ACADIA PHARMACEUTICALS INC
Form 10-Q
August 05, 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 June 30, 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 Incorporation)	**(I.R.S. Employer 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 July 31, 2014:

Class	**Number of Shares Outstanding**
Common Stock, $0.0001 par value	99,436,825

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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)

	June 30, 2014	December 31, 2013 (1)
Assets		
Cash and cash equivalents	$ 13,698	$ 11,707
Investment securities, available-for-sale	340,755	174,083
Interest and other receivables	1,320	750
Prepaid expenses and other current assets	3,081	1,820
Total current assets	358,854	188,360
Property and equipment, net	500	579
Other assets	111	179
Total assets	$ 359,465	$ 189,118
Liabilities and stockholders equity		
Accounts payable	$ 1,104	$ 372
Accrued expenses	8,206	6,552
Deferred revenue	29	55
Total current liabilities	9,339	6,979
Long-term liabilities	18	8
Total liabilities	9,357	6,987
Commitments and contingencies (Note 9)		
Stockholders equity		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized at June 30, 2014 and December 31, 2013; no shares issued and outstanding at June 30, 2014 and December 31, 2013		
Common stock, $0.0001 par value; 150,000,000 shares authorized at June 30, 2014 and December 31, 2013; 99,300,702 shares and 91,102,618 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively	10	9

Additional paid-in capital	794,995	587,742
Accumulated deficit	(444,991)	(405,668)
Accumulated other comprehensive income	94	48
Total stockholders equity	350,108	182,131
Total liabilities and stockholders equity	$ 359,465	$ 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 June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Revenues				
Collaborative revenues	$ 28	$ 451	$ 58	$ 868
Operating expenses				
Research and development (includes stock-based compensation expense of $1,089, $473, $2,095, and $727, respectively)	13,799	7,112	25,467	11,542
General and administrative (includes stock-based compensation expense of $3,242, $591, $5,398, and $919, respectively)	7,952	2,496	14,272	4,647
Total operating expenses	21,751	9,608	39,739	16,189
Loss from operations	(21,723)	(9,157)	(39,681)	(15,321)
Interest income, net	228	76	358	117
Net loss	$ (21,495)	$ (9,081)	$ (39,323)	$ (15,204)
Net loss per common share, basic and diluted	$ (0.22)	$ (0.11)	$ (0.41)	$ (0.19)
Weighted average common shares outstanding, basic and diluted	99,048	83,410	96,042	81,105

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 June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Net loss	$ (21,495)	$ (9,081)	$ (39,323)	$ (15,204)
Other comprehensive income (loss):				
Unrealized gain (loss) on investment securities	94	(41)	46	(30)
Comprehensive loss	$ (21,401)	$ (9,122)	$ (39,277)	$ (15,234)

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)

	Six Months Ended June 30,	
	2014	**2013**
Cash flows from operating activities		
Net loss	$ (39,323)	$ (15,204)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	7,493	1,646
Amortization of premiums on investment securities	(11)	473
Depreciation	85	24
Gain on disposal of assets		(11)
Changes in operating assets and liabilities:		
Interest and other receivables	(570)	(556)
Prepaid expenses and other current assets	(1,261)	(173)
Other assets	68	(56)
Accounts payable	732	(198)
Accrued expenses	1,654	2,349
Deferred revenue	(26)	(323)
Long-term liabilities	10	
Net cash used in operating activities	(31,149)	(12,029)
Cash flows from investing activities		
Purchases of investment securities	(288,639)	(162,032)
Maturities of investment securities	122,023	30,393
Purchases of property and equipment	(6)	(74)
Proceeds from sales of property and equipment		11
Net cash used in investing activities	(166,622)	(131,702)
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	199,762	110,079
Net cash provided by financing activities	199,762	110,079
Net increase (decrease) in cash and cash equivalents	1,991	(33,652)
Cash and cash equivalents		
Beginning of period	11,707	57,899

End of period	$ 13,698	$ 24,247

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

June 30, 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 June 30, 2014, the Company had an accumulated deficit of $445.0 million. The Company expects to continue to incur operating losses for at least the next few 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. Unless and 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.

