

ACADIA PHARMACEUTICALS INC

Form 10-Q

November 09, 2009

[Table of Contents](#)

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

**FORM 10-Q**

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended September 30, 2009

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)

Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-Q

**Delaware**  
(State of Incorporation)

**06-137651**  
(I.R.S. Employer

**3911 Sorrento Valley Boulevard**

**Identification No.)**

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

**92121**  
(Zip Code)

**(858) 558-2871**

**(Registrant's Telephone Number, Including Area Code)**

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Securities Exchange Act of 1934.

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

**(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

Total shares of common stock outstanding as of the close of business on October 30, 2009:

<b>Class</b>	<b>Number of Shares Outstanding</b>
Common Stock, \$0.0001 par value	38,266,843

**Table of Contents**

**ACADIA PHARMACEUTICALS INC.**

**FORM 10-Q**

**TABLE OF CONTENTS**

	<b>PAGE NO.</b>
<b>TABLE OF CONTENTS</b>	i
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
Item 1. <u>Condensed Consolidated Financial Statements (Unaudited)</u>	1
<u>Condensed Consolidated Balance Sheets as of September 30, 2009 and December 31, 2008</u>	1
<u>Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2009 and 2008</u>	2
<u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2009 and 2008</u>	3
<u>Notes to Condensed Consolidated Financial Statements</u>	4
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	9
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	16
Item 4. <u>Controls and Procedures</u>	16
<b><u>PART II. OTHER INFORMATION</u></b>	
Item 1A. <u>Risk Factors</u>	17
Item 6. <u>Exhibits</u>	30
<b><u>SIGNATURES</u></b>	31

**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)

	September 30, 2009	December 31, 2008(1)
<b>Assets</b>		
Cash and cash equivalents	\$ 17,322	\$ 21,171
Investment securities, available-for-sale	37,587	38,912
Prepaid expenses, receivables and other current assets	1,895	2,299
<b>Total current assets</b>	<b>56,804</b>	<b>62,382</b>
Property and equipment, net	1,498	2,103
Other assets	173	192
<b>Total assets</b>	<b>\$ 58,475</b>	<b>\$ 64,677</b>
<b>Liabilities and Stockholders' Equity</b>		
Accounts payable	\$ 2,554	\$ 2,283
Accrued expenses	6,340	7,535
Current portion of deferred revenue	5,904	438
Current portion of long-term debt	450	795
<b>Total current liabilities</b>	<b>15,248</b>	<b>11,051</b>
Long-term portion of deferred revenue	23,909	
Long-term debt, less current portion	154	430
Other long-term liabilities	197	204
<b>Total liabilities</b>	<b>39,508</b>	<b>11,685</b>
<b>Commitments (Note 9)</b>		
<b>Stockholders' equity</b>		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized at September 30, 2009 and December 31, 2008; no shares issued and outstanding at September 30, 2009 and December 31, 2008		
Common stock, \$0.0001 par value; 75,000,000 shares authorized at September 30, 2009 and December 31, 2008; 37,481,572 shares and 37,177,874 shares issued and outstanding at September 30, 2009 and December 31, 2008, respectively	4	4
Additional paid-in capital	349,322	346,815
Accumulated deficit	(330,556)	(294,100)
Accumulated other comprehensive income	197	273
<b>Total stockholders' equity</b>	<b>18,967</b>	<b>52,992</b>

Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-Q

Total liabilities and stockholders equity	\$	58,475	\$	64,677
---	----	--------	----	--------

- (1) The condensed consolidated balance sheet at December 31, 2008 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)**

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
<b>Revenues</b>				
Collaborative revenues	\$ 2,435	\$ 282	\$ 4,630	\$ 1,265
<b>Operating expenses</b>				
Research and development (includes stock-based compensation of \$280, \$346, \$784 and \$1,141, respectively)	9,215	13,397	33,749	44,604
General and administrative (includes stock-based compensation of \$331, \$446, \$1,018 and \$1,298, respectively)	1,994	2,974	7,643	9,428
Total operating expenses	11,209	16,371	41,392	54,032
Loss from operations	(8,774)	(16,089)	(36,762)	(52,767)
Interest income	67	521	376	2,630
Interest expense	(21)	(46)	(70)	(144)
Net loss	\$ (8,728)	\$ (15,614)	\$ (36,456)	\$ (50,281)
Net loss per common share, basic and diluted	\$ (0.23)	\$ (0.42)	\$ (0.98)	\$ (1.36)
Weighted average common shares outstanding, basic and diluted	37,383	37,137	37,262	37,098

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)**

	<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (36,456)	\$ (50,281)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	667	814
Stock-based compensation	1,802	2,439
Amortization of investment premium/discount	174	644
Other	(4)	1
Changes in operating assets and liabilities:		
Prepaid expenses, receivables and other current assets	540	1,527
Other assets	18	33
Accounts payable	252	(140)
Accrued expenses	(1,315)	(7,092)
Deferred revenue	29,374	(537)
Other long-term liabilities	(6)	(5)
<b>Net cash used in operating activities</b>	<b>(4,954)</b>	<b>(52,597)</b>
<b>Cash flows from investing activities</b>		
Purchases of investment securities	(39,222)	(56,089)
Maturities of investment securities	40,162	114,488
Purchases of property and equipment	(24)	(219)
<b>Net cash provided by investing activities</b>	<b>916</b>	<b>58,180</b>
<b>Cash flows from financing activities</b>		
Proceeds from issuance of common stock	705	495
Repayments of long-term debt	(621)	(759)
<b>Net cash provided by (used in) financing activities</b>	<b>84</b>	<b>(264)</b>
Effect of exchange rate changes on cash	105	(93)
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>(3,849)</b>	<b>5,226</b>
<b>Cash and cash equivalents</b>		
Beginning of period	21,171	16,987
<b>End of period</b>	<b>\$ 17,322</b>	<b>\$ 22,213</b>
<b>Supplemental schedule of noncash investing and financing activities</b>		
Unrealized loss on investment securities	\$ (215)	\$ (342)

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



**Table of Contents****ACADIA PHARMACEUTICALS INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****September 30, 2009****(Unaudited)****1. Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements of ACADIA Pharmaceuticals Inc. (together with its wholly owned subsidiaries, ACADIA Pharmaceuticals AB and ACADIA Pharmaceuticals A/S, the Company) should be read in conjunction with the audited financial statements and notes thereto as of and for the year ended December 31, 2008 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 Company evaluated all events or transactions that occurred after September 30, 2009 up through November 9, 2009, the date the Company issued these financial statements. During this period, the Company did not have any material recognizable subsequent events. The Company did have material non-recognizable subsequent events as set forth in Note 11. 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 not been profitable and has incurred substantial operating losses since its inception due in large part to expenditures for its research and development activities. At September 30, 2009, the Company had an accumulated deficit of \$330.6 million. The Company expects its operating losses to continue 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 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 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, or by licensing all or a portion of its product candidates or technology. The Company cannot be certain that funding will be available in the future on acceptable terms, or at all. Turmoil in the financial markets 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.

**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		Nine Months Ended	
September 30,		September 30,	
2009	2008	2009	2008
(unaudited)		(unaudited)	

Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-Q

Antidilutive options to purchase common stock	3,756	3,400	3,699	3,219
Antidilutive warrants to purchase common stock	1,678	1,627	1,711	1,471
	5,434	5,027	5,410	4,690

**Table of Contents****3. Stock-Based Compensation**

The fair value of each employee stock option and each employee stock purchase right granted is estimated on the grant date under the fair value method using the Black-Scholes valuation model. The estimated fair values of the stock option or purchase rights, including the effect of estimated forfeitures, are then expensed over the vesting period. Stock-based awards issued to non-employees other than directors are accounted for using a fair value method and are re-measured to fair value at each period end until the earlier of the date that performance by the non-employee is complete or a performance commitment has been obtained. The fair value of each non-employee award is estimated using the Black-Scholes valuation model. During the three and nine months ended September 30, 2009 and the three and nine months ended September 30, 2008, the Company recorded stock-based compensation expense related to employee and non-employee stock option awards and its employee stock purchase plan of \$611,000, \$1.8 million, \$792,000 and \$2.4 million, respectively. At September 30, 2009, total unrecognized compensation cost related to unvested stock-based awards and employee stock purchase rights was \$3.4 million, which is expected to be recognized over a weighted-average period of 2.3 years.

