ACADIA PHARMACEUTICALS INC
Form 10-Q
August 10, 2011
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended June 30, 2011

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.)**
3911 Sorrento Valley Boulevard	
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 ¨ Accelerated filer ¨ Non-accelerated filer ¨ Smaller reporting company x

(Do not check if a 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, 2011:

Class	**Number of Shares Outstanding**
Common Stock, $0.0001 par value	52,799,606

Table of Contents

ACADIA PHARMACEUTICALS INC.

FORM 10-Q

TABLE OF CONTENTS

Table of Contents

PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

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

(Unaudited)

	June 30, 2011	December 31, 2010(1)
Assets		
Cash and cash equivalents	$ 8,020	$ 6,849
Investment securities, available-for-sale	32,341	30,238
Prepaid expenses, receivables and other current assets	654	762
Total current assets	41,015	37,849
Property and equipment, net	208	426
Other assets	86	119
Total assets	$ 41,309	$ 38,394
Liabilities and Stockholders Equity		
Accounts payable	$ 1,139	$ 1,972
Accrued expenses	4,015	3,219
Current portion of deferred revenue	753	690
Current portion of long-term debt	40	78
Total current liabilities	5,947	5,959
Long-term portion of deferred revenue	2,481	2,623
Other long-term liabilities	60	124
Total liabilities	8,488	8,706
Commitments (Note 9)		
Stockholders equity		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized at June 30, 2011 and December 31, 2010; no shares issued and outstanding at June 30, 2011 and December 31, 2010		
Common stock, $0.0001 par value; 150,000,000 shares and 75,000,000 shares authorized at June 30, 2011 and December 31, 2010, respectively; 52,799,606 shares and 39,350,561 shares issued and outstanding at June 30, 2011 and December 31, 2010, respectively	5	4
Additional paid-in capital	369,301	353,278
Accumulated deficit	(336,495)	(324,106)
Accumulated other comprehensive income	10	512
Total stockholders equity	32,821	29,688

Total liabilities and stockholders equity	$ 41,309	$ 38,394

(1) The condensed consolidated balance sheet at December 31, 2010 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

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

Table of Contents

ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Revenues				
Collaborative revenues	$ 460	$ 2,297	$ 895	$ 4,430
Operating expenses				
Research and development (includes stock-based compensation of $134, $150, $255, and $379, respectively)	4,315	5,041	8,727	10,857
General and administrative (includes stock-based compensation of $279, $223, $534, and $475, respectively)	2,729	1,552	4,613	3,366
Total operating expenses	7,044	6,593	13,340	14,223
Loss from operations	(6,584)	(4,296)	(12,445)	(9,793)
Interest income, net	28	8	56	18
Net loss	$ (6,556)	$ (4,288)	$ (12,389)	$ (9,775)
Net loss per common share, basic and diluted	$ (0.12)	$ (0.11)	$ (0.24)	$ (0.25)
Weighted average common shares outstanding, basic and diluted	52,677	38,347	51,535	38,341

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

Table of Contents

ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(Unaudited)

	Six Months Ended June 30,	
	2011	**2010**
Cash flows from operating activities		
Net loss	$ (12,389)	$ (9,775)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	225	312
Stock-based compensation	789	854
Non-cash charge resulting from lease termination	806	
Other	219	(244)
Changes in operating assets and liabilities:		
Prepaid expenses, receivables and other current assets	117	(2,657)
Other assets	35	(7)
Accounts payable	(851)	(633)
Accrued expenses	786	(1,208)
Deferred revenue	(79)	623
Other long-term liabilities	(45)	(50)
Net cash used in operating activities	(10,387)	(12,785)
Cash flows from investing activities		
Purchases of investment securities	(33,156)	(25,057)
Maturities of investment securities	30,843	28,687
Proceeds from sales of property and equipment		128
Net cash provided by (used in) investing activities	(2,313)	3,758
Cash flows from financing activities		
Proceeds from issuance of common stock	13,914	44
Repayments of long-term debt	(57)	(251)
Net cash provided by (used in) financing activities	13,857	(207)
Effect of exchange rate changes on cash	14	(77)
Net increase (decrease) in cash and cash equivalents	1,171	(9,311)
Cash and cash equivalents		
Beginning of period	6,849	18,122
End of period	$ 8,020	$ 8,811

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

Table of Contents

ACADIA PHARMACEUTICALS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2011

(Unaudited)

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of ACADIA Pharmaceuticals Inc. (together with its wholly owned subsidiaries, the Company) should be read in conjunction with the audited financial statements and notes thereto as of and for the year ended December 31, 2010 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, 2011, the Company had an accumulated deficit of $336.5 million. The Company expects to continue to incur operating losses for at least the next several years as it pursues the development of its product candidates.