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 June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	(unaudited)		(unaudited)	
Antidilutive options to purchase common stock	7,772	7,217	7,629	7,129
Antidilutive warrants to purchase common stock	1,966	3,725	1,966	3,725
	9,738	10,942	9,595	10,854

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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 $4.3 million and $7.5 million during the three and six months ended June 30, 2014, respectively, and $1.1 million and $1.6 million during the three and six months ended June 30, 2013, respectively. During the first quarter of 2014, the Board of Directors approved modifications to the Company s former Chief Financial Officer s outstanding stock options in connection with his retirement from the Company on April 18, 2014. Stock-based compensation expense for the three and six months ended June 30, 2014 included $1.1 million and $1.7 million, respectively, related to the modification of the stock options held by the Company s former Chief Financial Officer. As of June 30, 2014, total unrecognized compensation cost related to stock options and purchase plan rights was approximately $34.5 million, which is expected to be recognized over a weighted-average period of 2.8 years.

4. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	June 30, 2014 (unaudited)	December 31, 2013
Accrued research and development services	$ 5,544	$ 4,207
Accrued compensation and benefits	1,245	1,865
Accrued consulting and professional fees	1,230	308
Other	187	172
Total	$ 8,206	$ 6,552

5. Investment Securities

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

	June 30, 2014			
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Estimated Fair Value
		(unaudited)		
U.S. Treasury notes	$ 2,745	$ 5	$	$ 2,750
Government sponsored enterprise securities	170,979	37	(22)	170,994
Corporate debt securities	143,998	33	(13)	144,018
Commercial paper	22,943	50		22,993

	$ 340,665	$ 125	$ (35)	$ 340,755

	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 available-for-sale investment securities, 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 June 30, 2014 and December 31, 2013, the Company held $52.1 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.

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6. Fair Value Measurements

As of June 30, 2014, the Company held $354.3 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 June 30, 2014 or December 31, 2013.

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

		Fair Value Measurements at Reporting Date Using		
	June 30, 2014	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	$ 13,555	$ 13,555	$	$
U.S. Treasury notes	2,750	2,750		
Government sponsored enterprise securities	170,994		170,994	
Corporate debt securities	144,018		144,018	
Commercial paper	22,993		22,993	
	$ 354,310	$ 16,305	$ 338,005	$

	Fair Value Measurements at Reporting Date Using

	December 31, 2013	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

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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 June 30, 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 June 30, 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 $14,000 and $22,000 during the three and six months ended June 30, 2014, respectively, and $257,000 and $544,000 during the three and six months ended June 30, 2013, respectively.

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 and planned commercialization of its product candidates. The Company was contractually obligated for up to approximately $22.7 million of future services under these agreements as of June 30, 2014. The nature of the work being conducted under the Company s agreements with external service providers is such that, in most cases, the services may be stopped with short notice. In such event, the Company would not be liable for the full amount of the contract. The Company s actual contractual obligations may vary depending upon several factors, including the progress and results of the underlying studies.

10. Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board issued authoritative accounting guidance related to revenue from contracts with customers. This guidance is a comprehensive new revenue recognition model that requires a company to recognize revenue to depict the transfer of goods or services to a customer at an amount that reflects the consideration it expects to receive in exchange for those goods or services. This guidance is effective for annual reporting periods beginning after December 15, 2016 and early adoption is not permitted. The Company will adopt this guidance on January 1, 2017. Companies may use either a full retrospective or a modified retrospective approach to adopt this guidance. The Company is evaluating which transition approach to use and its impact, if any, on its consolidated financial statements.

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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, regulatory and commercialization plans, 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, intend estimates, could, should, would, continue, seeks, aims, projects, predicts, pro forma, anticipates words. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Readers of this Quarterly Report are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date on which they 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, for which we have reported positive Phase III pivotal trial results in Parkinson s disease psychosis and which has the potential to be the first drug approved in the United States for this disorder. We are currently completing a New Drug Application, or NDA, along with enabling clinical and manufacturing activities for pimavanserin, and are planning to file the NDA with the U.S. Food and Drug Administration, or FDA, near the end of 2014. 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 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 an NDA for the treatment of Parkinson s disease psychosis. 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 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 schizophrenia.

We have incurred substantial operating losses since our inception due in large part to expenditures for our research and development activities. As of June 30, 2014, we had an accumulated deficit of $445.0 million. We expect to continue to incur operating losses for at least the next few 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.

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 June 30, 2014, we had received an aggregate of $115.8 million in payments under these agreements, including upfront payments, research funding, milestone payments, and reimbursed development

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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. Historically, we have used our internal research and development resources, including our employees and discovery infrastructure, across several projects and many of our costs have not been attributable to a specific project. Accordingly, we have not reported our internal research and development costs on a project basis. To the extent that external expenses are not attributable to a specific project, they are included in other programs. The following table summarizes our research and development expenses for the three and six months ended June 30, 2014 and 2013 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	(unaudited)		(unaudited)	
Costs of external service providers:				
Pimavanserin	$ 10,258	$ 5,154	$ 18,353	$ 7,828
Other programs	87	163	192	340
Subtotal	10,345	5,317	18,545	8,168
Internal costs	2,365	1,322	4,827	2,647
Stock-based compensation	1,089	473	2,095	727
Total research and development	$ 13,799	$ 7,112	$ 25,467	$ 11,542

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 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.