**4. Comprehensive Loss**

Comprehensive loss consisted of the following (in thousands):

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
	<b>(unaudited)</b>		<b>(unaudited)</b>	
Net loss	\$ (8,728)	\$ (15,614)	\$ (36,456)	\$ (50,281)
Unrealized loss on investment securities, net of tax	(12)	(94)	(216)	(342)
Foreign currency translation gain (loss), net of tax	109	(65)	140	(3)
Total comprehensive loss	\$ (8,631)	\$ (15,773)	\$ (36,532)	\$ (50,626)

**5. Accrued Expenses**

Accrued expenses consisted of the following (in thousands):

	<b>September 30, 2009</b>	<b>December 31, 2008</b>
	<b>(unaudited)</b>	
Accrued clinical and research services	\$ 4,714	\$ 5,494
Accrued compensation and benefits	1,249	1,434
Other	377	607
Total	\$ 6,340	\$ 7,535

**6. Segment Information**

Management has determined that the Company operates in one business segment. All revenues for the three and nine months ended September 30, 2009 and 2008 were generated in the United States. Information regarding long-lived assets by geographic area as of the dates indicated were as follows (in thousands):

<b>September 30, 2009</b>	<b>December 31, 2008</b>
<b>(unaudited)</b>	

Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-Q

United States	\$ 1,092	\$ 1,537
Europe	406	566
Total	\$ 1,498	\$ 2,103

**Table of Contents****7. Fair Value Measurements**

Effective January 1, 2008, the Company adopted authoritative guidance for fair value measurements for all financial assets and liabilities and any other assets and liabilities that are recognized or disclosed at fair value on a recurring basis. The Company did not record an adjustment to retained earnings (accumulated deficit) as result of adoption of this guidance for fair value measurements, and the adoption did not have a material effect on the Company's consolidated financial statements. The authoritative guidance defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. The guidance requires fair value measurements be classified and disclosed in one of the following three categories:

*Level 1.* Quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

*Level 2.* Inputs other than quoted prices in active markets that are observable for the asset or liability, either directly or indirectly.

*Level 3.* Inputs that are unobservable for the asset or liability.

As of September 30, 2009, the Company held \$54.1 million of cash equivalents and available-for-sale investment securities consisting of a money market fund invested in securities of government sponsored enterprises ( GSEs ) and securities collateralized by GSEs, U.S. Treasury notes, and high quality, marketable debt instruments of corporations and GSEs. 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 does not have any direct investments in auction-rate securities or securities that are collateralized by assets that include mortgages or subprime debt.

The Company's cash equivalents and available-for-sale investment securities are classified within Level 1 or Level 2 of the fair value hierarchy. 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 fair value measurements of the Company's cash equivalents and available-for-sale investment securities are identified in the following hierarchy (in thousands):

	September 30, 2009	Fair Value Measurements at Reporting Date using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market fund invested in government sponsored enterprises	\$ 16,547	\$ 16,547	\$	\$
U.S. Treasury notes	5,794	5,794		
Government sponsored enterprises	26,793		26,793	
Commercial paper	5,000		5,000	
	\$ 54,134	\$ 22,341	\$ 31,793	\$

**Table of Contents****8. Collaboration and License Agreements**

In May 2009, the Company entered into a collaboration and license agreement with Biovail Laboratories International SRL ( Biovail ), a subsidiary of Biovail Corporation, to co-develop and commercialize pimavanserin for neurological and psychiatric indications, including Parkinson's disease psychosis ( PDP ) and Alzheimer's disease psychosis ( ADP ), in the United States and Canada. The Company has retained the rights to pimavanserin in the rest of the world. Under the terms of the agreement, the Company is eligible to receive aggregate payments, excluding royalties, of up to \$395 million. These include an upfront cash payment of \$30 million, up to \$160 million in potential milestone payments associated with the successful completion of clinical trials, regulatory submissions and approvals of pimavanserin for PDP and ADP, up to \$45 million in potential milestones should the parties successfully pursue a third indication, and up to \$160 million in potential milestones as certain sales thresholds are met. The Company is also entitled to receive a 15 percent royalty on annual net sales of pimavanserin up to \$100 million and a 20 percent royalty on annual net sales over \$100 million. In addition to product royalties, the Company has the option to co-promote pimavanserin in the United States. Biovail is responsible for all future costs associated with the development, manufacturing, and commercialization of pimavanserin in all indications with the exception of specified PDP study costs, which will be funded by the Company. This agreement was amended by the parties in October 2009 as discussed in Note 11 below.

The upfront cash payment of \$30 million has been deferred and is being recognized as revenue on a straight-line basis over the estimated period of the Company's performance under the agreement. Payments received from Biovail for the reimbursement of specified development costs have been deferred and are being recognized as revenue using a contingency-adjusted performance model over the estimated period of the Company's performance. The Company recognized revenues relating to this collaboration of \$1.9 million and \$3.3 million for the three and nine months ended September 30, 2009. At September 30, 2009, \$27.3 million of revenue was deferred under this agreement, of which \$5.3 million was included in current liabilities and \$22.0 million was included in long-term liabilities.

In March 2009, the Company entered into a collaboration and license agreement with Meiji Seika Kaisha, Ltd. ( Meiji Seika ) to develop and commercialize a novel class of pro-cognitive drugs to treat patients with schizophrenia and related disorders in Japan and several other Asian countries. 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 Asian territory. Meiji Seika also is responsible for the first \$15 million of development expenses and the companies will share remaining expenses through clinical proof-of-concept, subject to possible adjustment in the event the Company further licenses the program outside of the Asian territory. Meiji Seika is responsible for all costs associated with the development, manufacturing and commercialization of the product candidate in the Asian territory after proof-of-concept. Meiji Seika is eligible to share a portion of any product-related revenues received by the Company in the rest of the world.

In April 2009, the Company received an aggregate of \$2 million in license fees pursuant to the agreement with Meiji Seika, which fees have been deferred and are being recognized as revenue ratably over the estimated period of the Company's performance under the agreement. Payments received from Meiji Seika for the reimbursement of specified development costs have been deferred and are being recognized as revenue using a contingency-adjusted performance model over the estimated period of the Company's performance. The Company recognized revenues relating to this collaboration of \$57,000 and \$110,000 for the three and nine months ended September 30, 2009. At September 30, 2009, \$2.1 million of revenue was deferred under this agreement, of which \$220,000 was included in current liabilities and \$1.9 million was included in long-term liabilities.

**9. Commitments**

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 \$15.1 million of future services under these agreements as of September 30, 2009, the majority of which are expected to be provided by the end of December 2010. The nature of the work being conducted under the Company's agreements with contract research organizations is such that, in most cases, the services may be stopped with short notice. In such event, the Company would not be liable for the full amount of the contract. The Company's actual contractual obligations may vary depending upon several factors, including the progress and results of the underlying studies.

**10. Recent Accounting Pronouncements**

In June, 2009, the Financial Accounting Standards Board ( FASB ) issued the Accounting Standards Codification ( ASC ) as the single source of authoritative U.S. GAAP recognized by the FASB to be applied by nongovernmental entities in preparation of financial statements in conformity with U.S. GAAP. While the adoption of the ASC as of September 30, 2009 changes how the Company provides references to accounting standards, the adoption did not have an impact on the Company's consolidated financial statements.

## Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-Q

In August 2009, the FASB issued authoritative guidance on the measurement of liabilities at fair value. The guidance provides clarification that in circumstances in which a quoted market price in an active market for an identical liability is not available, an

## **Table of Contents**

entity is required to measure fair value using a valuation technique that uses the quoted price of an identical liability when traded as an asset or, if unavailable, quoted prices for similar liabilities or similar assets when traded as assets. If none of this information is available, an entity should use a valuation technique in accordance with existing fair valuation principles. The Company adopted this guidance in the quarter ended September 30, 2009 and there was no material impact on the Company's consolidated financial statements.

In October 2009, the FASB issued authoritative guidance which amends existing guidance related to revenue recognition for arrangements with multiple deliverables. The guidance provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated to each deliverable. Assuming other criteria are met, this guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management's estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. This new approach is effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The Company is currently evaluating the impact of adopting this guidance on the Company's consolidated financial statements.

