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

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2005

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 or Other Jurisdiction of
Incorporation or Organization)

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)

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 an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes No

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

Total shares of common stock outstanding as of the close of business on July 22, 2005:

<u>Class</u>	<u>Number of Shares Outstanding</u>
Common Stock, \$0.0001 par value	23,463,991

ACADIA PHARMACEUTICALS INC.
FORM 10-Q
TABLE OF CONTENTS

	PAGE NO.
TABLE OF CONTENTS	i
PART I. FINANCIAL INFORMATION	
Item 1. Condensed Consolidated Financial Statements (Unaudited)	
Condensed Consolidated Balance Sheets as of June 30, 2005 and December 31, 2004	1
Condensed Consolidated Statements of Operations for the Three and Six Months Ended June 30, 2005 and 2004	2
Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2005 and 2004	3
Notes to Condensed Consolidated Financial Statements	4
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	8
Item 3. Quantitative and Qualitative Disclosures About Market Risk	31
Item 4. Controls and Procedures	31
PART II. OTHER INFORMATION	
Item 4. Submission of Matters to a Vote of Security Holders	32
Item 6. Exhibits	32
SIGNATURES	33

PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

ACADIA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	June 30, 2005	December 31, 2004(1)
Assets		
Cash and cash equivalents	\$ 15,812,400	\$ 8,301,700
Investment securities, available-for-sale	53,148,400	27,625,700
Prepaid expenses and other current assets	2,437,400	1,890,700
	<hr/>	<hr/>
Total current assets	71,398,200	37,818,100
Property and equipment, net	2,232,300	2,546,900
	<hr/>	<hr/>
	\$ 73,630,500	\$ 40,365,000
	<hr/>	<hr/>
Liabilities and Stockholders' Equity		
Accounts payable	\$ 2,317,200	\$ 2,152,800
Accrued expenses	3,404,700	3,681,100
Current portion of deferred revenue	4,501,300	1,320,300
Current portion of long-term debt	854,600	1,486,400
	<hr/>	<hr/>
Total current liabilities	11,077,800	8,640,600
	<hr/>	<hr/>
Long-term debt, less current portion	818,900	1,044,000
	<hr/>	<hr/>
Deferred revenue, less current portion	584,300	—
	<hr/>	<hr/>
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized at June 30, 2005 and December 31, 2004; no shares issued and outstanding at June 30, 2005 and December 31, 2004	—	—
Common stock, \$0.0001 par value; 75,000,000 shares authorized at June 30, 2005 and December 31, 2004; 23,457,804 shares and 16,922,850 shares issued and outstanding at June 30, 2005 and December 31, 2004, respectively	2,300	1,700
Additional paid-in capital	168,244,100	126,755,100
Accumulated deficit	(105,909,100)	(94,283,000)
Unearned stock-based compensation	(1,386,400)	(2,107,800)
Accumulated other comprehensive income	198,600	314,400
	<hr/>	<hr/>
Total stockholders' equity	61,149,500	30,680,400
	<hr/>	<hr/>
	\$ 73,630,500	\$ 40,365,000
	<hr/>	<hr/>

- (1) The condensed consolidated balance sheet at December 31, 2004 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.

ACADIA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Revenues				
Collaborative revenues	\$ 2,514,600	\$ 1,015,700	\$ 4,839,800	\$ 1,939,600
Operating expenses				
Research and development(1)	6,563,100	5,406,600	12,678,800	11,155,900
General and administrative(1)	2,050,300	879,900	3,688,900	1,791,300
Stock-based compensation	394,900	614,500	766,000	1,309,700
Total operating expenses	9,008,300	6,901,000	17,133,700	14,256,900
Loss from operations	(6,493,700)	(5,885,300)	(12,293,900)	(12,317,300)
Interest income	494,400	117,400	755,400	204,500
Interest expense	(37,600)	(118,600)	(87,600)	(254,900)
Net loss	\$ (6,036,900)	\$ (5,886,500)	\$ (11,626,100)	\$ (12,367,700)
Participation of preferred stock	—	(3,109,900)	—	(8,586,500)
Net loss available to common stockholders	(6,036,900)	(2,776,600)	(11,626,100)	(3,781,200)
Net loss per common share, basic and diluted	\$ (0.26)	\$ (0.42)	\$ (0.56)	\$ (0.94)
Weighted average common shares outstanding, basic and diluted	23,274,186	6,552,366	20,588,698	4,023,717
Net loss available to participating preferred stockholders	\$ —	\$ (3,109,900)	\$ —	\$ (8,586,500)
Net loss per participating preferred share, basic and diluted	\$ —	\$ (0.31)	\$ —	\$ (0.87)
Weighted average participating preferred shares outstanding, basic and diluted	—	9,900,913	—	9,900,913
<hr/>				
(1) Excludes stock-based compensation as follows:				
Research and development	\$ 205,700	\$ 279,400	\$ 416,800	\$ 686,200
General and administrative	189,200	335,100	349,200	623,500
	\$ 394,900	\$ 614,500	\$ 766,000	\$ 1,309,700

