from the Company no later than mid-year 2014. On March 7, 2014, the Board of Directors approved modifications to the Chief Financial Officer s outstanding stock options. On April 9, 2014, the Chief Financial Officer informed the Company that he would retire on April 18, 2014. Stock-based compensation expense for the three months ended March 31, 2014 included $531,000 related to the modification of the stock options held by the Chief Financial Officer. The Company will record stock-based compensation expense of $1.1 million during the three months ending June 30, 2014 related to the modification of these stock options. As of March 31, 2014, total unrecognized compensation cost related to stock options and purchase plan rights was approximately $35.2 million, which is expected to be recognized over a weighted-average period of 3.0 years.

4. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2014	December 31, 2013

	(unaudited)	
Accrued research and development services	$ 4,307	$ 4,207
Accrued compensation and benefits	1,265	1,865
Accrued professional fees	753	308
Other	104	172
Total	$ 6,429	$ 6,552

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5. Investment Securities

Investment securities, including investment securities available-for-sale and investment securities classified as cash equivalents, consisted of the following (in thousands):

	March 31, 2014			
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Estimated Fair Value
	(unaudited)			
U.S. Treasury notes	$ 2,744	$ 5	$	$ 2,749
Government sponsored enterprise securities	119,507	37	(15)	119,529
Corporate debt securities	130,866	3	(47)	130,822
Commercial paper	22,484	14		22,498
	$ 275,601	$ 59	$ (62)	$ 275,598

	December 31, 2013			
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Estimated Fair Value
U.S. Treasury notes	$ 2,743	$ 4	$	$ 2,747
Government sponsored enterprise securities	78,537	28	(5)	78,560
Corporate debt securities	65,290	1	(9)	65,282
Commercial paper	27,468	26		27,494
	$ 174,038	$ 59	$ (14)	$ 174,083

The Company has classified all of its investment securities available-for-sale, including those with maturities beyond one year, as current assets on the consolidated balance sheets based on the highly liquid nature of the investment securities and because these investment securities are considered available for use in current operations. As of March 31, 2014 and December 31, 2013, the Company held $64.3 million and $33.5 million, respectively, of available-for-sale investment securities with contractual maturity dates more than one year and less than two years.

6. Fair Value Measurements

As of March 31, 2014, the Company held $369.2 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 corporations, financial institutions and government sponsored enterprises. The Company has adopted an investment policy and established 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 and the Company s investment securities classified as Level 2 are valued using other observable inputs such as recent trades for the securities or similar securities, interest rates on similar securities, or yield curves or benchmark interest rates observable at commonly quoted intervals. 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. No other-than-temporary impairments were identified for the investment securities held by the Company as of March 31, 2014 or December 31, 2013.

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

	March 31, 2014	Fair Value Measurements at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
		(unaudited)		
Money market fund	$ 93,625	$ 93,625	$	$
U.S. Treasury notes	2,749	2,749		
Government sponsored enterprise securities	119,529		119,529	
Corporate debt securities	130,822		130,822	
Commercial paper	22,498		22,498	
	$ 369,223	$ 96,374	$ 272,849	$

	December 31, 2013	Fair Value Measurements at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market fund	$ 11,748	$ 11,748	$	$
U.S. Treasury notes	2,747	2,747		
Government sponsored enterprise securities	78,560		78,560	
Corporate debt securities	65,282		65,282	
Commercial paper	27,494		27,494	
	$ 185,831	$ 14,495	$ 171,336	$

7. Stockholders Equity

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. Collaborative Research and Licensing Agreements

The Company has been a party to three collaboration agreements with Allergan, Inc. The March 2003 research collaboration originally provided for a three-year research term, which was extended by the parties through March 2013. Pursuant to this agreement, the Company received an aggregate of $19.5 million in payments, consisting of an upfront payment, research funding and related fees, through the conclusion of the collaboration in March 2013. The Company s two ongoing collaboration agreements with Allergan involve the development of product candidates in the areas of glaucoma and chronic pain. Additional payments under these agreements, other than payments for a portion of patent costs for the ongoing collaborations, are dependent upon the successful advancement of an applicable product candidate. Under the glaucoma collaboration, the Company had received an aggregate of $9.9 million in payments as of March 31, 2014, and is eligible to receive up to an aggregate of approximately $15 million in additional payments per product upon the achievement of development and regulatory milestones. Under the chronic pain collaboration, the Company had received an aggregate of $10.5 million in payments as of March 31, 2014, and is eligible to receive up to an aggregate of $10 million in additional payments upon the achievement of development and regulatory milestones. The Company also is eligible to receive royalties on future product sales worldwide, if any, under each of the two ongoing collaboration agreements with Allergan. The Company recognized revenues, consisting of research funding and related fees, from its collaboration agreements with Allergan of $8,000 and $287,000 during the three months ended March 31, 2014 and 2013, respectively.