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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 are currently building our commercial launch infrastructure. We expect our general and administrative expenses to increase in future periods to support activities associated with our preparation for, and planned launch of, pimavanserin and our further development of pimavanserin in indications other than Parkinson s disease psychosis and the potential development of 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 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.

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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 progress and timing of expenditures related to our submission of an NDA for pimavanserin, our activities associated with preparations for, and our planned launch of, pimavanserin and our further development of pimavanserin in indications other than Parkinson s disease psychosis; the extent to which we generate revenues from product sales, if any, and the timing and amount of payments received pursuant to our current and potential future collaborations. 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 June 30, 2014 and 2013

Revenues

Revenues decreased to $28,000 for the three months ended June 30, 2014 from $451,000 for the three months ended June 30, 2013, primarily due to the conclusion of our 2003 research collaboration with Allergan in March 2013. Revenues from our collaborations with Allergan totaled $14,000 for the three months ended June 30, 2014 compared to $257,000 for the three months ended June 30, 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 $14,000 for the three months ended June 30, 2014, from $194,000 for the three months ended June 30, 2013, due to decreased activities under our research grants.

Research and Development Expenses

Research and development expenses increased to $13.8 million for the three months ended June 30, 2014, including $1.1 million in stock-based compensation expense, from $7.1 million for the three months ended June 30, 2013, including $473,000 in stock-based compensation expense. This increase was primarily due to an increase of $5.0 million in external service costs as well as an increase in costs associated with our expanded research and development organization, including $820,000 in increased personnel costs, and $616,000 in increased stock-based compensation expense. External service costs totaled $10.3 million, or 75 percent of our research and development expenses, for the three months ended June 30, 2014, compared to $5.3 million, or 75 percent of our research and development expenses, for the three months ended June 30, 2013. The increase in external service costs during the three months ended June 30, 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 the completion of NDA-enabling clinical and

manufacturing activities, our Phase II trial for Alzheimer s disease psychosis, and potential studies in other indications, including schizophrenia, as well as the potential development of our other product candidates.

General and Administrative Expenses

General and administrative expenses increased to $8.0 million for the three months ended June 30, 2014, including $3.2 million in stock-based compensation expense, from $2.5 million for the three months ended June 30, 2013, including $591,000 in stock-based compensation expense. The increase in general and administrative expenses for the three months ended June 30, 2014, was primarily due to an increase in costs associated with our expanded administrative and commercial preparation organization, including $2.6 million in increased stock-based compensation expense, of which $1.1 million in stock-based compensation expense was associated with the retirement of our former Chief Financial Officer. Also contributing to the quarter-over-quarter increase in general and administrative expenses was a $2.0 million increase in external service costs and $559,000 in increased personnel expenses. The increase in external service costs was largely attributable to increased consulting and professional fees related to our preparations for the planned launch of pimavanserin. We expect our general and administrative expenses to increase in future periods to support activities associated with our preparation for, and planned launch of, pimavanserin and our further development of pimavanserin in indications other than Parkinson s disease psychosis and the potential development of other product candidates.

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Comparison of the Six Months Ended June 30, 2014 and 2013

Revenues

Revenues decreased to $58,000 for the six months ended June 30, 2014 from $868,000 million for the six months ended June 30, 2013 primarily due to the conclusion of our 2003 research collaboration with Allergan in March 2013. Revenues from our collaborations with Allergan totaled $22,000 for the six months ended June 30, 2014 compared to $544,000 for the six months ended June 30, 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 $36,000 for the six months ended June 30, 2014, from $324,000 for the six months ended June 30, 2013, due to decreased activities under our research grants.

Research and Development Expenses

Research and development expenses increased to $25.5 million for the six months ended June 30, 2014, including $2.1 million in stock-based compensation expense, from $11.5 million for the six months ended June 30, 2013, including $727,000 in stock-based compensation expense. This increase was primarily due to an increase of $10.4 million in external service costs as well as an increase in costs associated with our expanded research and development organization, including $1.8 million in increased personnel costs, and $1.4 million in increased stock-based compensation expense. External service costs totaled $18.5 million, or 73 percent of our research and development expenses, for the six months ended June 30, 2014, compared to $8.2 million, or 71 percent of our research and development expenses, for the comparable period of 2013. The increase in external service costs was largely 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 the completion of NDA-enabling clinical and manufacturing activities, our Phase II trial for Alzheimer s disease psychosis, and potential studies in other indications, including schizophrenia, as well as the potential development of our other product candidates.