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

ACADIA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Six Months Ended June 30,	
	2005	2004
Cash flows from operating activities		
Net loss	\$ (11,626,100)	\$ (12,367,700)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	598,600	643,000
Stock-based compensation	766,000	1,309,700
Loss on disposal of property and equipment	67,600	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(599,500)	(423,100)
Other assets	—	12,500
Accounts payable	262,700	474,700
Accrued expenses	(199,200)	880,100
Deferred revenue	3,765,300	667,000
Net cash used in operating activities	<u>(6,964,600)</u>	<u>(8,803,800)</u>
Cash flows from investing activities		
Purchases of investment securities	(43,453,600)	(28,886,000)
Maturities of investment securities	17,900,000	9,110,000
Purchases of property and equipment	(480,000)	(300,400)
Net cash used in investing activities	<u>(26,033,600)</u>	<u>(20,076,400)</u>
Cash flows from financing activities		
Proceeds from issuance of common stock and warrants, net of issuance costs	41,445,000	31,110,300
Proceeds from issuance of long-term debt	215,500	1,296,300
Repayments of long-term debt	(1,074,200)	(1,651,800)
Net cash provided by financing activities	<u>40,586,300</u>	<u>30,754,800</u>
Effect of exchange rate changes on cash	(77,400)	(26,200)
Net increase in cash and cash equivalents	<u>7,510,700</u>	<u>1,848,400</u>
Cash and cash equivalents		
Beginning of period	8,301,700	6,308,100
End of period	<u>\$ 15,812,400</u>	<u>\$ 8,156,500</u>
Supplemental schedule of noncash investing and financing activities		
Unrealized loss on investment securities	\$ (30,900)	\$ (45,700)
Conversion of debt to common stock	\$ —	\$ 1,007,400
Conversion of convertible preferred stock to common stock upon initial public offering	\$ —	\$ 74,514,000

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

ACADIA PHARMACEUTICALS INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
June 30, 2005
(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, 2004 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.

2. Net Income (Loss) Per Share

Basic earnings (loss) per common share is computed by dividing net income (loss) available to common stockholders 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) available to common stockholders 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 dilutive effect of outstanding stock options and warrants is reflected, when dilutive, in diluted earnings (loss) per common share by application of the treasury stock method. The Company has excluded all outstanding stock options and warrants from the calculation of diluted net loss per common share because all such securities are antidilutive for all periods presented.

For the period prior to the closing of the Company's initial public offering, the Company computed its net income (loss) per common share using the two class method; therefore, the Company's net income (loss) was allocated between the common stockholders and the preferred stockholders based on their respective rights to share in dividends. For the three and six months ended June 30, 2004, the method by which the Company allocated net income (loss) to the preferred stock was based on the number of preferred shares outstanding compared to the total combined preferred and common shares outstanding as of the date of the completion of the initial public offering on June 2, 2004. The remaining net income (loss) was allocated to common stockholders. Upon the closing of the Company's initial public offering on June 2, 2004, all outstanding preferred stock was reclassified or converted into common stock. As there were no preferred shares outstanding during the three and six months ended June 30, 2005, the Company allocated net income (loss) solely to common stockholders.