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9. Commitments and Contingencies

The Company has entered into agreements with contract research organizations and other external service providers primarily for services in connection with the development of its product candidates. The Company was contractually obligated for up to approximately $20.8 million of future services under these agreements as of March 31, 2014. The nature of the work being conducted under the Company s agreements with contract research organizations 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.

10. Recent Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board issued authoritative guidance regarding the presentation of unrecognized tax benefits when a net operating loss carryforward exists. This authoritative guidance amends current guidance. The amended guidance clarifies that an unrecognized tax benefit, or a portion of an unrecognized tax benefit, should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward if such settlement is required or expected in the event the uncertain tax position is disallowed. In situations where a net operating loss carryforward, a similar tax loss, or a tax credit carryforward is not available at the reporting date under the tax law of the applicable jurisdiction or the tax law of the jurisdiction does not require, and the entity does not intend to use, the deferred tax asset for such purpose, the unrecognized tax benefit should be presented in the financial statements as a liability and should not be combined with deferred tax assets. This amended guidance is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013. The adoption of this accounting guidance did not have an impact on the Company s consolidated financial statements.

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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, 2013 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, product candidates, proprietary and external programs, financial condition and resources, and other statements that are not historical facts, including statements which may be preceded by the words believes, expects, hopes, may, will, plans, intends, estimates, could, should, seeks, aims, projects, predicts, pro forma, anticipates, potential or similar words. For such statements, we c 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 are 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 medicines that address unmet medical needs in neurological and related central nervous system disorders. We have a pipeline of product candidates led by pimavanserin, which is in Phase III development for Parkinson s disease psychosis and has the potential to be the first drug approved in the United States for this disorder. Pimavanserin is also in Phase II development for Alzheimer s disease psychosis and has successfully completed a Phase II trial as a co-therapy for schizophrenia. We hold worldwide commercialization rights to pimavanserin. Our pipeline also includes clinical-stage programs for chronic pain and glaucoma in collaboration with Allergan, and two advanced preclinical programs directed at Parkinson s disease and other neurological disorders. All of our product candidates are small molecules that emanate from internal discoveries.

We are pursuing Parkinson s disease psychosis as our lead indication for pimavanserin. We have completed a successful pivotal Phase III trial with pimavanserin in patients with Parkinson s disease psychosis, the -020 Study. Following this study, we met with the U.S. Food and Drug Administration, or FDA, and announced that the agency agreed that the data from the -020 Study, together with supportive data from our other studies with pimavanserin, are sufficient to support the filing of a New Drug Application, or NDA, for the treatment of Parkinson s disease psychosis. We are currently completing the remaining aspects of our development program that are needed for submission of this NDA. Subject to changes that could result from future interactions with the FDA or other developments, we are planning to submit the NDA near the end of 2014. If approved, we intend to commercialize pimavanserin for this indication in the United States by establishing a specialty sales force. We believe that pimavanserin also has the potential to address a range of other neurological and psychiatric disorders, including Alzheimer s disease psychosis and schizophrenia. We are currently conducting a Phase II trial to examine the efficacy and safety of pimavanserin as a treatment for patients with Alzheimer s disease psychosis. We have completed a successful Phase II trial with pimavanserin as a co-therapy for schizophrenia and we are currently planning additional studies for this indication.

We have incurred substantial operating losses since our inception due in large part to expenditures for our research and development activities. As of March 31, 2014, we had an accumulated deficit of $423.5 million. We expect to continue to incur operating losses for at least the next several years as we pursue the development and commercialization of our product candidates.

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.

Recent Developments

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

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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. As of March 31, 2014, we had received an aggregate of $115.7 million in payments under these agreements, including upfront payments, research funding, milestone payments, and reimbursed development expenses. Until such time as we may complete development of, receive regulatory approval for, and generate product sales from pimavanserin or other products, we expect our revenues to be derived primarily from payments under our current agreements with Allergan and potential additional collaborations, as well as grant funding.

We have been a party to three collaboration agreements with Allergan, one of which concluded in March 2013. Our two ongoing collaboration agreements with Allergan involve the development of product candidates in the areas of chronic pain and glaucoma. We are eligible to receive payments upon achievement of development and regulatory milestones, as well as royalties on future product sales, if any, under each of our ongoing collaboration agreements with Allergan. However, we no longer receive research funding from these agreements and additional payments, other than payments for a portion of patent costs for our ongoing collaborations, are dependent upon the advancement of an applicable product candidate. Each of our current agreements with Allergan 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, pimavanserin. We currently are responsible for all costs incurred in the development of pimavanserin as well as for the costs associated with our other internal programs. We are not responsible for, nor have we incurred, development expenses in our collaborative programs for chronic pain and glaucoma, which we are pursuing with Allergan.