### **11. Subsequent Events**

On October 6, 2009, the Company and Biovail announced an update on their development program with pimavanserin, which is being conducted pursuant to the parties' collaboration and license agreement (the Agreement). Following the announcement on September 1, 2009 of disappointing top-line results from the first Phase III PDP trial (the -012 Study), the parties established a development strategy for PDP that involves using the findings from the -012 Study together with those from the second, ongoing Phase III trial (the -014 Study), when available, to arrive at an enhanced study design that may be used for new Phase III trials. Accordingly, the ongoing -014 Study will be concluded at its current enrollment level to allow for the analysis of data as soon as practicable. Meanwhile, the parties will plan for a new Phase III PDP trial, which is expected to start in the first half of 2010. The parties also announced that Biovail intends to pursue adjunctive therapy with pimavanserin for schizophrenia as a third indication in the collaboration.

In connection with the update and the early conclusion of the -014 Study, the Company and Biovail entered into an amendment (the Amendment) to the Agreement. Pursuant to the Amendment, the new Phase III PDP trial will be funded by Biovail in accordance with the Agreement, provided however, that if the trial does not meet its primary endpoint, then the Company would reimburse Biovail 50 percent of the costs of this study. The Company estimates that the amount of the potential reimbursement would approximate the savings to ACADIA from the early conclusion of the -014 Trial. If the new Phase III PDP trial or a subsequent pivotal trial in PDP meets its primary endpoint, Biovail may credit 50 percent of the costs of the applicable trial against the potential milestone payment triggered by such trial under the Agreement. The Amendment also provides that the Company may elect to pursue an initial clinical trial in ADP at its own expense. However, if the new ADP trial meets its primary endpoint, then Biovail would reimburse the Company 100 percent of the costs of this trial.

On October 15, 2009, the Company initiated a restructuring designed to further streamline its operations, reduce its internal operating expenses, and extend its cash runway. In connection with the restructuring, the Company is reducing its total workforce by about 50 percent to 28 employees. The Company estimates that it will record charges of approximately \$1.3 million during the fourth quarter of 2009 for employment termination costs in connection with the workforce reduction.

---

**Table of Contents**

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

The following discussion and analysis of our consolidated financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included in this quarterly report on Form 10-Q (this Quarterly Report) and the audited financial statements and notes thereto as of and for the year ended December 31, 2008 included with our annual report on Form 10-K (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, programs, and other statements that are not historical facts, including statements which may be preceded by the words intends, may, will, plans, expects, anticipates, projects, predicts, estimates, aims, believes, hopes, potential or similar words. For such statements, 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. We currently are developing a portfolio consisting of our four most advanced product candidates including pimavanserin, which is in Phase III development for Parkinson's disease psychosis, or PDP, in collaboration with Biovail Laboratories International SRL (Biovail), a subsidiary of Biovail Corporation. In addition to pimavanserin, we have a product candidate in Phase II development for chronic pain and a product candidate in Phase I development for glaucoma, each in collaboration with Allergan, Inc., and a program in IND-track development in collaboration with Meiji Seika Kaisha, Ltd. 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. At September 30, 2009, we had an accumulated deficit of \$330.6 million. Although we implemented a restructuring in October 2009, which is designed to reduce our internal operating expenses, we expect our operating losses to continue 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](http://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***

On September 1, 2009, we announced top-line results from our first Phase III PDP trial with pimavanserin (the -012 Study). The -012 Study did not meet its primary endpoint of antipsychotic efficacy as measured using the Scale for the Assessment of Positive Symptoms, or SAPS. Pimavanserin met the key secondary endpoint of motoric tolerability as measured using the Unified Parkinson's Disease Rating Scale, or UPDRS. Pimavanserin was safe and well tolerated, with the frequency of adverse events generally similar in the pimavanserin and placebo arms. While the -012 Study did not meet its primary endpoint and had a larger than expected placebo response, signals of antipsychotic efficacy were observed in the pimavanserin 40 mg study arm.

Following further analysis of the data from the -012 Study, on October 6, 2009, we announced an update on our development program with pimavanserin, which we are pursuing with Biovail. In this update, we noted that efficacy signals observed in the 40 mg dose were most prominent in the United States portion of the study, which comprised nearly one-half of the patients in the trial. These signals also were supported by additional secondary and exploratory measures, including efficacy measures and favorable outcomes in assessments of sleep and caregiver burden. We also announced in the update that, together with Biovail, we have established a development strategy for PDP that involves using the findings from the -012 Study together with those from the second, ongoing Phase III PDP trial (the -014 Study), when available, to arrive at an enhanced study design that may be used for new Phase III trials. Accordingly, the ongoing -014 Study will be concluded at its current enrollment level to allow for the analysis of data as soon as practicable. Meanwhile, the parties will plan for a new Phase

III PDP trial, which is expected to start in the first half of 2010. We also

---

## **Table of Contents**

announced that Biovail intends to pursue adjunctive therapy with pimavanserin for schizophrenia as a third indication in the collaboration.

In connection with the update and the early conclusion of the -014 Study, we and Biovail entered into an amendment, or the Amendment, to the parties' collaboration agreement. Pursuant to the Amendment, the new Phase III PDP trial will be funded by Biovail in accordance with the collaboration agreement, provided however, that if the trial does not meet its primary endpoint, then we would reimburse Biovail 50 percent of the costs of this study. We estimate that the amount of the potential reimbursement would approximate the savings to us from the early conclusion of the -014 Study. If the new Phase III PDP trial or a subsequent pivotal trial in PDP meets its primary endpoint, Biovail may credit 50 percent of the costs of the applicable trial against the potential milestone payment triggered by such trial under the collaboration agreement. The Amendment also provides that we may elect to pursue an initial clinical trial in Alzheimer's disease psychosis, or ADP, at our own expense. However, if the new ADP trial meets its primary endpoint, then Biovail would reimburse us 100 percent of the costs of this trial.

On October 15, 2009, we initiated a restructuring designed to further streamline our operations, reduce our internal operating expenses, and extend our cash runway. In connection with the restructuring, we are reducing our total workforce by about 50 percent to 28 employees. We estimate that we will record charges of approximately \$1.3 million during the fourth quarter of 2009 for employment termination costs in connection with the workforce reductions.

### ***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 September 30, 2009, we had received an aggregate of \$93.0 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 payments under our current agreements with Biovail, Allergan, and Meiji Seika and potential additional collaborations.

In May 2009, we entered into a collaboration agreement with Biovail, pursuant to which we received a \$30 million upfront payment. Under the terms of the agreement, we are eligible to receive additional payments of up to an aggregate of \$365 million upon successfully achieving development, regulatory and sales milestones, subject to certain offsets for up to 50% of the costs of successful PDP trials. We also are entitled to receive royalties on annual net sales of pimavanserin. Our agreement with Biovail is subject to early termination upon specified events.

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 \$16.2 million in payments as of September 30, 2009, consisting of upfront fees, research funding and related fees. This collaboration originally provided for a three-year research term, which has been extended by the parties through March 2010. We have had a reduced level of research activities and related research funding under this collaboration during the extension. In our two other collaboration agreements with Allergan, the parties are pursuing 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.

In March 2009, we entered into a collaboration agreement with Meiji Seika, pursuant to which we received an aggregate of \$2 million in license fees in April 2009. Under the agreement, we are eligible to receive up to \$25 million in aggregate payments, including the \$2 million in license fees already received, in addition to royalties on product sales, if any, in the Asian territory. Meiji Seika also is responsible for the first \$15 million of 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 is subject to early termination upon specified events.

### ***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.

Prior to our collaboration with Biovail, which we established in May 2009, we were responsible for all costs incurred in the development of pimavanserin as well as the costs associated with our other internal programs. Pursuant to this agreement, Biovail is responsible for all future costs associated with the development of pimavanserin in all indications with the exception of specified PDP study costs and of a planned initial ADP study, which will be funded by ACADIA. These PDP studies include our ongoing -014 Study and related open-label safety extension

study. Pursuant to our collaboration with Meiji Seika, which we established in March 2009,

**Table of Contents**

Meiji Seika is responsible for the first \$15 million of development expenses for the product candidate, AM-831, and the companies will share remaining expenses through clinical proof-of-concept, subject to possible adjustment. Meiji Seika 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 related to our product candidates, including costs related to clinical trials, 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. Our internal research and development expenses decreased significantly in the three and nine months ended September 30, 2009 compared to the three and nine months ended September 30, 2008 primarily due to a strategic restructuring and related workforce reductions implemented in August 2008. 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 research and development expenses for the three and nine months ended September 30, 2009 and 2008 (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30, 2009 (unaudited)	September 30, 2008 (unaudited)	September 30, 2009 (unaudited)	September 30, 2008 (unaudited)
External costs:				
Pimavanserin	\$ 5,955	\$ 6,322	\$ 22,846	\$ 19,067
ACP-104 <sup>1</sup>	(26)	(50)	13	2,582
AM-831 and other	181	324	773	1,698
Subtotal	6,110	6,596	23,632	23,347
Internal costs	2,825	6,455	9,333	20,116
Stock-based compensation	280	346	784	1,141
Total research and development	\$ 9,215	\$ 13,397	\$ 33,749	\$ 44,604

1. ACP-104 was a product candidate that we were previously developing.

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 when and to what extent we will receive cash inflows, if any, from the development or commercialization of pimavanserin pursuant to our agreement with Biovail or the extent to which the parties will have to reimburse each other for certain clinical trial costs pursuant to the Amendment. We also 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.