The Company will 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 clinical trials, the scope, prioritization and number of its research and development programs, and the ability of its collaborators and the Company to reach the milestones, and other events or developments under its 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 private or public sales of its securities, debt financing, grant funding, or by licensing all or a portion of its product candidates or technology. The Company cannot be certain that 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 cannot raise adequate additional capital, it will be required to delay, further reduce the scope of, or eliminate one or more of its research or development programs or its commercialization efforts. In addition, the Company may 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, when dilutive, is reflected in diluted earnings (loss) 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,	
	2011	2010	2011	2010
	(unaudited)		(unaudited)	

Antidilutive options to purchase common stock	5,593	4,466	5,172	4,065
Antidilutive warrants to purchase common stock	4,692	954	4,423	1,174
	10,285	5,420	9,595	5,239

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,

Table of Contents

including the effect of estimated forfeitures, are then expensed over the vesting period. The Company recognized stock-based compensation expense of $413,000 and $789,000 during the three and six months ended June 30, 2011, respectively, and $373,000 and $854,000 during the three and six months ended June 30, 2010, respectively. At June 30, 2011, total unrecognized compensation cost related to stock options and purchase plan rights was $2.7 million, which is expected to be recognized over a weighted-average period of 2.6 years.

4. Comprehensive Loss

Comprehensive loss consisted of the following (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
	(unaudited)		(unaudited)	
Net loss	$ (6,556)	$ (4,288)	$ (12,389)	$ (9,775)
Unrealized gain (loss) on investment securities	(3)	8	10	6
Foreign currency translation adjustments	(524)	(76)	(512)	(88)
Total comprehensive loss	$ (7,083)	$ (4,356)	$ (12,891)	$ (9,857)

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	June 30, 2011	December 31, 2010
	(unaudited)	
Accrued clinical development services	$ 3,030	$ 2,339
Accrued compensation and benefits	522	537
Other	463	343
Total	$ 4,015	$ 3,219

6. Fair Value Measurements

As of June 30, 2011, the Company held $39.8 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 AA or A1+/p1 as determined by Moody s Investors Service and/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 assets between the fair value measurement classifications. No other-than-temporary impairments were identified for the investment securities held by the Company as of June 30, 2011.

Table of Contents

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

		Fair Value Measurements at Reporting Date Using		
	June 30, 2011	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market fund	$ 7,501	$ 7,501	$	$
U.S. Treasury notes	3,303	3,303		
Government sponsored enterprise securities	12,629		12,629	
Corporate debt securities	16,409		16,409	
	$ 39,842	$ 10,804	$ 29,038	$

		Fair Value Measurements at Reporting Date Using		
	December 31, 2010	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market fund	$ 6,403	$ 6,403	$	$
U.S. Treasury notes	4,291	4,291		
Government sponsored enterprise securities	23,428		23,428	
Corporate debt securities	2,519		2,519	
	$ 36,641	$ 10,694	$ 25,947	$

7. Collaboration and License Agreements

The Company is currently a party to three separate collaboration agreements with Allergan, Inc. Pursuant to the March 2003 collaboration agreement, the Company had received an aggregate of $18.0 million in payments as of June 30, 2011, consisting of an upfront payment, research funding and related fees. This collaboration originally provided for a three-year research term, which has been extended by the parties through March 2012. The Company s two other collaboration agreements with Allergan involve the development of product candidates in the areas of chronic pain and glaucoma. The Company is eligible to receive payments upon achievement of development and regulatory milestones, as well as royalties on product sales, if any, under each of the three collaboration agreements with Allergan. The Company recognized revenues from its collaboration agreements with Allergan of $271,000 and $535,000 during the three and six months ended June 30, 2011, respectively, and $263,000 and $534,000 during the three and six months ended June 30, 2010, respectively.

