

ACADIA PHARMACEUTICALS INC

Form 10-Q

November 05, 2007

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, 2007

or

**..** **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
Commission File Number: 000-50768

\_\_\_\_\_  
**ACADIA PHARMACEUTICALS INC.**

(Exact Name of Registrant as Specified in Its Charter)

\_\_\_\_\_

**Delaware**  
(State of Incorporation)

**06-1376651**  
(I.R.S. Employer Identification No.)

**3911 Sorrento Valley Boulevard**

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

**92121**  
(Zip Code)

**(858) 558-2871**

(Registrant's Telephone Number, Including Area Code)

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

---

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 is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of large accelerated filer and accelerated filer in Rule 12b-2 of the Securities Exchange Act of 1934:

Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date.

Total shares of common stock outstanding as of the close of business on October 31, 2007:

Class	Number of Shares Outstanding
Common Stock, \$0.0001 par value	36,967,340

---

**Table of Contents**

**ACADIA PHARMACEUTICALS INC.**

**FORM 10-Q**

**T A B L E O F C O N T E N T S**

	<b>PAGE NO.</b>
<b><u>TABLE OF CONTENTS</u></b>	i
<b><u>PART I. FINANCIAL INFORMATION</u></b>	1
Item 1. <u>Condensed Consolidated Financial Statements (Unaudited)</u>	1
<u>Condensed Consolidated Balance Sheets as of September 30, 2007 and December 31, 2006</u>	1
<u>Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2007 and 2006</u>	2
<u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2007 and 2006</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>	7
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	14
Item 4. <u>Controls and Procedures</u>	14
<b><u>PART II. OTHER INFORMATION</u></b>	16
Item 1A. <u>Risk Factors</u>	16
Item 6. <u>Exhibits</u>	28
<b><u>SIGNATURES</u></b>	29

**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,	December 31,
	2007	2006(1)
<b>Assets</b>		
Cash and cash equivalents	\$ 23,462	\$ 15,480
Investment securities, available-for-sale	117,500	67,775
Prepaid expenses, receivables and other current assets	3,989	2,528
<b>Total current assets</b>	<b>144,951</b>	<b>85,783</b>
Property and equipment, net	3,095	3,505
Other assets	300	256
<b>Total assets</b>	<b>\$ 148,346</b>	<b>\$ 89,544</b>
<b>Liabilities and Stockholders' Equity</b>		
Accounts payable	\$ 2,950	\$ 3,387
Accrued expenses	11,524	13,485
Current portion of deferred revenue	1,664	2,666
Current portion of long-term debt	1,017	996
<b>Total current liabilities</b>	<b>17,155</b>	<b>20,534</b>
<b>Other long-term liabilities</b>	<b>202</b>	<b>472</b>
Long-term debt, less current portion	1,255	1,379
<b>Total liabilities</b>	<b>18,612</b>	<b>22,385</b>
Commitments (Note 9)		
Stockholders' equity		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized at September 30, 2007 and December 31, 2006; no shares issued and outstanding at September 30, 2007 and December 31, 2006		
Common stock, \$0.0001 par value; 75,000,000 shares authorized at September 30, 2007 and December 31, 2006; 36,963,695 shares and 29,940,477 shares issued and outstanding at September 30, 2007 and December 31, 2006, respectively	4	3
Additional paid-in capital	342,115	240,446
Accumulated deficit	(212,818)	(173,466)
Unearned stock-based compensation		(64)
Accumulated other comprehensive income	433	240

Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-Q

Total stockholders' equity	129,734	67,159
Total liabilities and stockholders' equity	\$ 148,346	\$ 89,544

---

(1) The condensed consolidated balance sheet at December 31, 2006 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

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

**Table of Contents****ACADIA PHARMACEUTICALS INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(in thousands, except per share data)

(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2007	September 30, 2006	September 30, 2007	September 30, 2006
<b>Revenues</b>				
Collaborative revenues	\$ 1,957	\$ 1,943	\$ 5,972	\$ 6,360
<b>Operating expenses</b>				
Research and development (includes stock-based compensation of \$805, \$550, \$2,414 and \$1,417, respectively)	16,909	15,501	40,664	36,611
General and administrative (includes stock-based compensation of \$441, \$421, \$1,188 and \$1,141, respectively)	2,941	2,962	9,257	8,813
Provision for loss from (settlement of) litigation		(3,981)		(3,560)
<b>Total operating expenses</b>	<b>19,850</b>	<b>14,482</b>	<b>49,921</b>	<b>41,864</b>
Loss from operations	(17,893)	(12,539)	(43,949)	(35,504)
Interest income	1,919	1,327	4,803	2,993
Interest expense	(71)	(51)	(205)	(138)
Loss before change in accounting principle	(16,045)	(11,263)	(39,351)	(32,649)
Cumulative effect of change in accounting principle				51
<b>Net loss</b>	<b>\$ (16,045)</b>	<b>\$ (11,263)</b>	<b>\$ (39,351)</b>	<b>\$ (32,598)</b>
Net loss per common share, basic and diluted				
Before change in accounting principle	\$ (0.43)	\$ (0.38)	\$ (1.14)	\$ (1.20)
Cumulative effect of change in accounting principle				
<b>Net loss per common share, basic and diluted</b>	<b>\$ (0.43)</b>	<b>\$ (0.38)</b>	<b>\$ (1.14)</b>	<b>\$ (1.20)</b>
Weighted average common shares outstanding, basic and diluted	36,946	29,732	34,619	27,277