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**

## Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-Q

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

## **Table of Contents**

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. 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 and commercial co-promotion, however, we have not received revenue from these two sources 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 applicable to each 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 the fair value of any undelivered items can be determined. 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.

We assess 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 typically recognize revenue using a contingency-adjusted performance model over the remaining 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 estimated term of the study based on the number of patients enrolled in the trial on an ongoing basis, beginning with patient enrollment. 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.

### ***Stock-based Compensation***

The fair value of each employee stock option and each employee stock purchase right granted is estimated on the grant date under the fair value method using the Black-Scholes valuation model. The estimated fair values of the stock option or purchase rights, including the effect of estimated forfeitures, are then expensed over the vesting period. As of September 30, 2009, total unrecognized compensation cost related to stock options and purchase rights was approximately \$3.4 million, and the weighted average period over which this cost is expected to be recognized is 2.3 years.

Stock-based awards issued to non-employees other than directors are accounted for using a fair value method and are re-measured to fair value at each period end until the earlier of the date that performance by the non-employee is complete or a performance commitment has been obtained. The fair value of each non-employee award is estimated using the Black-Scholes valuation model.

### **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,

## **Table of Contents**

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 September 30, 2009 and 2008***

#### *Revenues*

Revenues increased to \$2.4 million for the three months ended September 30, 2009 compared to \$282,000 for the three months ended September 30, 2008. This increase was primarily due to \$1.9 million in revenues recognized under our collaboration with Biovail, which commenced in May 2009, as well as increased revenues from other agreements. Revenues from our collaborations with Allergan totaled \$273,000 for the three months ended September 30, 2009 compared to \$182,000 for the three months ended September 30, 2008. Revenues from our collaboration with Meija Seika and our agreements with other parties totaled \$294,000 for the three months ended September 30, 2009 compared to \$100,000 for the three months ended September 30, 2008.

#### *Research and Development Expenses*

Research and development expenses decreased to \$9.2 million for the three months ended September 30, 2009, including \$280,000 in stock-based compensation, compared to \$13.4 million for the three months ended September 30, 2008, including \$346,000 in stock-based compensation. The decrease in research and development expenses was primarily due to \$3.6 million in decreased costs associated with our internal research and development organization and \$486,000 in lower external service costs. The decrease in internal research and development costs was primarily attributable to \$3.1 million in decreased salaries and related personnel costs, and decreases in laboratory supply, equipment and other costs resulting from the strategic restructuring implemented in August 2008. Salaries and related personnel costs for the three months ended September 30, 2008 included a charge of \$1.7 million in connection with workforce reductions from the August 2008 restructuring. External service costs totaled \$6.1 million, or 66 percent of our research and development expenses for the three months ended September 30, 2009, compared to \$6.6 million, or 49 percent of our research and development expenses, for the comparable period in 2008. External service costs were primarily comprised of development expenses for pimavanserin.

#### *General and Administrative Expenses*

General and administrative expenses decreased to \$2.0 million for the three months ended September 30, 2009, including \$331,000 in stock-based compensation, compared to \$3.0 million for the three months ended September 30, 2008, including \$446,000 in stock-based compensation. The decrease in general and administrative expenses was primarily due to \$813,000 in decreased salaries and related personnel costs from the August 2008 restructuring, and decreases in external service costs. Salaries and related personnel costs for the three months ended September 30, 2008 included a charge of \$454,000 in connection with workforce reductions from the August 2008 restructuring.

#### *Interest Income*

Interest income decreased to \$67,000 for the three months ended September 30, 2009 from \$521,000 for the three months ended September 30, 2008. The decrease in interest income during the three months ended September 30, 2009 was due to decreased yields on our investment security portfolio and lower average levels of cash and investment securities.

### ***Comparison of the Nine Months Ended September 30, 2009 and 2008***

#### *Revenues*

Revenues increased to \$4.6 million for the nine months ended September 30, 2009 compared to \$1.3 million for the nine months ended September 30, 2008. The increase was primarily due to \$3.3 million in revenues recognized under our collaboration with Biovail, which commenced in May 2009. Revenues from our collaborations with Allergan totaled \$807,000 for the nine months ended September 30, 2009 compared to \$686,000 for the nine months ended September 30, 2008. Revenues from our collaboration with Meija Seika and our agreements with other parties totaled \$546,000 for the nine months ended September 30, 2009, compared to \$579,000 for the nine months ended September 30, 2008.

#### *Research and Development Expenses*

## Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-Q

Research and development expenses decreased to \$33.7 million for the nine months ended September 30, 2009, including \$784,000 in stock-based compensation, from \$44.6 million for the nine months ended September 30, 2008, including \$1.1 million in stock-based compensation. The decrease in research and development expenses was primarily due to \$10.8 million in decreased costs associated with our internal research and development organization, partially offset by \$285,000 in increased external service costs. The decrease in internal research and development costs was primarily attributable to \$8.0 million in decreased salaries and related personnel costs, \$1.4 million in decreased laboratory supply costs, and decreases in equipment and other costs resulting from the

---

## **Table of Contents**

restructuring implemented in August 2008. Salaries and related personnel costs for the nine months ended September 30, 2008 included a charge of \$1.7 million in connection with workforce reductions from the August 2008 restructuring. External service costs totaled \$23.6 million, or 70 percent of our research and development expenses, for the nine months ended September 30, 2009, compared to \$23.3 million, or 52 percent of our research and development expenses, for the comparable period in 2008. Increased external development costs for pimavanserin were largely offset by lower costs incurred for ACP-104 and other programs.

### *General and Administrative Expenses*

General and administrative expenses decreased to \$7.6 million for the nine months ended September 30, 2009, including \$1.0 million in stock-based compensation, compared to \$9.4 million for the nine months ended September 30, 2008, including \$1.3 million in stock-based compensation. The decrease in general and administrative expenses was primarily due to \$1.6 million in decreased salaries and related personnel costs from the August 2008 restructuring, partially offset by \$150,000 in increased external service costs. Salaries and related personnel costs for the nine months ended September 30, 2008 included a charge of \$454,000 in connection with workforce reductions from the restructuring implemented in August 2008.

### *Interest Income*

Interest income decreased to \$376,000 for the nine months ended September 30, 2009 from \$2.6 million for the nine months ended September 30, 2008. The decrease in interest income during the nine months ended September 30, 2009 was due to decreased yields on our investment security portfolio and lower average levels of cash and investment securities.

## **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 September 30, 2009, we had received \$325.5 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, \$93.0 million in payments from collaboration agreements, \$22.4 million in debt financing, and \$21.9 million in interest income.

At September 30, 2009, we had approximately \$54.9 million in cash, cash equivalents and investment securities compared to \$60.1 million at December 31, 2008. We have consumed substantial amounts of capital since our inception. In October 2009, we initiated a restructuring designed to further streamline our operations, reduce our internal operating expenses, and extend our cash runway. We anticipate that our cash, cash equivalents and investment securities will be in the range of \$43 to \$45 million at December 31, 2009, and that our existing cash resources and anticipated payments from our collaborations will be sufficient to fund our operations through December 31, 2011.

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, and 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;

## Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-Q

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, or by licensing all or a portion of our product candidates or technology. In August 2008, we entered into a Committed Equity Financing Facility, or CEFF, which provides us with access, at our discretion to capital during a three-year period through the sale of newly-issued shares of our common stock. The funds that can be raised under the CEFF, if available, will depend on the then-current price of our common stock and the number of shares actually sold, which may not exceed an aggregate of approximately 7 million shares. The aggregate amount raised under the CEFF may not exceed \$60 million. We may access capital under the CEFF in tranches of up to a maximum of between 2.0 and 3.5 percent of our market capitalization at the time of the draw down of each tranche, subject to certain conditions, including a minimum share price threshold of \$1.50. In October 2009, we completed a draw down under the CEFF in which we raised \$1.2 million through the issuance of 785,271 shares of our common stock.