In March 2009, the Company entered into a collaboration agreement with Meiji Seika Pharma Co., Ltd. (Meiji Seika Pharma). Under the agreement, the Company is eligible to receive up to $25 million in aggregate payments, including $3 million in license fees and up to $22 million in potential development and regulatory milestone payments, in addition to royalties on product sales, if any, in the licensed Asian territory. Meiji Seika Pharma also is responsible for the first $15 million of designated development expenses, of which approximately $1.5

million had been incurred through June 30, 2011. The Company recognized revenues relating to this collaboration of $99,000 and $194,000 during the three and six months ended June 30, 2011, respectively, and $83,000 and $237,000 during the three and six months ended June 30, 2010, respectively. At June 30, 2011, $2.8 million of revenue was deferred under this agreement, of which $368,000 was included in current liabilities and $2.5 million was included in long-term liabilities. At December 31, 2010, $3.0 million of revenue was deferred under this agreement, of which $362,000 was included in current liabilities and $2.6 million was included in long-term liabilities.

In May 2009, the Company entered into a collaboration agreement with Biovail Laboratories International SRL (Biovail), a subsidiary of Biovail Corporation, pursuant to which the Company received a non-refundable $30 million upfront payment. Under this collaboration, the Company also was eligible to receive potential development, regulatory and sales milestones as well as royalties on future net sales of pimavanserin. In October 2010, the Company and Biovail entered into an agreement pursuant to which the

Table of Contents

Company reacquired all rights to pimavanserin and the parties concluded their collaboration. In connection with this agreement, the Company recorded all remaining revenues related to its collaboration with Biovail, which totaled $34.7 million, during the fourth quarter of 2010. The Company has no future obligations to Biovail. The Company recognized revenues relating to this collaboration of $1.8 million and $3.2 million during the three and six months ended June 30, 2010, respectively.

8. Private Equity Financing

In January 2011, the Company raised net proceeds of approximately $13.8 million through the sale of 12,565,446 units at a price of $1.19375 per unit to a group of institutional investors in a private equity financing. Each unit consisted of one share of the Company s common stock and a warrant to purchase 0.35 shares of common stock. The warrants have an exercise price of $1.38 per share, became exercisable on July 12, 2011, and will expire on January 11, 2018. In accordance with authoritative accounting guidance, the allocated fair value of the warrants at the issuance date of $3.3 million was recorded as permanent equity during the three months ended March 31, 2011. The fair value of the warrants was determined using the Black-Scholes model. Pursuant to the terms of the private placement, the Company has an effective resale registration statement on file with the SEC covering the shares of common stock sold in the private placement and the shares of common stock issuable upon the exercise of the warrants.

9. Commitments

In April 2011, the Company entered into a termination agreement related to its Swedish research facility and ceased operations at this site. Pursuant to the agreement, the Company made a one-time payment of $690,000 and issued 782,339 shares of its common stock to the landlord in settlement of all lease-related obligations. General and administrative expenses for the three and six months ended June 30, 2011 included a net charge of $1.1 million, which amount consisted of $1.7 million in lease termination charges offset by a $539,000 reduction in the Company s cumulative translation adjustment balance related to the liquidation of substantially all assets of its Swedish subsidiary.

The Company has entered into agreements with contract research organizations and other external service providers for services in connection with the development of its product candidates. The Company was contractually obligated for up to approximately $9.0 million of future services under these agreements as of June 30, 2011. 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 generally not be liable for the full amount of the contract. The Company s actual contractual obligations will vary depending upon several factors, including the progress and results of the underlying services.

10. Recent Accounting Pronouncements

In May 2011, the Financial Accounting Standards Board (FASB) issued accounting guidance related to fair value measurements and disclosures to achieve common fair value measurements and disclosures between GAAP and International Financial Reporting Standards. This guidance clarifies the application of certain existing fair value measurement guidance and expands the disclosures for fair value measurements that are estimated using significant unobservable (Level 3) inputs. This guidance is effective on a prospective basis for annual and interim reporting periods beginning on or after December 15, 2011. The Company does not believe the adoption of this guidance will have a material impact on its consolidated financial statements.