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</b>	
	<b>September 30,</b>	
	<b>2007</b>	<b>2006</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (39,351)	\$ (32,598)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	811	603
Stock-based compensation	3,602	2,558
Amortization of investment premium/discount	(787)	
Other	(106)	(15)
Changes in operating assets and liabilities:		
Prepaid expenses, receivables and other current assets	(1,391)	1,457
Other assets	(44)	2
Accounts payable	(483)	1,133
Accrued expenses	(2,035)	7,286
Accrued loss from litigation		(8,710)
Current portion of deferred revenue	(1,002)	(655)
Other long-term liabilities	(272)	60
Net cash used in operating activities	(41,058)	(28,879)
<b>Cash flows from investing activities</b>		
Purchases of investment securities	(171,551)	(73,868)
Maturities of investment securities	122,827	38,791
Decrease in restricted cash		12,520
Purchases of property and equipment	(352)	(1,346)
Net cash used in investing activities	(49,076)	(23,903)
<b>Cash flows from financing activities</b>		
Proceeds from issuance of common stock, net of issuance costs	98,114	68,919
Proceeds from issuance of long-term debt	754	1,033
Repayments of long-term debt	(857)	(769)
Net cash provided by financing activities	98,011	69,183
Effect of exchange rate changes on cash	105	32
Net increase in cash and cash equivalents	7,982	16,433
<b>Cash and cash equivalents</b>		
Beginning of period	15,480	9,796
End of period	\$ 23,462	\$ 26,229

**Supplemental schedule of noncash investing and financing activities**

Unrealized gain on investment securities	\$	135	\$	146
--	----	-----	----	-----

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, 2007****(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, 2006 included in the Company's Annual Report on Form 10-K (Annual Report) filed with the Securities and Exchange Commission (the SEC). The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying financial statements do not include all of the information and notes required by GAAP for complete financial statements. In the opinion of management, the accompanying financial statements reflect all adjustments (consisting of normal recurring adjustments) that are necessary for a fair statement of the financial position, results of operations and cash flows for the interim periods presented. Interim results are not necessarily indicative of results for a full year.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the accompanying notes. Actual results could differ from those estimates.

Costs associated with patents and patent applications for the Company's intellectual property are included in general and administrative expenses. Such costs, which totaled \$598,000 and \$1.9 million in the three and nine months ended September 30, 2006, respectively, were previously included in research and development expenses and have been reclassified to general and administrative expenses in the Company's condensed consolidated statements of operations to conform to the current period presentation.

**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, restricted vesting common stock 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, restricted vesting common stock 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, 2007 (unaudited)	2006	September 30, 2007 (unaudited)	2006
Antidilutive options to purchase common stock	2,832	2,937	2,837	2,686
Antidilutive warrants to purchase common stock	1,393	1,393	1,393	1,393
Restricted vesting common stock	2	26	8	39
	4,227	4,356	4,238	4,118

**3. Stock-Based Compensation**

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

During the three and nine months ended September 30, 2007 and the three and nine months ended September 30, 2006, the Company recorded stock-based compensation expense related to employee and nonemployee stock option awards and its employee stock purchase plan (the Purchase Plan ) of \$1.2 million, \$3.6 million, \$971,000 and \$2.6 million, respectively. The Company adopted Statement of Financial Accounting Standards ( SFAS ) No. 123 (revised 2004), *Share-Based*

**Table of Contents**

*Payment* ( SFAS No. 123(R) ), using the modified prospective method on January 1, 2006, resulting in a cumulative benefit from accounting change of \$51,000 during the nine months ended September 30, 2006. The Company continues to account for compensation expense for options granted to non-employees other than directors in accordance with Emerging Issues Task Force, Issue No. 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling Goods or Services*.

The value of each employee stock option and Purchase Plan right is estimated on the grant date under the fair value method using the Black-Scholes option pricing model. For options granted prior to January 1, 2006, the Company amortizes the fair value on an accelerated basis. For options granted after January 1, 2006, the Company amortizes the fair value on a straight-line basis. All option expense is amortized over the requisite service period of the awards, which are generally the vesting periods. The following assumptions were used to estimate the fair value of employee stock options:

	Nine Months Ended	
	September 30,	
	2007	2006
	(unaudited)	
Expected volatility	64%-68%	64%-65%
Risk-free interest rate	4-5%	5%
Expected forfeiture rate	6%	6%-7%
Expected dividend yield	0%	0%
Expected life of options in years	5.4-5.5	5.3-5.4

The following assumptions were used to estimate fair value for the latest offering under the Purchase Plan that commenced June 1, 2007: expected volatility of 73 to 111 percent; risk-free interest rate of 5 percent; dividend yield of 0 percent; and expected life in years of 0.5 to 2.0.

At September 30, 2007, total unrecognized estimated compensation cost related to non-vested stock options granted prior to that date and existing Purchase Plan rights were \$6.2 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):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2007	2006	2007	2006
	(unaudited)		(unaudited)	
Net loss	\$ (16,045)	\$ (11,263)	\$ (39,351)	\$ (32,598)
Unrealized gain on investment securities	80	86	135	146
Foreign currency translation gain (loss)	40	(9)	58	56
Total comprehensive loss	\$ (15,925)	\$ (11,186)	\$ (39,158)	\$ (32,396)

**5. Accrued Expenses**

Accrued expenses consisted of (in thousands):

September 30,	December 31,
2007	2006

Edgar Filing: ACADIA PHARMACEUTICALS INC - Form 10-Q

	(unaudited)	
Accrued clinical and research services	\$ 7,600	\$ 9,768
Accrued compensation and benefits	3,012	2,649
Other	912	1,068
Total	\$ 11,524	\$ 13,485

**Table of Contents****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, 2007 and 2006 were generated in the United States. Information regarding long-lived assets by geographic area as of the dates indicated were as follows (in thousands):

	September 30,	December 31,
	2007	2006
		(unaudited)
United States	\$ 2,085	\$ 2,347
Europe	1,010	1,158
<b>Total</b>	<b>\$ 3,095</b>	<b>\$ 3,505</b>

**7. Income Taxes**

The Company has adopted Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* ( FIN 48 ), an interpretation of FASB Statement No. 109, as of January 1, 2007. At December 31, 2006, the Company had both federal and state net operating loss ( NOL ) carryforwards of approximately \$149.4 and \$97.9 million, respectively, which will begin to expire in 2012 and 2007, respectively. The Company also had federal research and development ( R&D ) credit carryforwards of approximately \$3.0 million that will begin to expire in 2012. In addition, the Company had state research and development credit carryforwards of approximately \$2.7 million that have no expiration date. The Company also had foreign net operating loss carryforwards of approximately \$3.9 million that have no expiration date. Due to uncertainties surrounding the Company's ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset its net deferred tax assets.