We use external service providers to manufacture our product candidates and for the majority of the services performed in connection with the preclinical and clinical development of our product candidates. 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 months ended March 31, 2014 and 2013 (in thousands):

	Three Months Ended March 31,	
	2014	2013
	(unaudited)	
Costs of external service providers:		
Pimavanserin	$ 8,095	$ 2,674
Other programs	105	177
Subtotal	8,200	2,851

Internal costs	2,462	1,325
Stock-based compensation	1,006	254
Total research and development	$ 11,668	$ 4,430

While we intend to submit an NDA to the FDA for our lead program with pimavanserin near the end of 2014, at this time, due to the risks inherent in completing the development activities necessary to support the NDA and in regulatory and approval processes, we are unable to estimate with any certainty the costs we will incur for the continued development of pimavanserin for Parkinson s disease psychosis. 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 or for the development of our other product candidates. 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 advancing the development of pimavanserin, 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 each product candidate s commercial potential and our financial position. We cannot forecast with any degree of certainty which product candidates 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 continue to be substantial and to increase in future periods as we pursue the development of pimavanserin, including development and regulatory activities in our Phase III Parkinson s disease psychosis

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program, development activities in our Phase II Alzheimer s disease psychosis program, and potential studies in other indications, including schizophrenia, and the development of our other product candidates. The lengthy process of completing clinical trials and supporting development activities and seeking regulatory approval for our product candidates 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, during 2013 and early 2014, we established our core commercial organization that will help us prepare for the planned future launch of pimavanserin. We expect our general and administrative expenses to increase in future periods to support our planned development and commercial activities for pimavanserin and other product candidates.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements. We have identified the accounting policies that we believe require application of management s most subjective judgments, often requiring the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Our actual results may differ substantially from these estimates under different assumptions or conditions.

Revenue Recognition

We recognize revenues in accordance with authoritative guidance established by U.S. Generally Accepted Accounting Principles, or GAAP. Our revenues are primarily related to our collaboration agreements, which may provide for various types of payments to us, including upfront payments, funding of research and development, milestone payments, and licensing fees. Our collaboration agreements also include potential payments for product royalties; however, we have not received any product royalties to date.

We consider a variety of factors in determining the appropriate method of accounting under our collaboration agreements, including whether the various elements can be separated and accounted for individually as separate units of accounting. Where there are multiple deliverables identified within a collaboration agreement that are combined into a single unit of accounting, revenues are deferred and recognized over the expected period of performance. The specific methodology for the recognition of the revenue is determined on a case-by-case basis according to the facts and circumstances of the applicable agreement.

Upfront, non-refundable payments that do not have stand-alone value are recorded as deferred revenue once received and recognized as revenues over the expected period of performance. Revenues from non-refundable license fees are recognized upon receipt of the payment if the license has stand-alone value, we do not have ongoing involvement or obligations, and we can determine the best estimate of the selling price for any undelivered items. When non-refundable license fees do not meet all of these criteria, the license revenues are recognized over the expected period of performance. Non-refundable payments for research funding are generally recognized as revenues over the period the related research activities are performed. Payments for reimbursement of external development costs are generally recognized as revenues using a contingency-adjusted performance model over the expected period of

performance. Payments received from grants are recognized as revenues as the related research and development is performed and when collectability is reasonably assured.

We evaluate milestone payments on an individual basis and recognize revenues from non-refundable milestone payments when the earnings process is complete and collectability is reasonably assured. Non-refundable milestone payments related to arrangements under which we have continuing performance obligations are recognized as revenues upon achievement of the associated milestone, provided that (i) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement and (ii) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with the milestone event. Where separate milestone payments do not meet these criteria, we recognize revenue using a contingency-adjusted performance model over the expected period of performance.

Accrued Expenses

We are required to estimate accrued expenses as part of our process of preparing financial statements. Examples of areas in which subjective judgments may be required include, among other things, costs associated with services provided by contract organizations for preclinical development, manufacturing of our product candidates, and clinical trials. We accrue for costs incurred as the services are being provided by monitoring the status of the trial or services provided, and the invoices received from our external service providers. In the case of clinical trials, a portion of the estimated cost normally relates to the projected cost to treat a patient in the trials, and this cost is recognized based on the number of patients enrolled in the trial. Other indirect costs are generally recognized

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on a straight-line basis over the estimated period of the study. As actual costs become known to us, we adjust our accruals. To date, our estimates have not differed materially from the actual costs incurred. However, subsequent changes in estimates may result in a material change in our accruals, which could also materially affect our balance sheet and results of operations.

Stock-Based Compensation

The fair value of each employee stock option and each employee stock purchase plan right granted is estimated on the grant date under the fair value method using the Black-Scholes model, which requires us to make a number of assumptions including the estimated expected life of the award and related volatility. The estimated fair values of stock options or purchase plan rights, including the effect of estimated forfeitures, are then expensed over the vesting period.

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 received pursuant to our current and potential future collaborations, the progress and timing of expenditures related to our development and commercialization efforts, and the extent to which we generate revenues from product sales, if any. Due to these fluctuations, we believe that the period-to-period comparisons of our operating results are not a good indication of our future performance.