In June 2011, the FASB issued authoritative guidance which amends existing guidance related to the presentation of comprehensive income. This guidance (1) eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders equity; (2) requires the consecutive presentation of the statement of net income and other comprehensive income; and (3) requires an entity to present reclassification adjustments on the face of the financial statements from other comprehensive income to net income. This guidance does not change the items that must be reported in other comprehensive income, when an item of other comprehensive income must be reclassified to net income, or affect how earnings per share is calculated or presented. This guidance is effective for interim reporting periods and fiscal years beginning after December 15, 2011 and will be applied on a retrospective basis for all periods presented. The Company believes this guidance will result in enhanced disclosure of its financial statements.

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, 2010 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, and other statements that are not historical facts, including statements which may be preceded by the words believes, expects, hopes, may, will, plans, intends, estimates, could, should, would, continue, seeks, aims forma, anticipates, potential or

Table of Contents

similar words. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Readers of this Quarterly Report are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date on which they 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 small molecule drugs for the treatment of central nervous system disorders. Our pipeline consists of four product candidates including pimavanserin, which is in Phase III development as a potential first-in-class treatment for Parkinson s disease psychosis. We hold worldwide commercialization rights to pimavanserin. In addition, we have a product candidate in Phase II development for chronic pain and a product candidate in Phase I development for glaucoma, both in collaboration with Allergan, as well as a program in IND-track development in collaboration with Meiji Seika Pharma. All of the product candidates in our pipeline emanate from discoveries made using our proprietary drug discovery platform.

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, 2011, we had an accumulated deficit of $336.5 million. We expect to continue to incur operating losses for at least the next several years as we pursue the clinical development 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 May 2011, we were awarded a grant from the National Institute of Neurological Disorders and Stroke, or NINDS, a division of the National Institutes of Health, for the development of novel ER-beta agonists for the treatment of neuropathic pain. The grant provides funding of up to $2.4 million over several years and was awarded under the NINDS Fast-Track Small Business Innovative Research Cooperative Program in Translational Research that supports the identification and preclinical testing of new therapeutics for neurological disorders.

In April 2011, in order to reduce our facilities expenses, we entered into a termination agreement related to our Swedish research facility and ceased operations at this site. Pursuant to the agreement, we made a one-time payment of $690,000 and issued 782,339 shares of our common stock to the landlord in settlement of all lease-related obligations. General and administrative expenses for the three and six months ended June 30, 2011 included a net charge of $1.1 million resulting from the termination of our Swedish facility lease. Following this lease termination, we expect to save approximately $1.5 million in facilities and related expenses on an annual basis.

Revenues

We have not generated any revenues from product sales to date, and we do not expect to generate revenues from product sales for at least the next several years, if at all. Our revenues to date have been generated substantially from payments under our current and past collaboration agreements. As of June 30, 2011, we had received an aggregate of $111.6 million in payments under these agreements, including upfront payments, research funding, and milestone payments. We expect our revenues for the next several years to consist primarily of revenues derived from payments under our current agreements with Allergan and Meiji Seika Pharma and potential additional collaborations as well as grant funding.

We currently are a party to three separate collaboration agreements with Allergan. Pursuant to our March 2003 collaboration agreement with Allergan, we had received an aggregate of $18.0 million in payments as of June 30, 2011, consisting of an upfront payment, research funding and related fees. This collaboration agreement originally provided for a three-year research term, which has been extended by the parties through March 2012. Our two other 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 product sales, if any, under each of our three collaboration agreements with Allergan. Each of our agreements with Allergan is subject to early termination upon specified events, including, in the case of one of our agreements, if we have a change in control. Upon the conclusion of the

research term under each agreement, Allergan may terminate the agreement by notice.

Table of Contents

In March 2009, we entered into a collaboration agreement with Meiji Seika Pharma. Under the agreement, we are eligible to receive up to $25 million in aggregate payments, including $3 million in license fees and up to $22 million in potential development and regulatory milestones, as well as royalties on product sales, if any, in the licensed Asian territory. As of June 30, 2011, we had received an aggregate of $4.1 million in payments from Meiji Seika Pharma, consisting of license fees and reimbursed research and development expenses. Meiji Seika Pharma is responsible for the first $15 million of designated development expenses and we will share the remaining expenses through clinical proof-of-concept, subject to possible adjustment in the event we further license the program outside of the Asian territory. Our agreement with Meiji Seika Pharma is subject to early termination upon specified events.