Utilization of the NOL and R&D credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by Section 382 of the Internal Revenue Code of 1986, as amended (the Code ), as well as similar state and foreign provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders or public groups. Since the Company's formation, the Company has raised capital through the issuance of capital stock on several occasions (both before and after its public offering) which, combined with the purchasing stockholders' subsequent disposition of those shares, may have resulted in such an ownership change, or could result in an ownership change in the future upon subsequent disposition.

The Company has not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since the Company's formation due to the complexity and cost associated with such a study, and the fact that there may be additional such ownership changes in the future. If the Company has experienced an ownership change at any time since its formation, utilization of the NOL or R&D credit carryforwards would be subject to an annual limitation under Section 382 of the Code, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term, tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the NOL or R&D credit carryforwards before utilization. Further, until a study is completed and any limitation known, no amounts are being considered as an uncertain tax position or disclosed as an unrecognized tax benefit under FIN 48. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact its effective tax rate. Any carryforwards that will expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of the valuation allowance.

The tax years 1997-2006 remain open to examination by the major taxing jurisdictions to which the Company is subject.

**8. Stockholders' Equity**

In April 2007, the Company raised net proceeds of \$96.1 million from the sale of 6,612,500 shares of its common stock in a public offering.

**9. Commitments**

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

The Company has entered into agreements with contract research organizations and other external service providers for services in connection with the development of its drug candidates. The Company was contractually obligated for up to approximately \$24.4 million of future services under these agreements as of September 30, 2007. The nature of the work

---

## **Table of Contents**

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 results of the underlying studies.

In September 2006, the Company entered into an agreement to fully settle a previously disclosed civil action inclusive of all fees and costs, which agreement resulted in a gain of \$4.0 million and \$3.6 million during the three and nine months ended September 30, 2006, respectively.

## **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, 2006 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, internal 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, we claim the protection of the Private Securities Litigation Reform Act of 1995. Readers of this Quarterly Report are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date on which they are made. We undertake no obligation to update publicly or revise any forward-looking statements. Actual events or results may differ materially from our expectations. Important factors that could cause actual results to differ materially from those stated or implied by our forward-looking statements include, but are not limited to, the risk factors identified in our filings with the SEC, including this Quarterly Report.

### **Overview**

#### ***Background***

We are a biopharmaceutical company focused on the discovery, development, and commercialization of small molecule drugs for the treatment of central nervous system disorders. We currently have five mid-to-late stage clinical programs and several additional programs in discovery and development. In our most advanced program, we are conducting the first pivotal Phase III trial with pimavanserin tartrate, previously referred to as ACP-103, for the treatment of Parkinson's disease psychosis. In March 2007, we reported positive top-line results from a Phase II trial in our program with pimavanserin as a co-therapy in schizophrenia. We also have two proprietary Phase II-stage clinical programs, which are ACP-104 for the treatment of schizophrenia and pimavanserin for the treatment of sleep maintenance insomnia. We have retained worldwide commercialization rights for all four of these proprietary programs. In addition, we have a neuropathic pain program in Phase II clinical trials in collaboration with Allergan, Inc. All of the drug candidates in our product 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, 2007, we had an accumulated deficit of \$212.8 million. We expect our operating losses to increase for at least the next several years as we pursue the clinical development of our lead drug candidates and expand our discovery and development pipeline.

#### ***Recent Developments***

We are enrolling patients in the first pivotal Phase III trial in our program with pimavanserin as a treatment for Parkinson's disease psychosis. This double-blind, placebo-controlled trial, which was initiated in June 2007, is designed to evaluate the safety and efficacy of pimavanserin in approximately 240 patients with Parkinson's disease psychosis.

We are enrolling patients in a Phase IIb clinical trial in our program with ACP-104 as a treatment for patients with schizophrenia. This double-blind, placebo-controlled trial, which was initiated in late-June 2007, is designed to evaluate the safety and efficacy of ACP-104 in approximately 250 patients with schizophrenia who are experiencing an acute psychotic episode.

In June 2007, we completed the full analysis of the data from our Phase II schizophrenia co-therapy trial with pimavanserin. This analysis confirmed the robustness of the top-line trial results announced in March 2007, which demonstrated several advantages of co-therapy with pimavanserin and a sub-maximal dose of risperidone. We are preparing to present data from the Phase II schizophrenia co-therapy trial in

December 2007.



---

## **Table of Contents**

### ***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 research and milestone payments under our collaboration and research agreements. We have entered into three separate collaboration agreements with Allergan and one with Sepracor Inc. We have also entered into a development agreement with The Stanley Medical Research Institute ( SMRI ) and smaller scale research and license agreements with other parties. As of September 30, 2007, we had received an aggregate of \$56.9 million in payments under these agreements, including research funding and upfront and milestone payments. We expect our revenues for the next several years to consist primarily of payments under our current agreements and any additional collaborations, including any upfront payments upon execution of new agreements, research funding throughout the research term of our agreements with these parties, and milestone payments contingent upon achievement of agreed-upon objectives.

Pursuant to the terms of our January 2005 collaboration agreement with Sepracor, we had received \$6.7 million in research funding as of September 30, 2007. The research term of this collaboration will expire in January 2008. In connection with this collaboration, Sepracor has also purchased an aggregate of \$20 million of our common stock in two \$10 million tranches. We are recognizing the premium from these stock purchases as revenue as the related research activities are performed over the research term. Pursuant to our agreement with Sepracor, if certain conditions are met, we are also eligible to receive milestone payments as well as royalties on product sales, if any, resulting from our collaboration.

Pursuant to the terms of our March 2003 collaboration agreement with Allergan, we had received an aggregate of \$14.2 million in payments as of September 30, 2007, consisting of upfront fees, and research funding and related fees. This collaboration originally provided for a three-year research term, which was extended by the parties for two additional years through March 2008. While we will receive additional research funding during this extended term, we anticipate lower revenues and related research activities under this collaboration during the extension. We may also receive milestone payments and royalties on product sales, if any, under each of our three collaboration agreements with Allergan. Pursuant to our development agreement with SMRI, we had received \$5.0 million in funding as of September 30, 2007 to support the development of ACP-104. The development term of this agreement expired in May 2007.