Comparison of the Three Months Ended March 31, 2014 and 2013

Revenues

Revenues decreased to $30,000 for the three months ended March 31, 2014 from $417,000 for the three months ended March 31, 2013, primarily due to the conclusion of our 2003 research collaboration with Allergan in March 2013. Revenues from our collaborations with Allergan totaled $8,000 for the three months ended March 31, 2014 compared to $287,000 for the three months ended March 31, 2013. Future revenues from our two ongoing collaboration agreements with Allergan are dependent upon the advancement of our applicable product candidates and we do not expect to receive significant revenues from these agreements unless and until a product is successfully developed and commercialized. Revenues recognized from our agreements with other parties decreased to $22,000 for the three months ended March 31, 2014, from $130,000 for the three months ended March 31, 2013, due to decreased activities under our research grants.

Research and Development Expenses

Research and development expenses increased to $11.7 million for the three months ended March 31, 2014, including $1.0 million in stock-based compensation expense, from $4.4 million for the three months ended March 31, 2013, including $254,000 in stock-based compensation expense. This increase was primarily due to an increase of $5.3 million in external service costs as well as an increase in costs associated with our expanded research and development organization, including $1.0 million in increased personnel costs, and $752,000 in increased stock-based compensation expense. External service costs totaled $8.2 million, or 70 percent of our research and development expenses for the three months ended March 31, 2014, compared to $2.9 million, or 64 percent of our research and development expenses, for the three months ended March 31, 2013. The increase in external service costs during the

three months ended March 31, 2014 was primarily attributable to increased development costs incurred in our Phase III program for pimavanserin. We expect our research and development expenses to increase in future periods as we continue to pursue the development of pimavanserin, including our Phase III Parkinson s disease psychosis program, our Phase II trial for Alzheimer s disease psychosis, and potential studies in other indications, including schizophrenia, as well as the development of our other product candidates.

General and Administrative Expenses

General and administrative expenses increased to $6.3 million for the three months ended March 31, 2014, including $2.2 million in stock-based compensation expense, from $2.2 million for the three months ended March 31, 2013, including $328,000 in stock-based compensation expense. The increase in general and administrative expenses was primarily due to an increase in costs associated with our expanded administrative organization, including $1.8 million in increased stock-based compensation and $1.0 million in increased personnel expenses, as well as an increase of $1.1 million in external service costs. The increase in external service costs was largely attributable to increased professional fees related to our pre-commercial activities. We anticipate that our general and administrative expenses will increase in future periods to support our planned development and commercial activities for pimavanserin.

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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. As of March 31, 2014, we had received $749.5 million in net proceeds from sales of our equity securities, including $6.9 million in debt that we had retired through the issuance of our common stock, $115.7 million in payments from collaboration agreements, $22.4 million in debt financing, and $22.7 million in interest income.

At March 31, 2014, we had $369.3 million in cash, cash equivalents, and investment securities compared to $185.8 million at December 31, 2013. We anticipate that the level of cash used in our operations will increase in future periods in order to fund our ongoing and planned development and commercial activities for pimavanserin. We expect that our cash, cash equivalents, and investment securities will be greater than $300 million at December 31, 2014, and that our cash resources will be sufficient to fund our operations at least into 2017.

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 development and pre-commercialization activities for pimavanserin and other research and development programs;
- the costs of preparing applications for regulatory approvals for our product candidates;
- our ability to obtain regulatory approval for, and generate product sales from, our products;
- the costs of establishing, or contracting for, sales and marketing capabilities for our product candidates;
- the scope, prioritization and number of research and development programs;
- the ability of our collaborators and us to reach the milestones or other events or developments triggering payments under our collaboration and licensing 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 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 product candidates.

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through strategic collaborations, public or private sales of our equity securities, debt financings, grant funding, or by licensing all or a portion of our product candidates or technology. We cannot be certain that adequate future funding will be available to us on acceptable terms, or at all. 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 financing in the future. In particular, any unfavorable development in our pimavanserin program could have a material adverse effect on our ability to raise additional capital.

If we need 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 corporations, financial institutions and government sponsored enterprises. We have adopted an investment policy and established 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 disruption in the credit markets that has occurred in the past. However, if there is future disruption in the credit markets, there can be no assurance that our investment portfolio will not be adversely affected in the future.

Net cash used in operating activities increased to $14.2 million for the three months ended March 31, 2014 from $6.6 million for the three months ended March 31, 2013. This increase was primarily due to the increase in our net loss, offset by an increase of $2.6 million in non-cash, stock-based compensation expense, as well as by changes in our operating assets and liabilities, including accounts payable and accrued expenses. Accounts payable and accrued expenses increased by an aggregate of $1.1 million for the three months ended March 31, 2014 compared to an aggregate increase of $41,000 for the three months ended March 31, 2013. This increase was primarily due to increased external service costs incurred in our development and pre-commercial activities, the timing and amount of which may fluctuate significantly from period to period.