In May 2009, we entered into a collaboration agreement with Biovail, pursuant to which we received a non-refundable $30 million upfront payment. Under this collaboration, we also were eligible to receive potential development, regulatory and sales milestones as well as royalties on future net sales of pimavanserin. In October 2010, we entered an agreement with Biovail to regain all rights to pimavanserin and conclude our collaboration. In connection with this agreement, we recorded all remaining revenues related to our collaboration with Biovail during the fourth quarter of 2010. We have no future obligations to Biovail.

Research and Development Expenses

Our research and development expenses consist 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 candidates, including pimavanserin. We currently are responsible for all future costs incurred in the development of pimavanserin as well as for the costs associated with our other internal programs.

Pursuant to our collaboration, Meiji Seika Pharma is responsible for the first $15 million of designated development expenses for the product candidate, AM-831, and we and Meiji Seika Pharma will share remaining expenses through clinical proof-of-concept, subject to possible adjustment. As of June 30, 2011, approximately $1.5 million of the designated development expenses had been incurred. We expect to coordinate a significant portion of the planned external development services and, accordingly, we may incur the related development costs for these external services and receive reimbursement of Meiji Seika Pharma s portion of these costs pursuant to the agreement. Meiji Seika Pharma is responsible for all costs associated with the development of AM-831 in the Asian territory. We are not responsible for, nor have we incurred, development expenses in our clinical programs for chronic pain and glaucoma, which we are pursuing in collaboration with Allergan.

We use external service providers to manufacture our product candidates to be used in clinical trials 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 but were directed to broadly applicable research activities. 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 external costs. The following table summarizes our development expenses for the three and six months ended June 30, 2011 and 2010 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
	(unaudited)		(unaudited)	
External costs:				
Pimavanserin	$ 2,751	$ 3,164	$ 5,116	$ 6,803
AM-831 and other	319	247	571	416
Subtotal	3,070	3,411	5,687	7,219
Internal costs	1,111	1,480	2,785	3,259
Stock-based compensation	134	150	255	379
Total research and development	$ 4,315	$ 5,041	$ 8,727	$ 10,857

At this time, due to the risks inherent in the clinical trial process and given the stage of development of our programs, we are unable to estimate with any certainty the costs we will incur for the continued development of our product candidates for potential commercialization. Due to these same factors, we are unable to determine the anticipated completion dates for our current research and development programs. Clinical

development timelines, probability of success, and development costs vary widely. While our current focus is primarily on advancing the clinical 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 such arrangements would affect our development plans and capital requirements.

Table of Contents

We expect our external research and development expenses to continue to be substantial as we pursue the development of pimavanserin and our other product candidates. The lengthy process of completing clinical trials 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.

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 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 as 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 based on the nature of the related agreement. Payments received from grants are recognized as revenue as the related research and development is performed and when collectability has been 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 the payment is reasonably assured. Non-refundable milestone payments related to arrangements under which we have continuing performance obligations are recognized as revenue 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 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 costs associated with services provided by contract organizations for preclinical development, manufacturing of clinical materials, and clinical trials. We accrue for costs incurred as the services are being provided by monitoring the status of the trials or services provided, and the invoices received from our external service providers. In the case of clinical trials, a portion of the cost normally relates to the projected cost to treat a patient in our trials and we recognize this cost over the term of the study based on the number of patients enrolled in the trial on an ongoing basis. As actual costs become known to us, we adjust our accruals. To date, our estimates have not differed

significantly 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.

Table of Contents

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. As of June 30, 2011, total unrecognized compensation cost related to stock options and purchase plan rights was approximately $2.7 million, and the weighted average period over which this cost is expected to be recognized is 2.6 years.