ACADIA PHARMACEUTICALS INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
June 30, 2005
(Unaudited)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
	(unaudited)		(unaudited)	
Antidilutive options to purchase common stock	2,133,969	1,686,102	2,013,937	1,742,095
Antidilutive warrants to purchase common stock	1,393,475	74,073	733,774	74,073
Restricted vesting common stock	98,804	273,609	113,776	182,406
	<u>3,626,248</u>	<u>2,033,784</u>	<u>2,861,487</u>	<u>1,998,574</u>

3. Stock-Based Compensation

The Company measures compensation expense for its employee stock-based compensation plans using the intrinsic value method and provides pro forma disclosures of net income (loss) as if a fair value method had been applied in measuring compensation expense. Accordingly, compensation cost for stock awards is measured as the excess, if any, of the fair value of the Company's common stock at the date of grant over the amount an employee must pay to acquire the stock. Compensation cost is amortized over the related vesting periods using an accelerated method. Accrued compensation costs for unvested awards that are forfeited are reversed against compensation expense or unearned stock-based compensation, as appropriate, in the period of forfeiture.

Stock-based awards issued to nonemployees are accounted for using a fair value method and are remeasured to fair value at each period end until the earlier of the date that performance by the nonemployee is complete or a performance commitment has been obtained. The fair value of each award is estimated using the Black-Scholes option pricing model.

Pro forma information regarding net income (loss) has been determined as if the Company had accounted for its employee stock options under the fair value methodology.

The value of each employee stock option granted is estimated on the grant date under the fair value method using the Black-Scholes option pricing model. Prior to the initial public trading of the Company's stock on May 27, 2004, the value of each employee stock option grant was estimated on the date of grant using the minimum value method. Under the minimum value method, a volatility factor of 0.0 percent is assumed. The following assumptions were used for the employee stock purchase plan, which became effective as of May 26, 2004: dividend yield of 0.0 percent; volatility of 50.0 percent; risk-free interest rate of 3.0 percent; and expected life in years of 0.5. The following weighted average assumptions were used for employee stock options:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
	(unaudited)		(unaudited)	
Dividend yield	0.0%	0.0%	0.0%	0.0%
Volatility	70.0%	70.0%	70.0%	70.0%
Risk-free interest rate	4.0%	3.0%	4.0%	3.0%
Expected life in years	5	5	5	5

ACADIA PHARMACEUTICALS INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
June 30, 2005
(Unaudited)

Pro forma information follows for the periods:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
	(unaudited)		(unaudited)	
Net loss, as reported	\$ (6,036,900)	\$ (5,886,500)	\$ (11,626,100)	\$ (12,367,700)
Add: Total stock-based employee compensation costs included in the determination of net loss	373,100	662,700	733,300	1,292,700
Deduct: Total stock-based employee compensation costs that would have been included in net loss if the fair value method had been applied	(791,800)	(740,100)	(1,422,300)	(1,409,300)
Pro forma net loss	\$ (6,455,600)	\$ (5,963,900)	\$ (12,315,100)	\$ (12,484,300)
Participation of preferred stock	—	(3,131,400)	—	(8,641,100)
Pro forma net loss available to common stockholders	\$ (6,455,600)	\$ (2,832,500)	\$ (12,315,100)	\$ (3,843,200)
Actual net loss per common share, basic and diluted	\$ (0.26)	\$ (0.42)	\$ (0.56)	\$ (0.94)
Pro forma net loss per common share, basic and diluted	\$ (0.28)	\$ (0.43)	\$ (0.60)	\$ (0.96)
Pro forma net loss available to participating preferred stockholders	\$ —	\$ (3,131,400)	\$ —	\$ (8,641,100)
Actual net loss per participating preferred share, basic and diluted	\$ —	\$ (0.31)	\$ —	\$ (0.87)
Pro forma net loss per participating preferred share, basic and diluted	\$ —	\$ (0.32)	\$ —	\$ (0.87)

4. Comprehensive Loss

For the three and six months ended June 30, 2005 and 2004, comprehensive loss consisted of the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
	(unaudited)		(unaudited)	
Net loss	\$ (6,036,900)	\$ (5,886,500)	\$ (11,626,100)	\$ (12,367,700)
Unrealized gain (loss) on investment securities	1,300	(58,100)	(30,900)	(45,700)
Foreign currency translation loss	(69,500)	(500)	(84,900)	(57,800)
Total comprehensive loss	\$ (6,105,100)	\$ (5,945,100)	\$ (11,741,900)	\$ (12,471,200)

ACADIA PHARMACEUTICALS INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
June 30, 2005
(Unaudited)