Net cash used in investing activities totaled $99.1 million for the three months ended March 31, 2014 compared to $33.1 million for the three months ended March 31, 2013. Net cash used in investing activities has fluctuated significantly from period to

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period primarily due to the timing of purchases of investment securities. The increase in net cash used in investing activities for the three months ended March 31, 2014 relative to the comparable period of 2013 was primarily due to increased purchases of investment securities relative to maturities of investment securities.

Net cash provided by financing activities increased to $198.0 million for the three months ended March 31, 2014 compared to a nominal amount for the three months ended March 31, 2013. The net cash provided by financing activities for the three months ended March 31, 2014 was primarily attributable to $196.8 million in net proceeds received from our public offering of common stock in March 2014.

The following table summarizes our contractual obligations at March 31, 2014 (in thousands):

	Total	Less than 1 Year	1-3 Years	4-5 Years	After 5 Years
Operating leases	$ 2,113	$ 858	$ 1,255	$	$

We also have entered into agreements with contract research organizations and other external service providers for services, primarily in connection with the development of our product candidates. We were contractually obligated for up to approximately $20.8 million of future services under these agreements as of March 31, 2014. The nature of the work being conducted under our agreements with contract research organizations 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 pimavanserin. If certain conditions are met, we would be required to make future payments, including milestones, sublicensing fees, and royalties. The amount of potential future milestone payments is $10.5 million in the aggregate, which would be offset by any sublicensing fees we may pay under the agreement. Because these milestone payments would only be payable upon the achievement of specified regulatory events and it is uncertain when, or if, such events will occur, we cannot forecast with any degree of certainty when, or if, we will be required to make payments under the agreement. 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 10 Recent Accounting Pronouncements .

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We invest our excess cash in investment-grade, interest-bearing securities. The primary objective of our investment activities is to preserve principal and liquidity. To achieve this objective, we invest in a money market fund, U.S. Treasury notes, and high quality marketable debt instruments of corporations, financial institutions and government sponsored enterprises with contractual maturity dates of generally less than two years. All investment securities have a credit rating of at least A3/A- or better, or P-1/A-1 or better, as determined by Moody s Investors Service or Standard & Poor s. We do not have any direct investments in auction-rate securities or securities that are collateralized by assets that include mortgages or subprime debt. If a 10 percent change in interest rates were to have occurred on March 31, 2014, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

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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 March 31, 2014. Based on this evaluation, our Chief Executive Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2014.

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.

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PART II. OTHER INFORMATION

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 (*) contain changes to the similarly titled risk factor 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 pimavanserin is delayed or not granted or pimavanserin 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, 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 pimavanserin in the United States and potentially in additional territories. The regulatory approval and successful commercialization of pimavanserin is subject to many risks, including the risks discussed in other risk factors, and pimavanserin 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 pimavanserin, are sufficient to support the filing of a New Drug Application, or NDA, for the treatment of Parkinson s disease psychosis, or PDP. We are currently focused on completing the remaining elements of our pimavanserin Parkinson s disease psychosis development program that are needed for submission of an NDA. These include customary supportive studies, such as drug-drug interaction studies, and Chemistry, Manufacturing and Controls, or CMC, development, such as stability testing of registration batches. While the FDA has agreed to accept and review an NDA for pimavanserin on the basis of our positive pivotal -020 study data, along with supportive efficacy and safety data from other pimavanserin studies, the NDA will be subject to a standard FDA review to determine whether the entire filing package is adequate to support approval of pimavanserin for PDP. We plan to have pre-NDA meetings with the FDA and may learn that additional studies or CMC development that we are not currently expecting are required before the pimavanserin NDA would be accepted for filing by the FDA. Notwithstanding the guidance that we received in April 2013, the FDA retains complete discretion in deciding whether to file an NDA for pimavanserin and there are many components to an NDA submission beyond the efficacy and safety data reviewed by the FDA in 2013. Even if our NDA submission for pimavanserin is accepted for filing, the FDA retains complete discretion in deciding whether or not to approve an NDA and there is no guarantee that pimavanserin will be approved for the treatment of PDP. Thus, significant uncertainty remains regarding the clinical

development and regulatory approval process for pimavanserin.

Even if the FDA grants us approval of pimavanserin for PDP, the terms of the approval may limit its commercial potential.

The FDA has complete discretion over the approval of pimavanserin for PDP. If it grants approval, the scope of the approval may limit our ability to commercialize pimavanserin, and in turn, limit our ability to generate substantial sales revenues. For example, the FDA may not approve the labeling claims for pimavanserin 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 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 pimavanserin, 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.

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. Approval by the FDA does not ensure that foreign jurisdictions will also approve our products for commercial

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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 will be required by us to submit pimavanserin 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 that required to obtain regulatory approval in the United States. 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.