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 and the progress and timing of expenditures related to our development efforts. 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, 2011 and 2010

Revenues

Revenues decreased to $460,000 for the three months ended June 30, 2011 from $2.3 million for the three months ended June 30, 2010. This decrease was primarily due to the conclusion of our collaboration with Biovail in October 2010, at which time we recognized all remaining revenues related to this collaboration. We recognized $1.8 million in revenues from this collaboration during the three months ended June 30, 2010. Revenues from our collaborations with Allergan totaled $271,000 for the three months ended June 30, 2011 and were comparable to the revenues from these collaborations for the three months ended June 30, 2010. Revenues from our agreements with other parties, including our collaboration with Meiji Seika Pharma, totaled $189,000 for the three months ended June 30, 2011 compared to $218,000 for the three months ended June 30, 2010.

Research and Development Expenses

Research and development expenses decreased to $4.3 million for the three months ended June 30, 2011, including $134,000 in stock-based compensation, from $5.0 million for the three months ended June 30, 2010, including $150,000 in stock-based compensation. The decrease in research and development expenses was primarily due to $384,000 in decreased facility and other costs associated with our internal research and development organization and $342,000 in decreased external service costs. External service costs totaled $3.1 million, or 71 percent of our research and development expenses, for the three months ended June 30, 2011, compared to $3.4 million, or 68 percent of our research and development expenses, for the comparable period in 2010. The decrease in external expenses was largely attributable to decreased costs incurred on our Phase III program for pimavanserin.

General and Administrative Expenses

General and administrative expenses increased to $2.7 million for the three months ended June 30, 2011, including $279,000 in stock-based compensation, from $1.6 million for the three months ended June 30, 2010, including $223,000 in stock-based compensation. The increase in general and administrative expenses was primarily attributable to a net charge of $1.1 million resulting from the termination of our Swedish facility lease.

Comparison of the Six Months Ended June 30, 2011 and 2010

Revenues

Revenues decreased to $895,000 for the six months ended June 30, 2011 from $4.4 million for the six months ended June 30, 2010. This decrease was primarily due to the conclusion of our collaboration with Biovail in October 2010, at which time we recognized all remaining revenues related to this collaboration. We recognized $3.2 million in revenues from this collaboration during the six months ended June 30, 2010. Revenues from our collaborations with Allergan totaled $535,000 for the six months ended June 30, 2011 and were comparable to the

revenues from these collaborations for the six months ended June 30, 2010. Revenues from our agreements with other parties, including our collaboration with Meiji Seika Pharma, totaled $360,000 for the six months ended June 30, 2011 compared to $668,000 for the six months ended June 30, 2010.

Research and Development Expenses

Research and development expenses decreased to $8.7 million for the six months ended June 30, 2011, including $255,000 in stock-based compensation, from $10.9 million for the six months ended June 30, 2010, including $379,000 in stock-based compensation. The decrease in research and development expenses was primarily due to $1.5 million in decreased external service

Table of Contents

costs and $598,000 in decreased facility and personnel costs associated with our internal research and development organization. External service costs totaled $5.7 million, or 65 percent of our research and development expenses, for the six months ended June 30, 2011, compared to $7.2 million, or 66 percent of our research and development expenses, for the comparable period in 2010. The decrease in external service costs was largely attributable to decreased costs incurred on our Phase III program for pimavanserin.

General and Administrative Expenses

General and administrative expenses increased to $4.6 million for the six months ended June 30, 2011, including $534,000 in stock-based compensation, from $3.4 million for the six months ended June 30, 2010, including $475,000 in stock-based compensation. The increase in general and administrative expenses was primarily attributable to a net charge of $1.1 million resulting from the termination of our Swedish facility lease.

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, 2011, we had received $341.5 million in net proceeds from sales of our equity securities, including $6.9 million in debt we had retired through the issuance of our common stock, $111.6 million in payments from collaboration agreements, $22.4 million in debt financing, and $22.1 million in interest income.

At June 30, 2011, we had $40.4 million in cash, cash equivalents and investment securities compared to $37.1 million at December 31, 2010. We currently expect that our cash, cash equivalents, investment securities and anticipated payments from our collaborations will be sufficient to fund our operations at least into the first half of 2013.

We will 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:

- progress in, and the costs of, our clinical trials, preclinical studies and other research and development programs;
- 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, under our collaboration agreements;
- the extent to which we are obligated to reimburse our collaborators or our collaborators are obligated to reimburse us for clinical trial costs under our 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 of establishing, or contracting for, sales and marketing capabilities if we obtain regulatory clearances to market our product candidates.