5. Segment Information

Management has determined that the Company operates in one business segment. All revenues for the three and six months ended June 30, 2005 and 2004 were generated in the United States. Information regarding long-lived assets by geographic area as of the dates indicated is as follows:

	June 30, 2005	December 31, 2004
	(unaudited)	
United States	\$ 1,283,700	\$ 1,364,500
Europe	948,600	1,182,400
Total	\$ 2,232,300	\$ 2,546,900

6. Collaboration Agreement With Sepracor

On January 10, 2005, the Company entered into a collaboration agreement with Sepracor for the development of new drug candidates targeted toward the treatment of central nervous system disorders. Under the agreement, the parties will investigate potential clinical candidates resulting from the Company's preclinical muscarinic program. The Company will receive research funding from Sepracor over the three-year research term of the collaboration and, if certain conditions are met, is eligible to receive milestone payments as well as royalties on future product sales worldwide, if any. The agreement also includes an option to select a preclinical compound from the Company's 5-HT_{2A} program for use in combination with LUNESTA, Sepracor's insomnia drug, for sleep-related indications. Should this option be exercised, the Company will be eligible to receive additional license and milestone payments as well as royalties on future product sales worldwide, if any.

In connection with the collaboration, Sepracor purchased 1,077,029 shares of the Company's common stock for \$10 million based on a per share price of approximately \$9.28, which represented a 40 percent premium to the 30-day trailing average closing price. The Company recorded the aggregate premium amount of \$3.1 million, which was computed based on the excess of the purchase price over the closing price of the Company's common stock on January 10, 2005, as deferred revenue and the remaining purchase amount of \$6.9 million as stockholders' equity. The deferred revenue will be recognized as revenue as the related research activities are performed over the research term. Sepracor also agreed to purchase an additional \$10 million of ACADIA common stock at a 25 percent premium to the 30-day trailing average closing price on the one-year anniversary of the collaboration, subject to customary closing conditions. These stock purchases, in the aggregate, shall not exceed 19.99 percent of the Company's outstanding common stock after giving effect to the second purchase. During the three and six months ended June 30, 2005, revenue of \$923,000 and \$1.7 million was recognized under this collaboration, respectively.

7. Private Placement

On April 20, 2005, the Company completed a private placement in which it raised net proceeds of approximately \$34 million through the sale, at a price of \$6.82125 per share, of 5,277,621 shares of its common stock and warrants to purchase 1,319,402 shares of its common stock. The warrants have an exercise price of \$8.148 per share, become exercisable on October 17, 2005, and will expire on April 19, 2010, unless earlier terminated. In accordance with EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock," the allocated fair value of the warrants at the issuance date of \$4.5 million has been included as permanent equity. The fair value was determined at the date of issuance using the Black-Scholes model. Pursuant to the terms of the private placement documents, the Company filed a registration statement with the SEC to register for resale the shares of common stock sold in the private placement and the shares of common stock issuable upon the exercise of the warrants. This registration statement became effective June 7, 2005.

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, 2004 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 four drug programs in clinical development and several additional programs in preclinical and discovery stages. Our three Phase II clinical programs are ACP-103 as an adjunctive therapy for schizophrenia, ACP-103 for treatment-induced dysfunctions in Parkinson's disease, and ACP-104 for the treatment of schizophrenia. We have retained worldwide commercialization rights for these programs. We also have a neuropathic pain program in Phase I clinical trials and a glaucoma program in preclinical development, each in collaboration with Allergan.

We have incurred substantial operating losses since our inception due in large part to expenditures for our research and development activities. At June 30, 2005, we had an accumulated deficit of \$105.9 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

On April 20, 2005, we completed a private placement in which we raised net proceeds of approximately \$34 million through the sale, at a price of \$6.82125 per share, of 5,277,621 shares of our common stock and warrants to purchase 1,319,402 shares of our common stock. The warrants have an exercise price of \$8.148 per share, become exercisable on October 17, 2005, and will expire on April 19, 2010, unless earlier terminated.