**Table of Contents**

We cannot be certain that funding will be available to us on acceptable terms, or at all. Turmoil in the financial markets has 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 current market conditions, the disappointing results from our first Phase III PDP trial with pimavanserin, which we announced on September 1, 2009, and any unfavorable outcome over the next year in our development of pimavanserin could have a material adverse effect on our ability to raise additional capital. To the extent that the average price of our common stock is below the minimum share price of \$1.50, we will not be able to raise money under the CEFF.

If we cannot raise adequate additional capital in the future under the CEFF or from other sources, 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. In addition, in connection with our recent restructuring, we are reducing the scope of our research and development activities, and we may be required to further reduce the scope of our research and development activities. This may lead to an impairment of our equipment and additional charges, which could materially affect our balance sheet and results of operations.

We have invested a substantial portion of our available cash in a money market fund invested in securities of government sponsored enterprises, or GSEs, and securities collateralized by GSEs, U.S. Treasury notes, and high quality, marketable debt instruments of corporations and GSEs. 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. We do not have any direct investments in auction-rate securities or securities that are collateralized by assets that include mortgages or subprime debt. Our investment portfolio has not been adversely impacted by the disruption in the credit markets. However, if there is continued 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 \$5.0 million for the nine months ended September 30, 2009 from \$52.6 million for the nine months ended September 30, 2008. This decrease was primarily due to a decrease in our net loss and changes in operating assets and liabilities, including an increase in deferred revenue of \$29.4 million during the nine months ended September 30, 2009. The increase in deferred revenue was primarily attributable to the upfront payment received from our collaboration with Biovail and initial licensing fees received from our collaboration with Meiji Seika, offset by initial revenues recognized pursuant to these agreements. During the nine months ended September 30, 2008, there was an aggregate decrease in accounts payable and accrued expenses of \$7.2 million largely reflecting payments made for external service costs related to our clinical trials.

Net cash provided by investing activities totaled \$916,000 for the nine months ended September 30, 2009 compared to \$58.2 million for the nine months ended September 30, 2008, and has fluctuated significantly from period to period primarily due to the timing of purchases and maturities of investment securities. During the nine months ended September 30, 2009, maturities of investment securities exceeded purchases by an aggregate of \$940,000. During the comparable period of 2008, maturities of investment securities exceeded purchases by an aggregate of \$58.4 million.

Net cash provided by financing activities totaled \$84,000 during the nine months ended September 30, 2009 compared to net cash used in financing activities of \$264,000 during the nine months ended September 30, 2008. The increase in net cash provided by financing activities was attributable to increased proceeds from the issuance of common stock and lower repayments of long-term debt.

We have entered into equipment financing agreements from time to time, which we have utilized to fund the majority of our property and equipment purchases. The agreements contain fixed interest rates ranging from 9.55 to 10.41 percent per annum. At September 30, 2009, we had \$604,000 in outstanding borrowings under these agreements, which are secured by the related equipment.

The following table summarizes our contractual obligations, including interest, at September 30, 2009 (in thousands):

	Total	Less than 1 Year	1-3 Years	4-5 Years
Operating leases	\$ 10,757	\$ 2,359	\$ 5,699	\$ 2,699
Long-term debt	654	490	164	
<b>Total</b>	<b>\$ 11,411</b>	<b>\$ 2,849</b>	<b>\$ 5,863</b>	<b>\$ 2,699</b>

We also have 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 \$15.1 million of future services under these agreements as of September 30, 2009, the majority of which are expected to be provided by the end of December 2010. The nature of the work being conducted under our agreements with contract research organizations is such that, in

---

## **Table of Contents**

most cases, the services may be stopped with short notice. In such event, we would not be liable for the full amount of the contract. Our actual contractual obligations may vary depending upon several factors, including the progress and results of the underlying studies.

In addition, we have entered into an agreement 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 milestone payments, 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 those 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, in U.S. Treasury notes and in high quality marketable debt instruments of corporations 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 September 30, 2009, 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 Sweden and Denmark, which expose us to foreign exchange risk. The functional currency of our subsidiary in Sweden is the Swedish kroner and the functional currency of our subsidiary in Denmark is the Danish kroner. Accordingly, 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 and we do not have any derivative financial instruments.

## **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

## Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-Q

design will succeed in achieving its stated goals under all potential future conditions; over time, control 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.

As of September 30, 2009, 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 our disclosure controls and procedures, as

---

## **Table of Contents**

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 as of September 30, 2009.

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.

## **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**

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

We have experienced significant net losses since our inception. As of September 30, 2009, we had an accumulated deficit of approximately \$330.6 million. We expect our annual net losses to continue over the next several years as we advance our programs and incur significant clinical development costs.

We have not received, and do not expect to receive for at least the next several years, any revenues from the commercialization of our product candidates. Substantially all of our revenues for the three and nine months ended September 30, 2009 were from our collaborations with Biovail and Allergan as well as our agreements with other parties. We anticipate that collaborations, which provide us with research funding and potential milestone payments and royalties, will continue to be our primary source of revenues for the next several years. 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, and 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.

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

A key aspect of our strategy is to selectively enter into collaborations 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. The ongoing research term of our agreements with Allergan will end in March 2010 and, other than \$1 million in licensing fees expected to be received under our agreement with Meiji Seika, additional payments from our agreements with Biovail, Allergan, and Meiji Seika are dependent on successful advancement of our applicable product candidates. There is no guarantee that revenues from our collaborations will continue at current or past levels. Given the current economic environment, it is possible that our existing collaborators may elect to reduce their external spending.

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.

Each of Biovail, Meiji Seika and Allergan can terminate our existing collaborations under specific circumstances, including in some cases the right to terminate without cause upon prior notice. We may not be able to renew our existing collaborations on acceptable terms, if at all. We also face competition in our search for new collaborators. Given the current economic environment, it is possible that competition for new collaborators may increase.

## **Table of Contents**

*Our most advanced product candidates are in clinical trials, which are long, expensive and unpredictable, 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 recently had an unsuccessful Phase III trial with our product candidate, pimavanserin. We expect to start a new Phase III trial with pimavanserin for the treatment of PDP in the first half of 2010 and have announced plans with Biovail to pursue additional trials with pimavanserin for adjunctive therapy in schizophrenia and for ADP. An unfavorable outcome in one or more studies with pimavanserin would be a major set-back for the program, our collaboration with Biovail and for our company, generally. In particular, given the current conditions in the financial markets, an unfavorable outcome in one or more of these indications may require us to delay, reduce the scope of, or eliminate this program and could have a material adverse effect on our company and the value of our common stock. In addition, pursuant to an October 2009 amendment to our collaboration agreement with Biovail, if the new Phase III trial planned for pimavanserin in PDP does not meet its primary endpoint, then we would be obligated to reimburse Biovail 50% of the costs of such trial, which could be significant. We also have chronic pain and glaucoma clinical programs in collaboration with Allergan, which are in 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 confirm the positive results of earlier trials; and

the results may not meet the level of statistical significance required by the U.S. Food and Drug Administration, or FDA, or other regulatory agencies.

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

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

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

demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;

reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;

## Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-Q

manufacturing sufficient quantities of a product candidate;

obtaining approval of an Investigational New Drug Application, or IND, from the FDA;

obtaining institutional review board approval to conduct a clinical trial at a prospective clinical trial site; and

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

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

ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials or requests by them for supplemental information with respect to our clinical trial results;

failure to conduct clinical trials in accordance with regulatory requirements;

lower than anticipated retention rate of patients in clinical trials;

serious adverse events or side effects experienced by participants; and

insufficient supply or deficient quality of product candidates or other materials necessary for the conduct of our clinical trials.

---

**Table of Contents**

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

*If 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 and investment securities totaled approximately \$54.9 million at September 30, 2009. We believe our existing cash resources and anticipated payments from our collaborations will be sufficient to fund our cash requirements through December 31, 2011. However, we will 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:

progress in, and the costs of, our preclinical studies and clinical trials and other research and development programs;

the scope, prioritization and number of our research and development programs;

the ability of our collaborators and us to reach the milestones, and other events or developments, triggering payments under our collaboration agreements or to otherwise make payments under these 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;

the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory clearances to market our 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, private or public sales of our securities, debt financings, or by licensing all or a portion of our product candidates or technology. The recent deterioration in the financial markets has adversely affected the market capitalizations of many biotechnology companies, including us, and generally made equity and debt financing more difficult to obtain. This, coupled with other factors, may limit our access to additional financing over the near-term future. This could have a material adverse effect on our ability to access sufficient funding, including pursuant to our CEFF or from other sources. Specifically, we will not be able to raise money under the CEFF if the average price of our common stock is below the minimum share price of \$1.50. We cannot be certain that additional funding will be available to us on acceptable terms, if at all. If funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. Additional funding, if obtained, may significantly dilute existing stockholders, including any funds that may be raised under the CEFF.