General and Administrative Expenses

General and administrative expenses increased to $14.3 million for the six months ended June 30, 2014, including $5.4 million in stock-based compensation expense, from $4.6 million for the six months ended June 30, 2013, including $919,000 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 and commercial preparation organization, including $4.5 million in increased stock-based compensation expense and $1.6 million in increased personnel expenses, as well as an increase of $3.1 million in external service costs. The increase in external service costs was largely attributable to increased consulting and 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.

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 June 30, 2014, we had received $751.2 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, $115.8 million in payments from collaboration agreements, $22.9 million

in interest income, and $22.4 million in debt financing.

At June 30, 2014, we had $354.5 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 sufficient to fund our planned 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 planned 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;

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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 public or private sales of our equity securities, debt financings, grant funding, strategic collaborations, or by otherwise 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 disruptions in the credit markets that have occurred in the past. However, if there are future disruptions in the credit markets, there can be no assurance that our investment portfolio will not be adversely affected.

Net cash used in operating activities increased to $31.1 million for the six months ended June 30, 2014 from $12.0 million for the six months ended June 30, 2013. This increase was primarily due to the increase in our net loss, offset in part by an increase of $5.8 million in non-cash, stock-based compensation expense, together with changes in our operating assets and liabilities, including prepaid expenses and other current assets. Prepaid expenses and other current assets increased by $1.3 million during the six months ended June 30, 2014 compared to an increase of $173,000 during the six months ended June 30, 2013. The increase in prepaid expenses and other current assets during the six months ended June 30, 2014 was primarily due to advanced payments made on certain development activities.

Net cash used in investing activities totaled $166.6 million for the six months ended June 30, 2014 compared to $131.7 million for the six months ended June 30, 2013. Net cash used in investing activities has fluctuated significantly from period to period primarily due to the timing of purchases of investment securities. The increase in net cash used in investing activities for the six months ended June 30, 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 $199.8 million for the six months ended June 30, 2014 compared to $110.1 million for the six months ended June 30, 2013. The net cash provided by financing activities for

the six months ended June 30, 2014 was primarily attributable to $196.8 million in net proceeds received from our public offering of common stock in March 2014. The net cash provided by financing activities for the six months ended June 30, 2013 was primarily attributable to $107.9 million in net proceeds received from our public offering of common stock in May 2013.

The following table summarizes our lease obligations at June 30, 2014 (in thousands):

	Total	Less than 1 Year	1-3 Years	4-5 Years	After 5 Years
Operating leases	$ 2,091	$ 1,032	$ 1,059	$	$

In addition, we have entered into agreements with contract research organizations and other external service providers for services, primarily in connection with the development and planned commercialization of our product candidates. We were contractually obligated for up to approximately $22.7 million of future services under these agreements as of June 30, 2014. The nature of the work being conducted under our agreements with external service providers is such that, in most cases, the services may be stopped on short notice. In such event, we would not be liable for the full amount of the contract. Our actual contractual obligations will vary depending upon several factors, including the progress and results of the underlying services.

In addition, we have entered into an agreement with the Ipsen Group pursuant to which we licensed certain intellectual property rights that complement our patent portfolio for our serotonin platform, including pimavanserin. If certain conditions are met, we

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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 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. If a 10 percent change in interest rates were to have occurred on June 30, 2014, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

ITEM 4. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial 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 and Chief Financial 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. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of June 30, 2014.

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial 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. 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 distribution. The regulations in foreign jurisdictions vary, we will be required to comply with different regulations and policies of the

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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 the next few years and are unable to predict the extent of future losses or when we will become profitable, if ever.*

We have experienced significant net losses since our inception. As of June 30, 2014, we had an accumulated deficit of approximately $445.0 million. We expect to incur net losses over the next few years as we advance our programs and incur significant development and commercialization costs.

We have not received any revenues from the commercialization of our product candidates. 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 the next few 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 six months ended June 30, 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 had 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 marketing.

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. In July 2014, Allergan announced that it would be reducing its worldwide headcount by approximately 13% and that it would be restructuring its operations. Following this restructuring, or if Allergan is acquired or it 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 entirely.

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 $354.5 million at June 30, 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.

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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 commercial