Each of our collaboration agreements is subject to early termination by the collaborator upon specified events, including if we breach the agreement or, in the case of one of our agreements with Allergan, if we have a change in control. Upon the conclusion of the research term under each agreement, our collaborator may terminate the agreement by notice.

### ***Research and Development Expenses***

Our research and development expenses consist primarily of salaries and related personnel expenses, fees paid to external service providers, laboratory supplies and costs for facilities and equipment. We charge all research and development expenses to operations as incurred. Our research and development activities are primarily focused on our most advanced clinical and preclinical programs. We are responsible for all costs incurred in the development of both pimavanserin and ACP-104 as well as the costs associated with our other proprietary programs. We are not responsible for, nor have we incurred, development expenses, including costs related to clinical trials, in the programs that we are pursuing under our collaboration agreements, including our clinical programs for neuropathic pain and glaucoma that we are pursuing in collaboration with Allergan.

We use our internal research and development resources, including our employees and discovery infrastructure, across several projects and many of our costs are not attributable to a specific project but are directed to broadly applicable research activities. Accordingly, we do not report our internal research and development costs on a project basis. We use external service providers to manufacture our drug 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 drug candidates. To the extent that costs associated with external service providers are not attributable to a specific project, they are included in other external costs.

**Table of Contents**

The following table summarizes our research and development expenses for the three and nine months ended September 30, 2007 and 2006 (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30, 2007 (unaudited)	2006	September 30, 2007 (unaudited)	2006
Costs of external service providers:				
Pimavanserin	\$ 2,718	\$ 7,890	\$ 7,730	\$ 14,172
ACP-104	6,404	970	9,670	3,131
Other	566	173	1,235	569
Subtotal	9,688	9,033	18,635	17,872
Internal costs	6,416	5,918	19,615	17,322
Stock-based compensation	805	550	2,414	1,417
Total research and development	\$ 16,909	\$ 15,501	\$ 40,664	\$ 36,611

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 in the continued development of our drug 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 we are currently focused on advancing the clinical development of pimavanserin and ACP-104, 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 drug candidate, as well as an ongoing assessment as to each drug candidate's commercial potential. We cannot forecast with any degree of certainty which drug 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. As a result, we cannot be certain when and to what extent we will receive cash inflows from the commercialization of our drug candidates.

We expect our research and development expenses to be substantial and to increase as we continue the development of our clinical programs and expand our discovery and development pipeline. The lengthy process of completing clinical trials and seeking regulatory approval for our drug candidates requires the expenditure of substantial resources. Any failure by us or delay in completing clinical trials, or in obtaining regulatory approvals could cause our research and development expenses to increase and, in turn, have a material adverse effect on our results of operations.

**General and Administrative Expenses**

Our general and administrative expenses consist primarily of salaries and other costs for employees serving in executive, finance, business development, and business operations functions, as well as professional fees and costs associated with legal services, accounting services and patents and patent applications for our intellectual property. Costs associated with patents and patent applications for our intellectual property, which totaled \$598,000 and \$1.9 million in the three and nine months ended September 30, 2006, respectively, were previously included in research and development expenses and have been reclassified to general and administrative expenses in our statement of operations to conform to the current period presentation. We anticipate that our general and administrative expenses may increase in future periods as we support the future growth of our business and incur additional professional fees, including costs associated with our intellectual property.

**Critical Accounting Policies and Estimates**

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



**Table of Contents*****Revenue Recognition***

We recognize revenues in accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 104, *Revenue Recognition*. Arrangements with multiple elements are accounted for in accordance with Emerging Issues Task Force Issue No. 00-21 ( EITF 00-21 ), *Revenue Arrangements With Multiple Deliverables*. We analyze our multiple element arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting in accordance with EITF 00-21. Our revenues are primarily related to our collaboration agreements, and such agreements may provide for various types of payments to us, including upfront payments, research funding during the term of the agreement, milestone payments based on the achievement of established development objectives, licensing fees, and royalties on future product sales.

Upfront, non-refundable payments under collaboration agreements are recorded as deferred revenue once received and recognized ratably over the term of the agreement. Non-refundable payments for research funding are generally recognized as revenues ratably over the period as the related research activities are performed. Revenues from non-refundable milestones are recognized 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 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 triggering event. 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.

***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 estimated 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 materially from the actual costs incurred. However, we expect to expand the level of our clinical trials and related services in the future. As a result, we anticipate that our estimated accruals for clinical services will be more material to our operations in future periods. 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***

Effective January 1, 2006, we adopted the fair value recognition provisions of Statement of Financial Accounting Standards ( SFAS ) No. 123 (revised 2004), *Share-Based Payment* ( SFAS No. 123(R) ), which is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation* ( SFAS No. 123 ), using the modified prospective transition method. Under that transition method, compensation cost recognized for the three and nine months ended September 30, 2007 and 2006 included (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, excluding stock options granted prior to December 31, 2003, which were valued using the minimum value method, and for which the related compensation cost will continue to be determined by using the intrinsic value method under Accounting Principles Board ( APB ) Opinion No. 25, and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123(R). Results for prior periods have not been restated.

The value of each employee stock option and each employee stock purchase plan right is estimated on the grant date under the fair value method using the Black-Scholes option pricing model. For options granted prior to January 1, 2006, we amortize the fair value on an accelerated basis. For options granted after January 1, 2006, we amortize the fair value on a straight-line basis. All options are amortized over the requisite service period of the awards, which is generally the vesting period. At September 30, 2007, total unrecognized estimated compensation cost related to non-vested stock options granted prior to that date and employee stock purchase plan rights existing on that date were \$6.2 million, which is expected to be recognized over a weighted-average period of 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 award is estimated using the Black-Scholes option pricing model.