*Our Committed Equity Financing Facility, or CEFF, may not be available to us if we elect to make a draw down, may require us to make additional blackout or other payments to Kingsbridge and may result in dilution to our stockholders.\**

Pursuant to the CEFF, Kingsbridge committed to purchase up to the lesser of \$60 million or up to approximately 7 million shares of our common stock over a three-year period. To date, we have sold approximately 785,000 shares of our common stock for proceeds of \$1.2 million

## Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-Q

under the CEFF. Kingsbridge will not be obligated to purchase shares under the CEFF unless specified conditions are met, which include a minimum price of \$1.50 for our common stock, the effectiveness of a registration statement registering for resale the shares of common stock to be issued in connection with the CEFF, and customary other conditions, such as accuracy of representations and warranties and compliance with applicable laws. Kingsbridge is permitted to terminate the CEFF under certain circumstances. If we are unable to access funds through the CEFF or Kingsbridge terminates the CEFF, we may be unable to access capital on favorable terms or at all.

In connection with the CEFF, we filed a registration statement with the SEC to register the resale of shares of our common stock that may be issued pursuant to the CEFF or upon exercise of the warrant we issued to Kingsbridge in connection with establishing the CEFF. This registration statement was declared effective by the SEC on September 23, 2008. We are entitled, in certain circumstances, to deliver a blackout notice to Kingsbridge to suspend the use of the prospectus, which is a part of such registration statement, and prohibit Kingsbridge from selling shares under that prospectus for a certain period of time. If we deliver a blackout notice in the 15 trading days following the settlement of a draw down, or if the registration statement covering the resale of the shares of common stock to be issued in connection with the CEFF is not effective in circumstances not permitted by our registration rights agreement with Kingsbridge, then we must make a payment to Kingsbridge, or issue Kingsbridge additional shares in lieu of this payment, calculated on the basis of a specified number of shares held by Kingsbridge immediately prior to the blackout period and the change in the market price of our common stock during the period in which the use of the resale registration statement is suspended. If the trading price of our common stock declines during a suspension of the resale registration statement, the blackout or other payment could be significant.

## **Table of Contents**

If we sell shares to Kingsbridge under the CEFF, or issue shares in lieu of any blackout payment, it will have a dilutive effect on the holdings of our current stockholders, and may result in downward pressure on the price of our common stock. If we draw down amounts under the CEFF, we will issue shares to Kingsbridge at a discount of up to 12% from the volume weighted average price of our common stock. If we draw down amounts under the CEFF when our share price is decreasing, we will need to issue more shares to raise the same amount than if our stock price was higher. Issuances in the face of a declining share price will have an even greater dilutive effect than if our share price were stable or increasing and may further decrease our share price.

*If we do not realize the expected benefits from the restructuring that we announced in October 2009, our operating results and financial conditions would be negatively impacted.\**

In October 2009, we implemented a restructuring designed to further streamline our operations, reduce our internal operating expenses, and extend our cash runway. If we are unable to realize the expected operational efficiencies from our restructuring, our operating results and financial condition would be adversely affected. We cannot guarantee that we will not have to undertake additional restructuring activities, that any of our restructuring efforts will be successful, or that we will be able to realize the cost savings and other anticipated benefits from this restructuring.

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

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

disputes or breaches with respect to payments that we believe are due under the applicable agreements, particularly in the current economic environment when companies, including large established ones, may be seeking to reduce external payments;

disputes on strategy as to what development or commercialization activities should be pursued under the applicable agreements;

disputes as to the responsibility for conducting development and commercialization activities pursuant to the applicable collaboration, including the payment of costs related thereto;

disagreements with respect to ownership of intellectual property rights;

unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities, or to permit public disclosure of these activities;

delay of a collaborator's development or commercialization efforts with respect to our product candidates; or

termination or non-renewal of the collaboration.

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

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

## Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-Q

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

Our collaboration with Meiji Seika is initially focused on the advancement of precognitive drugs ( PCAPs ) as a treatment for schizophrenia and related disorders. While Meiji Seika has rights to the PCAPs in the Asian territory, we have the right to pursue them, alone or with a partner, in the rest of the world. Under our collaboration for pimavanserin, Biovail has licensed the rights to Canada and the United States for the treatment of PDP, ADP and other neurological and psychiatric conditions, which include schizophrenia. We have retained the rights to pimavanserin for the rest of the world. It is possible that the product candidates being developed under these programs could compete with each other. In addition, Biovail s strategy is to pursue the commercialization of product candidates for central nervous system indications that are independent of our efforts to develop and commercialize pimavanserin.

## **Table of Contents**

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

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

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

these third parties do not successfully carry out their contractual duties or fail to meet regulatory obligations or expected deadlines;

these third parties need to be replaced; or

the quality or accuracy of the data obtained by these third parties is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons.

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

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

Even if we or our collaborators successfully complete the clinical trials of product candidates, the product candidates may fail for other reasons, including the possibility that the product candidates will:

fail to receive the regulatory clearances required to market them as drugs;

be subject to proprietary rights held by others requiring the negotiation of a license agreement prior to marketing;

be difficult or expensive to manufacture on a commercial scale;

have adverse side effects that make their use less desirable; or

fail to compete with product candidates or other treatments commercialized by competitors.

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

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

the ability to provide acceptable evidence of safety and efficacy;

relative convenience and ease of administration;

the prevalence and severity of any adverse side effects;

availability of alternative treatments;

pricing and cost effectiveness, which may be subject to regulatory control;

effectiveness of our or our collaborators' sales and marketing strategy; and

our ability to obtain sufficient third-party insurance coverage or reimbursement.

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

---

**Table of Contents**

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

Our success depends on our ability to attract, retain, and motivate highly qualified management and scientific personnel. In particular, our development programs depend on our ability to attract and retain highly skilled development personnel, especially in the fields of central nervous system disorders, including neuropsychiatric and related disorders. In the future, we may need to hire additional personnel if we expand our research and development efforts from our current levels. We face competition for experienced scientists, clinical operations personnel, and other technical personnel from numerous companies and academic and other research institutions. Competition for qualified personnel is particularly intense in the San Diego, California area. If we are unable to attract and retain the necessary personnel, this will significantly impede the achievement of our research and development objectives and our ability to meet the demands of our collaborators in a timely fashion.

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

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

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

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

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

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

***We will need to transition our organization in connection with our most recent restructuring, and we may encounter difficulties managing this transition, which could adversely affect our results of operations.\****

We will need to effectively manage our operations and facilities in order to advance our drug development programs, including those covered by our collaborations with Biovail and Meiji Seika, achieve milestones under our collaboration agreements, facilitate additional collaborations, and pursue other development activities. Following our most recent restructuring, it is possible that our infrastructure may be inadequate to support our future efforts and growth. To manage our transition, we will be required to continue to improve our operational, financial and management controls, and reporting systems and procedures. In addition, we may have to develop internal sales, marketing, and distribution capabilities if we decide to market any drug that we may successfully develop. We may not successfully manage the transition of our operations and, accordingly, may not achieve our research, development, and commercialization goals.

***We face financial and administrative challenges in coordinating the operations of our European activities with our activities in California, which could have an adverse impact on our operations.\****

Our principal executive offices are located in San Diego and we also have a subsidiary, ACADIA Pharmaceuticals AB, located in Malmö, Sweden that employed a small percentage of our total personnel as of September 30, 2009. The additional administrative expense required to coordinate activities in both Europe and California could divert management resources from other important endeavors and, in turn, delay our development and commercialization efforts. In addition, currency fluctuations involving our Swedish operations may cause foreign currency gains and losses. These exchange-rate fluctuations could have a negative effect on our operations. We do not engage in currency hedging transactions.