We expect our net losses to continue for at least several 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 March 31, 2014, we had an accumulated deficit of approximately $423.5 million. We expect to incur net losses over the next several 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. We plan to submit our NDA for pimavanserin in PDP near the end of 2014. The regulatory approval process is time consuming and uncertain and there is no guarantee that our planned NDA submission for pimavanserin will be accepted for filing or, if accepted, approved for marketing. Even if our NDA for pimavanserin is approved, we would still expect to incur significant expenses and net losses for at least several years as we begin our first ever commercialization efforts and pursue the development and commercialization of pimavanserin and other product candidates. Substantially all of our revenues for the three months ended March 31, 2014 were from our agreements with various parties, including our research and development grants. The research term of our 2003 collaboration with Allergan concluded in March 2013 and we no longer recognize revenues from this collaboration. Thus, any significant payments from Allergan pursuant to our continuing collaborations 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.

The pivotal Phase III study with pimavanserin 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 pimavanserin for the treatment of PDP. Following our April 2013 meeting with the FDA, we have been conducting customary supportive studies, such as drug-drug interaction studies and CMC development, which are needed prior to filing an NDA. Even though we successfully completed the -020 study, those results are not predictive of results of the supportive studies and CMC development needed before an NDA may be submitted to 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. However, prior to the first efficacy study that we commenced in late 2013, we have never tested pimavanserin in clinical studies for ADP 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.

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

We depend on collaborations with third parties to develop and commercialize selected product candidates and to provide substantially all of our revenues.*

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. Our 2003 research agreement with Allergan ended in March 2013, and additional payments from our two ongoing agreements with Allergan, other than payments for a portion of patent costs for these collaborations, are dependent upon successful advancement of our applicable product candidates. Unless these milestones are met, we will not receive significant future revenues from our current collaborations with Allergan.

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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.

For example, Allergan has announced that it is seeking a partner for further development and commercialization of drug candidates in our chronic pain program. If Allergan is unable to successfully partner this 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 our chronic pain program to date. In April 2014, Valeant Pharmaceuticals International, Inc. and Pershing Square Capital Management L.P. announced a proposed acquisition of Allergan. If Allergan is acquired pursuant to this or another transaction or elects to pursue a different transaction, then substantially less resources could be devoted to the programs covered by our collaborations with Allergan or such programs could be discontinued.

In addition, Allergan can terminate our existing collaborations upon prior notice to us. We may not be able to renew our other existing collaborations on acceptable terms, if at all. We also face competition in our search for new collaborators, if we seek a new partner for our pimavanserin program or other programs. Given the current economic environment, it is possible that competition for new collaborators may increase. If we are unable to renew any existing collaboration or find new collaborations, we may not be able to continue advancing our programs alone.

If we fail to obtain the capital necessary to fund our operations, we will be unable to successfully develop products.*

We have consumed substantial amounts of capital since our inception. Our cash, cash equivalents and investment securities totaled $369.3 million at March 31, 2014. While we believe that our existing cash resources will be sufficient to fund our cash requirements at least into 2017, 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 development and pre-commercialization activities for pimavanserin and other research and development programs;
- the costs of preparing applications for regulatory approvals for our product candidates and the timing of any approvals;
- the costs of establishing, or contracting for, sales and marketing capabilities;

our ability to obtain regulatory approval for, and generate product sales from, our products;

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 product candidates; and

the costs associated with litigation.

Until we can generate significant continuing revenues, 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, if 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.

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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 supportive studies and CMC work for an NDA filing, 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, if we do not secure a partner. Following any potential approval by the FDA, our current strategy is to commercialize pimavanserin for Parkinson s disease psychosis in the United States by establishing a specialty sales force focused primarily on neurologists. In addition, if we commercialize pimavanserin 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 pimavanserin.

Even if pimavanserin 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. Following any potential approval by the FDA, in addition to building a sales force, we will need to successfully coordinate the commercialization of the product. Prior to commercialization, pimavanserin could also be subject to review and potential scheduling by the Drug Enforcement Administration of the US Department of Justice, or DEA, which could 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 pimavanserin for PDP. If any product launch of pimavanserin is unsuccessful or perceived as disappointing, our stock price could decline significantly and the long-term success of the product could be harmed.

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, pimavanserin. Following the reporting of successful results from the Phase III -020 study with pimavanserin in November 2012 and our meeting with the FDA in April 2013, we are conducting customary supportive studies, such as drug-drug interaction studies, and CMC development, such as stability testing of registration batches, prior to our planned submission of an NDA for pimavanserin in PDP near the end of 2014. An unfavorable outcome in any of the foregoing development efforts for pimavanserin would be a major set-back for the program and for us, generally. In particular, an unfavorable outcome in our pimavanserin program may require us to delay, 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 with pimavanserin, 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 schizophrenia. We also have clinical programs in collaboration with

Allergan for the treatment of chronic pain and glaucoma, which have reached Phase II and Phase I development, respectively.

In connection with clinical trials, we face risks that:

- a product candidate may not prove to be efficacious;
- 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.

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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
- 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;
- 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.