## **Table of Contents**

### **Results of Operations**

#### ***Fluctuations in Operating Results***

Our results of operations have fluctuated significantly from period to period in the past and are likely to continue to do so in the future. We anticipate that our quarterly and annual results of operations will be impacted for the foreseeable future by several factors, including the timing and amount of payments received pursuant to our current and any future collaborations, and the progress and timing of expenditures related to our discovery and 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, 2007 and 2006***

##### *Revenues*

Revenues totaled \$2.0 million for the three months ended September 30, 2007 compared to \$1.9 million for the three months ended September 30, 2006, and were comprised of revenues from our collaborations with Sepracor and Allergan as well as smaller scale research and license agreements with other parties. Revenues from our collaboration agreements with Sepracor and Allergan totaled \$820,000 and \$325,000, respectively, for the three months ended September 30, 2007, compared to \$945,000 and \$348,000, respectively, for the three months ended September 30, 2006. The ongoing research terms of our agreements with Sepracor and Allergan will end in the first quarter of 2008.

##### *Research and Development Expenses*

Research and development expenses totaled \$16.9 million for the three months ended September 30, 2007, including \$805,000 in stock-based compensation, compared to \$15.5 million for the three months ended September 30, 2006, including \$550,000 in stock-based compensation. The increase was primarily due to \$655,000 in increased fees paid to external service providers and \$636,000 in increased salaries and related personnel costs, partially offset by a decrease in laboratory supplies costs and other expenses. External service costs increased to \$9.7 million, or 57 percent of our research and development expenses, for the three months ended September 30, 2007, compared to \$9.0 million, or 58 percent of our research and development expenses, for the comparable period in 2006. This increase was primarily due to costs related to ongoing clinical trials in our advanced proprietary clinical programs, including a Phase IIb trial in our program with ACP-104 for schizophrenia and a pivotal Phase III trial in our program with pimavanserin for Parkinson's disease psychosis. We expect that our research and development costs will continue to increase in future years as we continue to pursue the development of our advanced clinical programs and expand our discovery and development pipeline.

##### *General and Administrative Expenses*

General and administrative expenses totaled \$2.9 million for the three months ended September 30, 2007, including \$441,000 in stock-based compensation, compared to \$3.0 million for the three months ended September 30, 2006, including \$421,000 in stock-based compensation. Increased personnel and other costs during the three months ended September 30, 2007 were offset by lower professional fees. We anticipate that our general and administrative expenses may increase in future periods as we support the future growth of our business and incur additional professional fees, including costs associated with our intellectual property.

##### *Provision for Loss From (Settlement of) Litigation*

During the three months ended September 30, 2006, we recorded a gain of \$4.0 million associated with an agreement we entered into to fully settle a civil action inclusive of all fees and costs.

##### *Interest Income*

Interest income increased to \$1.9 million for the three months ended September 30, 2007 from \$1.3 million for the three months ended September 30, 2006. The increase in interest income was primarily due to higher average levels of cash and investment securities resulting from sales of our common stock and, to a lesser degree, increased yields on our investment portfolio.

#### ***Comparison of the Nine Months Ended September 30, 2007 and 2006***

##### *Revenues*

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

Revenues totaled \$6.0 million for the nine months ended September 30, 2007 compared to \$6.4 million for the comparable period of 2006, and were comprised of revenues from our collaborations with Sepracor and Allergan as well as our agreements with SMRI and other parties. This decrease in revenues was primarily due to a lower level of research

## **Table of Contents**

funding during the extended term of our March 2003 collaboration with Allergan and lower revenues from our agreement with SMRI, partially offset by increased revenues from smaller scale research and license agreements with other parties. Revenues from our collaborations with Allergan totaled \$1.3 million for the nine months ended September 30, 2007 compared to \$1.9 million for the nine months ended September 30, 2006. Revenues from our collaboration agreement with Sepracor totaled \$2.5 million for the nine months ended September 30, 2007 compared to \$2.8 million for the nine months ended September 30, 2006. Revenues from our agreement with SMRI totaled \$1.0 million for the nine months ended September 30, 2007 compared to \$1.5 million for the nine months ended September 30, 2006.

### *Research and Development Expenses*

Research and development expenses totaled \$40.7 million for the nine months ended September 30, 2007, including \$2.4 million in stock-based compensation, compared to \$36.6 million for the nine months ended September 30, 2006, including \$1.4 million in stock-based compensation. This increase in expenses was primarily due to \$2.5 million in increased salaries and related personnel costs, \$998,000 in increased stock-based compensation, and \$763,000 in increased external service costs, partially offset by a decrease in laboratory supplies costs. External service costs totaled \$18.6 million, or 46 percent of our research and development expenses, for the nine months ended September 30, 2007, compared to \$17.9 million, or 49 percent of our research and development expenses, for the comparable period in 2006.

### *General and Administrative Expenses*

General and administrative expenses totaled \$9.3 million for the nine months ended September 30, 2007, including \$1.2 million in stock-based compensation, compared to \$8.8 million for the nine months ended September 30, 2006, including \$1.1 million in stock-based compensation. The increase in general and administrative expenses was primarily due to \$398,000 in increased salaries and related personnel costs, and increased facilities and other expenses, partially offset by lower professional fees.

### *Provision for Loss From (Settlement of) Litigation*

During the nine months ended September 30, 2006, we recorded a gain of \$3.6 million associated with an agreement we entered into to fully settle a civil action inclusive of all fees and costs.

### *Interest Income*

Interest income increased to \$4.8 million for the nine months ended September 30, 2007 from \$3.0 million for the nine months ended September 30, 2006. The increase in interest income was primarily due to higher average levels of cash and investment securities resulting from sales of our common stock and, to a lesser degree, increased yields on our investment portfolio.

## **Liquidity and Capital Resources**

Since inception, we have funded our operations primarily through sales of our equity securities, payments under our collaboration agreements, debt financings, and interest income. As of September 30, 2007, we had received \$323.8 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, \$56.9 million in payments from collaboration agreements, \$22.4 million in debt financing, and \$16.9 million in interest income.

At September 30, 2007, we had approximately \$141.0 million in cash, cash equivalents and investment securities compared to \$83.3 million at December 31, 2006. We have invested a substantial portion of our available cash in investment securities consisting of high quality, marketable debt instruments of corporations and financial institutions. We have adopted an investment policy and established guidelines relating to diversification and maturities of our investments to preserve principal and maintain liquidity.