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through strategic collaborations, private or public sales of our securities, debt financings, grant funding, or by licensing all or a portion of our product candidates or technology. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. Over the last few years, 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. This, coupled with other factors, may limit access to additional financing over the near-term future. In

particular, given the disappointing results from an initial Phase III Parkinson s disease psychosis trial with pimavanserin that we announced in September 2009, any unfavorable outcome in our development of pimavanserin could have a material adverse effect on our ability to raise additional capital.

If we cannot raise adequate additional capital in the future, we will be required to delay, further 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 AA or A1+/p1 as determined by Moody s Investors Service and/or Standard & Poor s. Our investment portfolio has not been adversely impacted by the disruption in the credit markets that has occurred during the last few years. However, if there is further and expanded 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 decreased to $10.4 million for the six months ended June 30, 2011 from $12.8 million for the six months ended June 30, 2010. This decrease was primarily due to changes in operating assets and liabilities, including changes

Table of Contents

in prepaid expenses, receivables and other current assets, accounts payable and accrued expenses, and a non-cash charge resulting from termination of our Swedish facility lease incurred during the six months ended June 30, 2011, offset by an increase in our net loss. During the six months ended June 30, 2011, prepaid expenses, receivables and other current assets decreased by $117,000 compared to an increase of $2.7 million for the comparable period of 2010. The increase in prepaid expenses, receivables and other current assets during the six months ended June 30, 2010 was primarily attributable to a collaborative receivable, which was subsequently collected. During the six months ended June 30, 2011, accounts payable and accrued expenses decreased by an aggregate of $65,000, compared to an aggregate decrease in accounts payable and accrued expenses of $1.8 million for the six months ended June 30, 2010. The decreases in accounts payable and accrued expenses during these comparable six month periods were primarily due to payments made for external service costs related to our clinical trials, the timing and amount of which may fluctuate significantly from period to period.

Net cash used in investing activities totaled $2.3 million for the six months ended June 30, 2011 compared to net cash provided by investing activities of $3.8 million for the six months ended June 30, 2010. Net cash used in or provided by investing activities has fluctuated significantly from period to period primarily due to the timing of purchases and maturities of investment securities. The increase in net cash used in investing activities for the six months ended June 30, 2011 compared to net cash provided by investing activities for the six months ended June 30, 2010 was primarily due to increased purchases of investment securities, net of maturities of investment securities.

Net cash provided by financing activities totaled $13.9 million for the six months ended June 30, 2011 compared to net cash used in financing activities of $207,000 for the six months ended June 30, 2010. The net cash provided by financing activities in the six months ended June 30, 2011 was primarily due to $13.8 million in net proceeds received from our January 2011 private equity financing.

The following table summarizes our contractual obligations, including interest, at June 30, 2011 (in thousands):

	Total	Less than 1 Year	1-3 Years	4-5 Years	After 5 Years
Operating leases	$ 1,006	$ 680	$ 326	$	$
Long-term debt	56	43	13		
Total	$ 1,062	$ 723	$ 339	$	$

We have also entered into agreements with contract research organizations and other external service providers for services in connection with the development of our product candidates. We were contractually obligated for up to approximately $9.0 million of future services under these agreements as of June 30, 2011. 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. 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 amount 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.

13

Table of Contents

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We invest our excess cash in investment-grade, interest-bearing securities. The primary objective of our investment activities is to preserve principal and liquidity. To achieve this objective, we invest in a money market fund, U.S. Treasury notes, and high quality marketable debt instruments of corporations, financial institutions and government sponsored enterprises with contractual maturity dates of generally less than two years. All investment securities have a credit rating of at least AA or A1+/p1 as determined by Moody s Investors Service and/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 June 30, 2011, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

Foreign Currency Risk

We have wholly owned subsidiaries in Europe, which expose us to foreign exchange risk. All assets and liabilities of our subsidiaries are translated to U.S. dollars based on the applicable exchange rate on the balance sheet date. Expense components are translated to U.S. dollars at weighted average exchange rates in effect during the period. Gains and losses resulting from foreign currency translation are included as a component of our stockholders equity. Other foreign currency transaction gains and losses are included in our results of operations and, to date, have not been significant. We have not hedged exposures denominated in foreign currencies or any other derivative financial instrument.

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 un