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 economic 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 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.

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We have collaborations with Allergan for the development of product candidates related to chronic pain and ophthalmic diseases, including glaucoma. Allergan currently markets therapeutic products to treat glaucoma and is engaged in other research programs related to glaucoma and other ophthalmic products that are independent from our development program in this therapeutic area. Allergan is also pursuing other research programs related to pain management that are independent from our collaboration in this therapeutic area.

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.

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.

Relying on third-party manufacturers may result in delays in our clinical trials, regulatory approvals and product introductions.

We have no manufacturing facilities and only limited experience 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 pimavanserin, for clinical trials. If any of our product candidates 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. While we believe that there will be alternative sources available to manufacture our product candidates, including pimavanserin, 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. We have not yet entered into long-term agreements with our current third-party manufacturers or with any alternate suppliers. Although we intend to do so prior to any commercial launch of a product that is approved by the FDA in order to ensure that we maintain adequate supplies of commercial drug product, we may be unable to enter into such agreements or do so on commercially reasonable terms, which could delay a product launch or subject our commercialization efforts to significant supply risk.

The manufacturers of our product candidates are obliged to operate in accordance with FDA-mandated current good manufacturing practices, or cGMPs. In addition, the facilities used by our contract manufacturers or other third party manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we request regulatory approval from the FDA. A failure by any of our contract 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 or

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the ultimate launch of products based on our product candidates into the market. 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.

Our product candidates, including pimavanserin, may not gain acceptance among physicians, patients, and the medical community, thereby limiting our potential to generate revenues.

Even if our product candidates are 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 any product candidate that we discover and/or develop does not provide a treatment regimen that is 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.

If we are unable to attract, retain, and motivate key management and research and development staff, our drug development programs and our research and discovery efforts may be delayed and we may be unable to successfully develop or commercialize our product candidates, including pimavanserin.*

Our success depends on our ability to attract, retain, and motivate highly qualified management and scientific 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 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. In addition, in April 2014, our Chief Financial Officer, who had been with the Company since 1998 and served as our Chief Business Officer, retired. While we have begun to recruit a replacement, there is no guarantee that we will be able to replace the skills and expertise of our prior Chief Financial Officer and we may experience difficulties in transitioning this position, which could adversely impact us. If we are unable to attract and retain the necessary personnel for this and other positions, this will significantly impede the achievement of our research and development objectives, our commercialization efforts for pimavanserin, 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 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 pimavanserin. 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, 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.

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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.

We will need to continue to manage our organization and we may encounter difficulties with our staffing and any future growth, which could adversely affect our results of operations.

We will need to effectively manage our operations and facilities in order to advance our drug development programs, including those covered by our collaborations with Allergan, achieve milestones under our collaboration agreements, facilitate additional collaborations, and pursue other development and commercialization activities. As we advance the pimavanserin program towards submitting an NDA, we already have added several capabilities. However, we will need to add qualified personnel and resources if the NDA 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 pimavanserin. We may not successfully manage our operations and, accordingly, may not achieve our research, development, and commercialization goals.

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:

- the status of development and commercialization of pimavanserin and our other product candidates, including compounds being developed under our collaborations;
- 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 potential 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; 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.

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.

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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 Global 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.

Our ability to generate product revenues will be diminished if our products do not receive coverage from payors or sell 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. Adequate coverage and 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 any approved products, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use any products we may market unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of those products.

In addition, the market for any products for which we may receive regulatory approval 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, our products from 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 any approved products 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 profitably, described in greater detail in the Government Regulation section of this 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 civil and/or criminal penalties, damages, fines, 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

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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, 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. An expansion in the government s role in the U.S. healthcare industry may cause general downward 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 the annual excise tax on certain drug product sales enacted under the ACA, subject to limited exceptions. It is possible that the tax burden, if we are not excepted, would adversely affect our financial performance, which in turn could cause the price of our stock to decline. 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.

If we receive marketing approval from the FDA, we could face liability if a regulatory authority determines that we are promoting off-label use of our products.

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 or for uses that differ from those approved by other 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, 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 any product, we intend to comply with 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.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any products we may develop, we may not be able to generate product revenues.

While we have begun to establish a small commercial team, we do not currently have a complete organization for the sales, marketing and distribution of pharmaceutical products. In order to market any products that may be approved by the FDA, 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.

We will need to obtain FDA approval of our proposed product name for pimavanserin, 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 approve any product name we intend to use for pimavanserin regardless of whether we have obtained a formal 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 objects to our proposed name, 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.

If we engage in any acquisition, we will incur a variety of costs and may never realize the anticipated benefits of the acquisition.

We may attempt to acquire, or license in, businesses, technologies, product candidates or products that we believe are a strategic fit with our business. 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. 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.