Net cash used in operating activities increased to \$41.1 million for the nine months ended September 30, 2007 from \$28.9 million for the nine months ended September 30, 2006. This increase was primarily due to an increase in our net loss, and an aggregate decrease of \$2.5 million in accounts payable and accrued expenses during the nine months ended September 30, 2007 compared to an aggregate increase of \$8.4 million in accounts payable and accrued expenses in the comparable period of 2006. In addition, net cash used in operating activities during the nine months ended September 30, 2006 was impacted by an \$8.7 million reduction in accrued loss from litigation related to settlement of a civil action. The decrease in accounts payable and accrued expenses during the nine months ended September 30, 2007 was largely due to payments incurred for external service costs related to our clinical trials.





**Table of Contents**

Net cash used in investing activities has fluctuated significantly from period to period primarily due to the timing of purchases and maturities of investment securities. The increase in net cash used in investing activities during the nine months ended September 30, 2007, relative to the comparable period of 2006, was primarily due to increased purchases of investment securities following the completion of our public offering, net of maturities of investment securities.

Net cash provided by financing activities totaled \$98.0 million for the nine months ended September 30, 2007, compared to \$69.2 million for the nine months ended September 30, 2006. This increase was primarily attributable to increased proceeds from sales of our equity securities. The net cash provided by financing activities for the nine months ended September 30, 2007 consisted primarily of net proceeds received from sales of our common stock and stock option exercises, including \$96.1 million received from our public offering in April 2007. The net cash provided by financing activities for the nine months ended September 30, 2006 consisted primarily of \$68.9 million in net proceeds received from sales of our common stock, including \$59.4 million received from a public offering and \$8.9 million received from the second purchase of our common stock by Sepracor, which amount did not include the \$1.1 million premium received in connection with this stock purchase that was included in deferred revenue in operating activities.

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 interest rates ranging from 8.16 to 10.41 percent per annum. At September 30, 2007, we had \$2.3 million in outstanding borrowings under these agreements, which are secured by the related equipment. We were in compliance with required financial covenants and conditions at September 30, 2007.

The following table summarizes our long-term contractual obligations, including interest, at September 30, 2007 (in thousands):

	Total	Less than 1 Year	1-3 Years	4-5 Years	After 5 Years
Operating leases	\$ 14,160	\$ 2,087	\$ 6,099	\$ 3,038	\$ 2,936
Long-term debt	2,566	1,196	1,370		
<b>Total</b>	<b>\$ 16,726</b>	<b>\$ 3,283</b>	<b>\$ 7,469</b>	<b>\$ 3,038</b>	<b>\$ 2,936</b>

We have also entered into agreements with contract research organizations and other external service providers for services in connection with the development of our drug candidates. We were contractually obligated for up to approximately \$24.4 million of future services under these agreements as of September 30, 2007. The nature of the work being conducted under our agreements with contract research organizations is such that, in most cases, the services may be stopped 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 results and timing of the underlying studies.

We have also entered into certain other agreements that may require us to make payments in the future and currently cannot forecast with any degree of certainty when or if we will be required to make payments under these agreements. Under our agreement with SMRI, assuming the successful development and commercialization of our drug candidate ACP-104, we are required to pay to SMRI royalties on product sales up to a specified level. Under another agreement, we have provided initial seed funding to help establish Abbey Pharmaceuticals, Inc. and have agreed to increase our investment to an aggregate of \$1 million upon Abbey's satisfaction of certain conditions. Under the terms of another agreement in which we licensed certain intellectual property rights that complement our patent portfolio, if certain conditions are met, we are required to make future payments, including milestones, royalties and sublicensing fees for compounds covered by the agreement.

We have consumed substantial amounts of capital since our inception. We anticipate that our cash, cash equivalents and investment securities will be greater than \$120 million at December 31, 2007. Although we believe our existing cash resources and the anticipated payments from our existing collaborators will be sufficient to fund our anticipated cash requirements through 2009, 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 preclinical studies and clinical trials and other research and development programs;

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

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 costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;

---

**Table of Contents**

the costs of securing manufacturing arrangements for clinical or commercial production of drug candidates; and

the costs of establishing, or contracting for, sales and marketing capabilities if we obtain regulatory clearances to market our drug 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 drug candidates or technology. We cannot be certain that funding will be available to us on acceptable terms, or 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.

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.

**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 while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in highly liquid and high quality marketable debt instruments of corporations, financial institutions, and government agencies with contractual maturities of generally less than two years. If a 10 percent change in interest rates were to have occurred on September 30, 2007, 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 or any other derivative financial instrument.

**ITEM 4. CONTROLS AND PROCEDURES**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals 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, 2007, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2007.



**Table of Contents**

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.

---

**Table of Contents**

**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, 2007, we had an accumulated deficit of approximately \$212.8 million. We expect our annual net losses to increase over the next several years as we expand our research and development activities, incur significant preclinical and clinical development costs, and enhance our infrastructure.

We have not received, and do not expect to receive for at least the next several years, any revenues from the commercialization of our drug candidates. Substantially all of our revenues for the nine months ended September 30, 2007 were from our collaborations with Allergan and Sepracor as well as our agreements with SMRI and other parties. We anticipate that collaborations with pharmaceutical companies, 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 drug 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.

*Our most advanced drug 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 drug candidates is extremely high. Our four proprietary clinical programs are pimavanserin for the treatment for Parkinson's disease psychosis, pimavanserin as a co-therapy for schizophrenia, ACP-104 for the treatment of schizophrenia, and pimavanserin for the treatment for sleep maintenance insomnia. We also have neuropathic pain and glaucoma programs in collaboration with Allergan.

In connection with clinical trials, we face risks that:

a drug 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 drug candidate being tested;

the results may not confirm the positive results of earlier trials; and

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

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

If we do not successfully complete preclinical and clinical development, we will be unable to market and sell products derived from our drug 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 (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.



## **Table of Contents**

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

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

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

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

manufacturing sufficient quantities of a drug candidate;

obtaining approval of an Investigational New Drug Application ( 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 drug candidates or other materials necessary for the conduct of our clinical trials.