## **Table of Contents**

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

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

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

whether we generate revenues or reimbursements by achieving specified research, development or commercialization milestones under any agreements or otherwise receive potential payments under these agreements;

whether we are required to make payments due to achieving specified milestones under any licensing or similar agreements or otherwise make potential payments under these agreements;

the incurrence of preclinical or clinical expenses that could fluctuate significantly from period to period, including reimbursement obligations pursuant to our collaboration agreements;

the initiation, termination, or reduction in the scope of our collaborations or any disputes regarding these collaborations;

the timing of our satisfaction of applicable regulatory requirements;

the rate of expansion of our clinical development and other internal research and development efforts;

the effect of competing technologies and products and market developments;

the costs and benefits associated with our restructuring;

the costs associated with litigation; and

general and industry-specific economic conditions.

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

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

We have no manufacturing facilities and have no experience in the manufacturing of drugs or in designing drug-manufacturing processes. We have contracted with third-party manufacturers to produce, in collaboration with us, our product candidates for clinical trials. If any of our product candidates are approved by the FDA or other regulatory agencies for commercial sale, we may need to contract with a third party to manufacture them in larger quantities. We currently use third-party manufacturers to produce clinical supplies of our compounds for us, including pimavanserin. While we believe that there are alternative sources available to manufacture our product candidates, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without delays or additional expenditures. We cannot

## Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-Q

estimate these delays or costs with certainty but, if they were to occur, they could cause a delay in our development and commercialization efforts.

The manufacturers of our product candidates are obliged to operate in accordance with FDA-mandated current good manufacturing practices, or cGMPs. A failure of any of our contract manufacturers to establish and follow cGMPs and to document their adherence to such practices may lead to significant delays in clinical trials or in obtaining regulatory approval of product candidates or the ultimate launch of products based on our product candidates into the market. Failure by our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of products, operating restrictions, and criminal prosecutions.

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

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

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

Laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002, or SOX, and rules adopted or proposed by the SEC and by The Nasdaq Global Market, have resulted in, and will continue to result in, significant costs to us as we evaluate the implications of these rules and respond to their requirements. We issued an evaluation of our internal

---

## **Table of Contents**

control over financial reporting under Section 404 of SOX with our Annual Report. In the future, if we are not able to issue an evaluation of our internal control over financial reporting as required or we or our independent registered public accounting firm determine that our internal control over financial reporting is not effective, this shortcoming could have an adverse effect on our business and financial results and the price of our common stock could be negatively affected. New rules could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the coverage that is the same or similar to our current coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors and board committees, and as our executive officers. We cannot predict or estimate the total amount of the costs we may incur or the timing of such costs to comply with these rules and regulations.

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

We do not currently have an organization for the sales, marketing and distribution of pharmaceutical products. In order to market any products that may be approved by the FDA, we must build our sales, marketing, managerial, and related capabilities or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing, and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable.

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

We may attempt to acquire businesses, technologies, services, or products or license in technologies that we believe are a strategic fit with our business. We have limited experience in identifying acquisition targets, successfully completing proposed acquisitions and integrating any acquired businesses, technologies, services or products into our current infrastructure. The process of integrating any acquired business, technology, service, or product may result in unforeseen operating difficulties and expenditures and may divert significant management attention from our ongoing business operations. As a result, we will incur a variety of costs in connection with an acquisition and may never realize its anticipated benefits.

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

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

### **Risks Related to Our Intellectual Property**

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

Our commercial success depends on obtaining and maintaining proprietary rights to our product candidates and technologies and their uses, as well as successfully defending these rights against third-party challenges. We will only be able to protect our product candidates, proprietary technologies, and their uses from unauthorized use by third parties to the extent that valid and enforceable patents, or effectively protected trade secrets, cover them. Although we have filed numerous patent applications worldwide with respect to pimavanserin, we have been issued only a limited number of patents with respect to these filings.

Our ability to obtain patent protection for our product candidates and technologies is uncertain due to a number of factors, including:

we may not have been the first to make the inventions covered by our pending patent applications or issued patents;

we may not have been the first to file patent applications for our product candidates or the technologies we rely upon;

others may independently develop similar or alternative technologies or duplicate any of our technologies;

our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;

any or all of our pending patent applications may not result in issued patents;

we may not seek or obtain patent protection in all countries that will eventually provide a significant business opportunity;

any patents issued to us or our collaborators may not provide a basis for commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties;

---

## **Table of Contents**

our proprietary technologies may not be patentable;

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

others may identify prior art which could invalidate our patents.

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

We regularly conduct searches to identify patents or patent applications that may prevent us from obtaining patent protection for our proprietary compounds or that could limit the rights we have claimed in our patents and patent applications. Disputes may arise regarding the ownership or inventorship of our inventions. It is difficult to determine how such disputes would be resolved. Others may challenge the validity of our patents. If our patents are found to be invalid, we will lose the ability to exclude others from making, using or selling the inventions claimed therein.

Some of our academic institutional licensors, research collaborators and scientific advisors have rights to publish data and information to which we have rights. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations, then our ability to receive patent protection or protect our proprietary information will be impaired. Additionally, employees whose positions were eliminated in connection with restructurings may seek future employment with our competitors. Although each of our employees is required to sign a confidentiality agreement with us at the time of hire, we cannot guarantee that the confidential nature of our proprietary information will be maintained in the course of such future employment. In addition, technology that we may license in may become important to some aspects of our business. We generally will not control the patent prosecution, maintenance or enforcement of in-licensed technology.

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

Because we operate in the highly technical field of drug discovery and development of small molecule drugs, we rely in part on trade secret protection in order to protect our proprietary technology and processes. However, trade secrets are difficult to protect. We enter into confidentiality and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. These agreements also generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. The failure to obtain or maintain trade secret protection could adversely affect our competitive position. In addition, we have not entered into any noncompete agreements with any of our employees.

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

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

## Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-Q

genes or polypeptides for the identification or development of drug compounds. There are also many patents relating to chemical compounds and the uses thereof. If our compounds are found to infringe any such patents, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from making, using or selling the patented compounds. We may need to resort to litigation to enforce a patent issued to us, protect our trade secrets or determine the scope and validity of third-party proprietary rights. From time to time, we may hire scientific personnel formerly

## **Table of Contents**

employed by other companies involved in one or more areas similar to the activities conducted by us. Either we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of their prior affiliations. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. We may not be able to afford the costs of litigation. Any legal action against us or our collaborators could lead to:

payment of damages, potentially treble damages, if we are found to have willfully infringed a party's patent rights;

injunctive or other equitable relief that may effectively block our ability to further develop, commercialize, and sell products; or

we or our collaborators having to enter into license arrangements that may not be available on commercially acceptable terms, if at all.

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

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

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. For example, some of our patent applications will cover gene sequences and products and the uses of those gene sequences and products. Public disclosures and patent applications related to the Human Genome Project and other genomics efforts may limit the scope of our claims or make unpatentable subsequent patent applications. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. The United States Patent and Trademark Office's standards are uncertain and could change in the future. Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. U.S. patents and patent applications may also be subject to interference proceedings, and U.S. patents may be subject to reexamination proceedings in the United States Patent and Trademark Office (and foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent office), which proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, reexamination and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

In addition, changes in or different interpretations of patent laws in the United States and foreign countries may permit others to use our discoveries or to develop and commercialize our technology and products without providing any compensation to us or may limit the number of patents or claims we can obtain. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws and those countries may lack adequate rules and procedures for defending our intellectual property rights. For example, some countries, including many in Europe, do not grant patent claims directed to methods of treating humans and, in these countries, patent protection may not be available at all to protect our product candidates. In addition, U.S. patent laws may change which could prevent or limit us from filing patent applications or patent claims to protect our products and/or technologies.

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

### **Risks Related to Our Industry**

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

The pharmaceutical industry is subject to stringent regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Neither we nor our collaborators can market a pharmaceutical product in the United States until it has completed rigorous preclinical testing and clinical trials and an extensive regulatory clearance process implemented by the FDA. Satisfaction of regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product, and requires substantial resources. Even if regulatory approval is obtained, it may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, and/or marketing of such products, and requirements for post-approval studies, including additional research and development and

## Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-Q

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

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

---

## **Table of Contents**

approval by regulatory authorities outside the United States and, similarly, approval by regulatory authorities outside the United States will not automatically lead to FDA approval.