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

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

Risks Related to Our Intellectual Property

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

Our commercial success depends on obtaining and maintaining proprietary rights to our product candidates and technologies and their uses, as well as successfully defending these rights against third-party challenges. We will only be able to protect our product candidates, proprietary technologies, and their uses from unauthorized use by third parties to the extent that valid and enforceable patents, or effectively protected trade secrets, cover them. Although we have filed numerous patent applications worldwide with respect to pimavanserin, we have not been issued patents with respect to each of our filings.

Our ability to obtain patent protection for 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 independently develop similar or alternative technologies or duplicate any of our technologies;
- our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- any or all of our pending patent applications may not result in issued patents;

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 may be challenged by third parties;

our proprietary technologies may not be patentable;

others may design around our patent claims to produce competitive products which fall outside of the scope of our patents;

others may identify prior art which could invalidate our patents; or

changes to patent laws that limit the exclusivity rights of patent holders.

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 ability to develop our product candidates or sell our products. 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. It is difficult to determine how such disputes would be resolved. Others may challenge the validity of our patents. If our patents are found to be invalid, we will lose the ability to exclude others from making, using or selling the inventions claimed therein.

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Some of our academic institutional licensors, research collaborators and scientific advisors have rights to publish data and information to which we have rights. 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. Additionally, former employees of ours may seek future employment with our competitors. 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 such future employment. In addition, technology that we may license in may become important to some aspects of our business. We generally will not control the patent prosecution, maintenance or enforcement of in-licensed technology.

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. The failure to obtain or maintain trade secret protection could adversely affect our competitive position. In addition, we have not entered into any noncompete agreements with any of our employees.

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 significant litigation in our industry regarding patent and other intellectual property rights. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such threatened litigation, 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, 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, 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, potentially treble damages, 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, if at all.

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

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 patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. For example, some of our patent applications will cover gene sequences and products and the uses of those gene sequences and products. Public disclosures and patent applications related to the Human Genome Project and other genomics efforts may limit the scope of our claims or make unpatentable subsequent patent applications. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. The U.S. Patent and Trademark Office s standards 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, and

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U.S. patents may be subject to reexamination proceedings in the U.S. Patent and Trademark Office (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 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 Leahy-Smith America Invents Act, or the Leahy-Smith Act, was recently signed into law and includes a number of significant changes to U.S. patent law. These include 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. The U.S. Patent and Trademark Office has been in the process of implementing regulations and procedures to administer the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act may affect our ability to obtain, enforce or defend our patents. Accordingly, it is not clear what, if any, impact the Leahy-Smith 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, 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 in the United States until it has completed rigorous preclinical testing and clinical trials and an extensive regulatory clearance process implemented by the FDA. Satisfaction of regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product, and requires substantial resources. Even if regulatory approval is obtained, it may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, and/or marketing of such products, and requirements for post-approval studies,

including additional research and development and clinical trials. These limitations may limit the size of the market for the product or result in the incurrence of additional costs. Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues from the particular product candidate.

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

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

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If our competitors develop and market products that are more effective than our product candidates, 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 pimavanserin for PDP would compete with off-label use of antipsychotic drugs, including Seroquel, marketed by Astra-Zeneca, and with the generic drug clozapine. Our potential products for the treatment of schizophrenia would compete with Zyprexa, marketed by Eli Lilly, Risperdal, marketed by Johnson & Johnson, Abilify, marketed jointly by Bristol-Myers Squibb and Otsuka Pharmaceutical, Seroquel, and clozapine. Our potential product for ADP would compete with Risperdal and with off-label use of antipsychotic drugs. 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.

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.

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Risks Related to Our Common Stock

Our stock price may be particularly volatile because we are a drug discovery and development company.

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 or our chronic pain or glaucoma collaborations;
- the timing, or developments regarding the timing, of submission and review of filings for our product candidates 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 pimavanserin;
- 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 commercial products, or other material events by our competitors or us;
- 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 Global 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;

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 particular, our development program with pimavanserin encompasses a number of studies, open-label safety extension trials and a range of supporting studies, such as drug-drug interaction studies and CMC development, including stability testing of registration batches. Any unfavorable outcome in one or more of the studies in the development of pimavanserin, or the CMC development related thereto, could be a major set-back for our company, generally. Such an unfavorable outcome could have a material adverse effect on our company and the value of our common stock.

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. We may become subject to this type of litigation, which is often extremely expensive and diverts management s attention.

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.

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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;
- 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.

ITEM 4. MINE SAFETY DISCLOSURES

This item is not applicable.

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ITEM 6. EXHIBITS

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant s Quarterly Report on Form 10-Q, filed August 10, 2011).
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).
31.1	Certification of Uli Hacksell, Ph.D., 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 Uli Hacksell, Ph.D., 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 March 31, 2014, filed on May 6, 2014, formatted in 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.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ACADIA Pharmaceuticals Inc.

Date: May 6, 2014

By: /s/ Uli Hacksell, Ph.D.
Uli Hacksell, Ph.D.
Chief Executive Officer

(on behalf of the registrant and as the registrant s Principal Executive, Financial and Accounting Officer)