Many of these factors may also ultimately lead to denial of regulatory approval of a current or potential drug candidate. If we experience delays, suspensions or terminations in a clinical trial, the commercial prospects for the related drug 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. For the nine months ended September 30, 2007 we used \$41.1 million in net cash to fund our operating activities. Our cash and investment securities totaled approximately \$141.0 million at September 30, 2007 and we anticipate that this total will be greater than \$120 million at December 31, 2007. Although we believe our existing cash resources and anticipated

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

payments from our existing collaborators will be sufficient to fund our cash requirements through 2009, 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 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 drug candidates; and

the costs associated with litigation.

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 drug candidates or technology. 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 may significantly dilute existing stockholders.

## **Table of Contents**

***We depend on collaborations with third parties to develop and commercialize selected drug 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 drug candidates. Substantially all of our revenues for the nine months ended September 30, 2007 and the year ended December 31, 2006 were from our collaborations with Allergan and Sepracor as well as our agreements with SMRI and other parties. The ongoing research terms of our agreements with Allergan and Sepracor will end in the first quarter of 2008. In addition, the development term of our agreement with SMRI expired May 3, 2007. There is no guarantee that revenues from our collaborations will continue at current or past levels.

Our collaborators may fail to develop or effectively commercialize products using our drug 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;

decide to pursue a competitive product developed outside of the collaboration; or

cannot obtain the necessary regulatory approvals.

The continuation of our collaborations is dependent on our collaborators' periodic renewal of the governing agreements. Allergan and Sepracor can terminate our existing collaborations before the full term of these collaborations under specific circumstances, including in some cases the right to terminate upon notice. We may not be able to renew these collaborations on acceptable terms, if at all. We also face competition in our search for new collaborators.

***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 with respect to payments that we believe are due under the applicable agreements;

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 drug candidates; or

termination or non-renewal of the collaboration.

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

In addition, in each of 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 our collaborations. 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.

We have collaborations with Allergan for the development of drug candidates related to neuropathic 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 Sepracor is targeted toward the development of new drug candidates to treat central nervous system disorders. Sepracor currently is engaged in other research and development programs related to this field that are independent from our collaboration project in this therapeutic area. 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 drug candidates or may otherwise result in lower demand for our potential products.

***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 drug 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 drug candidates. 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 drug candidates.

## **Table of Contents**

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 drug 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 drug candidates, the drug candidates may fail for other reasons.***

Even if we or our collaborators successfully complete the clinical trials of drug candidates, the drug candidates may fail for other reasons, including the possibility that the drug 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 drug candidates or other treatments commercialized by competitors.

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

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

our 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 drug candidate that we discover and 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.

***We do not know whether one of our drug candidates, ACP-104, will have the same adverse effects as clozapine, a currently available therapy.***

One of our drug candidates under development is ACP-104 for the treatment of schizophrenia. ACP-104 is formed in the body from clozapine, a generic drug that is currently approved as a second-line therapy for schizophrenia in the United States. This means that clozapine will only be prescribed to a patient after a doctor determines that the patient has failed to progress under a first-line therapy consisting of antipsychotic drugs. Clozapine is associated with the occurrence of a rare and potentially fatal blood disorder leading to a complete loss of white blood cells, known as agranulocytosis, in approximately one percent of patients treated with clozapine. As a result, patients being treated with clozapine are subject to weekly blood monitoring for the first six months of treatment followed by twice monthly monitoring thereafter. In addition, one of the other side effects of clozapine is the occurrence of seizures, which is found in approximately five percent of users.

## **Table of Contents**

ACP-104 may have the same adverse effects of clozapine or other significant adverse effects and, if successfully developed, may also only be approved as a second-line therapy. These factors could substantially limit the commercial potential of ACP-104 and may substantially restrict its potential market and our ability to generate revenues from it.

***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 drug candidates.***

Our success depends on our ability to attract, retain, and motivate highly qualified management and scientific personnel. In particular, our drug discovery and development programs depend on our ability to attract and retain highly skilled chemists, biologists, pharmacologists, and development personnel, especially in the fields of central nervous system disorders, including neuropsychiatric and related disorders. We will need to hire additional personnel as we continue to expand our clinical development and other research and development activities. We face competition for experienced scientists 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 drug candidates.***

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

Much of our research 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 drug candidates to treat diseases or conditions in other therapeutic areas. If we are not able to use our technologies to discover and develop drug 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 drug candidates to augment the results of our internal discovery activities. If we are unable to identify new drug 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 drug candidates.

***We will need to increase the size of our organization, and we may encounter difficulties managing our growth, which could adversely affect our results of operations.***

We will need to expand and effectively manage our operations and facilities in order to advance our drug development programs, achieve milestones under our collaboration agreements, facilitate additional collaborations, and pursue other development activities. It is possible that our human resources and infrastructure may be inadequate to support our future growth. To manage our growth, we will be required to continue to improve our operational, financial and management controls, and reporting systems and procedures in at least two countries, and be required to attract and retain sufficient numbers of talented employees in at least two countries. 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 expansion 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.***

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

Our subsidiary in Malmö, Sweden, ACADIA Pharmaceuticals AB, employs approximately 29 percent of our total personnel and is engaged in research and development activities, with primary responsibility for combinatorial, medicinal and analytical chemistry. Our principal executive offices, however, are located in San Diego. The additional administrative



## **Table of Contents**

expense required to follow and 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.

*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 ACP-104 and the preclinical and clinical development of our other drug candidates, including compounds being developed under our collaborations;

whether we generate revenues by achieving specified research 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;

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 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 drug candidates for clinical trials. If any of our drug 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 and ACP-104. While we believe that there are alternative sources available to manufacture our drug candidates, in the event that

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

we seek such alternative sources, we may not be able to enter into replacement arrangements without delays or additional expenditures. We cannot estimate these delays or costs with certainty but do not expect them to be material.

The manufacturers of our drug 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 drug candidates or the ultimate launch of products based on our drug 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.