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

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

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

For example, our potential product for Parkinson's disease psychosis and Alzheimer's disease psychosis would compete with off-label use of antipsychotic drugs, including Seroquel, marketed by Astra-Zeneca, and with the generic drug clozapine. In the area of chronic pain, potential products would compete with Neurontin and Lyrica, marketed by Pfizer, and Cymbalta, marketed by Eli Lilly, as well as a variety of generic or proprietary opioids. Our potential products for the treatment of glaucoma would compete with Xalatan, marketed by Pfizer, and Lumigan and Alphagan, marketed by Allergan. Our potential products for the treatment of schizophrenia would compete with Zyprexa, marketed by Eli Lilly, Fanapt to be marketed by Vanda Pharmaceuticals, Risperdal, marketed by Johnson & Johnson, Abilify, marketed jointly by Bristol-Myers Squibb and Otsuka Pharmaceutical, Seroquel, and clozapine. Our potential products for the treatment of sleep maintenance insomnia would compete with Ambien and Ambien CR, marketed by Sanofi-Aventis, Lunesta, marketed by Sepracor, Sonata, marketed by King Pharmaceuticals, Inc., Rozerem, marketed by Takeda Pharmaceuticals North America, Inc., and various benzodiazepines.

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

identifying and validating targets;

screening compounds against targets;

preclinical studies and clinical trials of potential pharmaceutical products; and

obtaining FDA and other regulatory approvals.

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

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

Our research and development activities involve the controlled use of potentially harmful hazardous materials, including volatile solvents, biological materials such as blood from patients that has the potential to transmit disease, chemicals that cause cancer, and various radioactive compounds. Our operations also produce hazardous waste products. We face the risk of contamination or injury from the use, storage, handling

## Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-Q

or disposal of these materials. We are subject to federal, state and local laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations could be significant, and current or future environmental regulations may impair our research, development, or production efforts. If one of our employees were accidentally injured from the use, storage, handling, or disposal of these materials, the medical costs related to his or her treatment would be covered by our workers compensation insurance policy. However, we do not carry specific biological or hazardous waste insurance coverage and our general liability insurance policy specifically excludes coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be subject to criminal sanctions or fines or be held liable for damages, our operating licenses could be revoked, or we could be required to suspend or modify our operations and our research and development efforts.

## **Table of Contents**

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

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

## **Risks Related to Our Common Stock**

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

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

the development status of our product candidates, including results of our clinical trials for pimavanserin or our chronic pain and glaucoma collaborations;

the initiation, termination, or reduction in the scope of our collaborations or any disputes or developments regarding these collaborations;

market conditions or trends related to biotechnology and pharmaceutical industries, or the market in general;

announcements of technological innovations, new commercial products, or other material events by our competitors or us;

disputes or other developments concerning our proprietary rights;

changes in, or failure to meet, securities analysts' or investors' expectations of our financial performance;

additions or departures of key personnel;

discussions of our business, products, financial performance, prospects, or stock price by the financial and scientific press and online investor communities such as chat rooms;

public concern as to, and legislative action with respect to, genetic testing or other research areas of biopharmaceutical companies, the pricing and availability of prescription drugs, or the safety of drugs and drug delivery techniques;

regulatory developments in the United States and in foreign countries;

the announcement of, or developments in, any litigation matters; or

economic and political factors, including but not limited to economic and financial crises, wars, terrorism, and political unrest. In particular, our Phase III program with pimavanserin for Parkinson's disease psychosis encompasses a number of studies, including Phase III pivotal trials, open-label safety extension trials and a range of supporting studies, including carcinogenicity studies, a QTc study, and drug-drug interaction studies. Another unfavorable outcome in one or more of the studies in this program could be a major set-back for our collaboration with Biovail and for our company, generally. Given the recent turmoil in the financial markets, such an unfavorable outcome could have a material adverse effect on our company and the value of our common stock.

In the past, following periods of volatility in the market price of a particular company's securities, securities class action litigation has often been brought against that company. We may become subject to this type of litigation, which is often extremely expensive and diverts management's attention.

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

Our directors, executive officers and holders of five percent or more of our outstanding common stock and their affiliates beneficially own a substantial portion of our outstanding common stock. As a result, these stockholders, acting together, have the ability to significantly influence all matters requiring approval by our stockholders, including the election of all of our board members, amendments to our certificate of incorporation, going-private transactions, and the approval of mergers or other business combination

## **Table of Contents**

transactions. The interests of this group of stockholders may not always coincide with the company's interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of our other stockholders.

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

A significant number of shares of our common stock are held by a small number of stockholders. Sales of a significant number of shares of our common stock, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. Holders of a significant number of shares of our common stock, from investments made when we were a private company, have rights to cause us to file a registration statement on their behalf or include their shares in registration statements that we may file on our behalf or on behalf of other stockholders. Additionally, in connection with the CEFF, we filed a registration statement with the SEC to register the resale of up to a total of approximately 7.4 million shares of our common stock that may be issued pursuant to the CEFF or upon exercise of the warrant we issued in connection with establishing the CEFF. In addition, we have filed a registration statement to sell shares of our common stock on our own behalf, which registration statement was declared effective by the SEC on August 18, 2009, and may elect to sell shares pursuant to such registration from time to time. Our stock price may decline as a result of the sale of the shares of our common stock included in any of these registration statements.

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

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

establish that members of the board of directors may be removed only for cause upon the affirmative vote of stockholders owning at least a majority of our capital stock;

authorize the issuance of blank check preferred stock that could be issued by our board of directors to increase the number of outstanding shares and prevent or delay a takeover attempt;

limit who may call a special meeting of stockholders;

establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings;

prohibit our stockholders from making certain changes to our amended and restated certificate of incorporation or amended and restated bylaws except with 66 <sup>2</sup>/<sub>3</sub> percent stockholder approval; and

provide for a board of directors with staggered terms.

We are also subject to provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15 percent or more of our common stock for 3 years unless the holder's acquisition of our stock was approved in advance by our board of directors. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders.

*Adverse securities and credit market conditions have reduced our market capitalization and may significantly affect our ability to raise capital.*

## Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-Q

The turmoil in the financial markets has adversely affected the market capitalizations of many biotechnology companies, including us, and generally made equity and debt financing more difficult to obtain. This, coupled with other factors, may limit access to financing over the near-term future. This could have a material adverse effect on our ability to access funding pursuant to our CEFF or from other sources on acceptable terms, or at all, and our stock price may suffer further as a result.

***If the price of our common stock trades below \$1.00 per share for a sustained period, our common stock may be delisted from the Nasdaq Global Market.\****

The Nasdaq Global Market imposes, among other requirements, listing maintenance standards as well as minimum bid and public float requirements. In particular, Nasdaq rules require us to maintain a minimum bid price of \$1.00 per share of our common stock. Our stock did trade below \$1.00 per share earlier in 2009. If the closing bid price of our common stock is below \$1.00 per share for 30 consecutive trading days, we would fail to be in compliance with Nasdaq's continued listing standards and, if we are unable to cure the non-compliance within 180 days, our common stock may be delisted from the Nasdaq Global Market and we may not be able to maintain the continued listing of our common stock on the Nasdaq Global Market. Delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease. Such delisting could also adversely affect our ability to obtain financing for the continuation of our operations.

**Table of Contents**

**ITEM 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Description of Document</b>
3.1	Amended and Restated Certificate of Incorporation (filed as Exhibit 3.3 to Registration Statement No. 333-113137).
3.2	Amended and Restated Bylaws (filed as Exhibit 3.5 to Registration Statement No. 333-113137).
4.1	Form of common stock certificate of Registrant (filed as Exhibit 4.1 to Registration Statement No. 333-52492, dated December 21, 2000).
4.2	Form of Warrant to Purchase Preferred Stock issued to GATX Ventures on May 31, 2002 (filed as Exhibit 4.3 to Registration Statement No. 333-113137).
4.3	Form of Warrant to Purchase Common Stock issued to purchasers in a private placement on April 20, 2005 (filed as Exhibit 4.3 to Registration Statement No. 333-124753).
4.4	Warrant to Purchase Common Stock issued to Kingsbridge Capital Limited on August 4, 2008 (filed as Exhibit 4.4 to Registrant's Quarterly Report on Form 10-Q, filed August 7, 2008).
31.1	Certification of Uli Hacksell, Ph.D., Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Thomas H. Aasen, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Uli Hacksell, Ph.D., Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Thomas H. Aasen, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

**Table of Contents**

**SIGNATURES**

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

**ACADIA Pharmaceuticals Inc.**

Date: November 9, 2009

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

(on behalf of the registrant and as the  
registrant's Principal Executive Officer)

By: /s/ Thomas H. Aasen  
Thomas H. Aasen  
Vice President and Chief Financial Officer

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