---

## **Table of Contents**

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

Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 ( SOX ) and rules adopted or proposed by the SEC and by The Nasdaq Global Market, have resulted in, and will continue to result in, significant costs to us as we evaluate the implications of these rules and respond to their requirements. We issued an evaluation of our internal control over financial reporting under Section 404 of SOX with our Annual Report. In the future, if we are not able to issue an evaluation of our internal control over financial reporting as required or we or our independent registered public accounting firm determine that our internal control over financial reporting is not effective, this shortcoming could have an adverse effect on our business and financial results and the price of our common stock could be negatively affected. New rules could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the coverage that is the same or similar to our current coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors and board committees, and as our executive officers. We cannot predict or estimate the total amount of the costs we may incur or the timing of such costs to comply with these rules and regulations.

***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 were not adversely impacted by the October 2007 fires, 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 drug 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 drug 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 and ACP-104, we have been issued only a limited number of patents with respect to pimavanserin and only one foreign patent with respect to ACP-104.

## **Table of Contents**

Our ability to obtain patent protection for our products 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 drug candidates or the technologies we rely upon;

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

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

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

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

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

our proprietary technologies may not be patentable;

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

others may identify prior art which could invalidate our patents.

Even if we have or obtain patents covering our drug candidates or technologies, we may still be barred from making, using and selling our drug 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 drug 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 drug 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. 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.

***We have limited proprietary rights to one of our drug candidates, ACP-104, which may limit our ability to prevent competitors from exploiting that compound.***

One of our drug candidates, ACP-104, is a publicly available compound and, if the claims of our pending patent applications issue, we will have limited proprietary rights in this candidate. Other companies may obtain patents or regulatory approvals to use the same drug for treatments other than to treat the indications for which we have filed for patent protection. We are aware of an issued patent not owned by us that claims the use of N-desmethylozapine, which is the chemical name for ACP-104, to induce analgesia. ACP-104, which we are developing for treatment of schizophrenia, is formed in the body from clozapine and its structure was known prior to our filing of patent applications relating to its use to treat certain conditions. Accordingly, we will not be able to obtain composition of matter patents directed to the form of ACP-104 known prior to the filing of our patent applications. We have filed method of use patent applications for ACP-104, but a competitor could use ACP-104, and patent its method of use, for a treatment not covered by our patent applications. In addition, while we have filed patent applications directed to methods of synthesis of ACP-104 and various crystalline polymorphs thereof, those claims, if they issue, will not prevent a potential competitor from making ACP-104 using any method of synthesis or from using any polymorphic form of ACP-104, which is outside the scope of the claims that ultimately may issue.

---

## **Table of Contents**

***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 drug 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 drug candidates. Some of these may encompass genes or polypeptides that we utilize in our drug development activities. If our drug development activities are found to infringe any such patents, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from using the patented genes or polypeptides for the identification or development of drug compounds. There are also many patents relating to chemical compounds and the uses thereof. If our compounds are found to infringe any such patents, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from making, using or selling the patented compounds. We may need to resort to litigation to enforce a patent issued to us, protect our trade secrets or determine the scope and validity of third-party proprietary rights. From time to time, we may hire scientific personnel formerly employed by other companies involved in one or more areas similar to the activities conducted by us. Either we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of their prior affiliations. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. We may not be able to afford the costs of litigation. Any legal action against our company 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

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

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.

## **Table of Contents**

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 drug candidates.

If we fail to obtain and maintain patent protection and trade secret protection of our drug 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 drug candidates, which could delay the development and commercialization of our products.*

The pharmaceutical industry is subject to stringent regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Neither we nor our collaborators can market a pharmaceutical product in the United States until it has completed rigorous preclinical testing and clinical trials and an extensive regulatory clearance process implemented by the FDA. Satisfaction of regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product, and requires substantial resources. Even if regulatory approval is obtained, it may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, and/or marketing of such products, and requirements for post-approval studies, including additional research and development and clinical trials. These limitations may limit the size of the market for the product or result in the incurrence of additional costs. Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues from the particular drug candidate.

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

In addition, U.S. and foreign government regulations control access to and use of some human or other tissue samples in our research and development efforts. U.S. and foreign government agencies may also impose restrictions on the use of data derived from human or other tissue samples. Accordingly, if we fail to comply with these regulations and restrictions, the commercialization of our drug 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 drug 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 would compete with off-label use of antipsychotic drugs, including Seroquel, marketed by Astra-Zeneca, and with the generic drug clozapine. Our potential products for the treatment of schizophrenia would compete with Zyprexa, marketed by Eli Lilly, Risperdal, marketed by Johnson & Johnson, Abilify, marketed jointly by Bristol-Myers Squibb and Otsuka Pharmaceutical, Seroquel, and clozapine. Our potential 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. In the area of neuropathic 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.





## **Table of Contents**

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

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

Researching, developing, and commercializing drug products entails significant product liability risks. Liability claims may arise from our and our collaborators' use of products in clinical trials and the commercial sale of those products. Consumers may make these claims directly and our collaborators or others selling these products may seek contribution from us if they receive claims from consumers. Although we currently have product liability insurance that covers our clinical trials, we will need to increase and expand this coverage as we commence larger scale trials and if our drug 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.\****

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

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 drug candidates, including results of our clinical trials for pimavanserin, ACP-104, or our neuropathic pain and glaucoma collaborations;

**Table of Contents**

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, new litigation matters; or

economic and political factors, including but not limited to wars, terrorism, and political unrest.

In the past, following periods of volatility in the market price of a particular company's securities, securities class action litigation has often been brought against that company. 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 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

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

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. In addition, we included all of the 1.9 million shares of our common stock purchased by Sepracor pursuant to our collaboration in a registration statement that we filed in January 2006. Our stock price may decline as a result of the sale of the shares of our common stock included in 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;

**Table of Contents**

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 5 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.

**ITEM 6. EXHIBITS**

**Exhibit**

<b>Number</b>	<b>Description of Document</b>
3.1	Amended and Restated Certificate of Incorporation (filed as Exhibit 3.3 to Registration Statement File No. 333-113137).
3.2	Amended and Restated Bylaws (filed as Exhibit 3.5 to Registration Statement File 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).
10.1	Description of Outside Director Compensation Program, updated September 7, 2007 and to be effective commencing with our annual meeting of stockholders in June 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 5, 2007

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)