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 agreements. We have entered into three separate collaboration agreements with Allergan and one with Sepracor. We have also entered into a

[Table of Contents](#)

development agreement with The Stanley Medical Research Institute (“SMRI”), and smaller scale collaboration and license agreements with other parties. As of June 30, 2005, we had received \$40.7 million in payments under these agreements, including research funding and related fees and upfront and milestone payments. We expect our revenues for the next several years to consist of payments under our current agreements and any additional collaborations, including potential upfront payments upon execution of new agreements, research funding and related fees throughout the research term of the agreements and milestone payments contingent upon achievement of agreed upon objectives.

Pursuant to the terms of our March 2003 collaboration agreement with Allergan, we had received an aggregate of \$10.4 million in research funding and other fees through June 30, 2005, and we are entitled to receive additional research funding and related fees through March 2006. In addition, we may receive milestone payments and royalties on product sales, if any, under each of our three collaboration agreements with Allergan. Pursuant to the terms of our January 2005 collaboration agreement with Sepracor, we had received \$2.0 million in initial research funding through June 30, 2005, and we are entitled to receive additional research funding through January 2008. In addition, in connection with this collaboration, Sepracor purchased \$10 million of our common stock at a 40 percent premium to the 30-day trailing average closing price. We recorded the aggregate premium amount of \$3.1 million resulting from this stock purchase as deferred revenue, which we will recognize as revenue over the research term. Pursuant to our collaboration with Sepracor, if certain conditions are met, we are also eligible to receive license fees and milestone payments as well as royalties on product sales, if any. 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. Pursuant to our development agreement with SMRI, we are entitled to receive up to \$5 million in funding to support the development of ACP-104, of which \$1 million had been received as of June 30, 2005.

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 ACP-103 for both schizophrenia and treatment-induced dysfunctions in Parkinson’s disease and in the development of ACP-104 for schizophrenia, as well as the costs associated with our other internal drug programs. We are not responsible for, nor have we incurred, development expenses, including costs related to clinical trials, in the drug programs that we are pursuing under our collaboration agreements, including our clinical program for neuropathic pain and our preclinical development program for glaucoma, each of which we are pursuing in collaboration with Allergan.

[Table of Contents](#)

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. The following table summarizes our research and development expenses for the three and six months ended June 30, 2005 and 2004 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Costs of external service providers:				
ACP-103	\$ 1,462	\$ 1,127	\$ 2,353	\$ 2,511
ACP-104	218	114	317	164
Other	420	404	779	654
Subtotal	2,100	1,645	3,449	3,329
Internal costs	4,463	3,762	9,230	7,827
Total research and development	\$ 6,563	\$ 5,407	\$12,679	\$11,156

At this time, due to the risks inherent in the clinical trial process and given the early stage of development of our drug 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 ACP-103 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 the drug candidate's commercial potential. In addition, 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.

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.

Revenue Recognition

We recognize revenues in accordance with SEC Staff Accounting Bulletin, or SAB, No. 104, *Revenue Recognition*. SAB No. 104 requires that four basic criteria must be met before revenue can be recognized; persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed and determinable; and collectibility is reasonably assured. Our revenues are primarily related to our collaboration agreements, and such agreements provide for various types of payments to us, including research funding and related fees, upfront payments, milestone payments, and royalties. 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-0021.

Upfront, nonrefundable payments under collaboration agreements are recognized ratably over the term of the agreement. Payments for research funding are recognized as revenues as the related research activities are performed. Our collaborations do not require scientific achievement as a performance obligation and amounts received under the agreements are nonrefundable. Revenues from nonrefundable milestones are recognized when earned, provided that (i) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement and (ii) we do not have ongoing performance obligations. Any amounts received under the agreements in advance of performance are recorded as deferred revenue. Revenues from licenses of our technology are generally recognized at the inception of the license term. When arrangements contain extended payment terms, revenues are recognized upon the receipt of the payment. None of the revenues recognized to date are refundable even if the related research activities are not successful.

Accrued Expenses

We are required to estimate accrued expenses as part of our process of preparing financial statements. This process involves estimating the level of service performed on our behalf and the associated cost incurred in instances where we have not been invoiced or otherwise notified of actual costs. 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 account for expenses associated with these external services by determining the total cost of a given study or service based on the terms of the related contract. 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 significantly from the actual costs incurred. However, we expect to expand the level of our clinical trials and related research and development services in the future. As a result, we anticipate that our estimated accruals for clinical and research services will be more material to our operations in future periods. Subsequent changes in estimates may result in a material change in our accrual, which could also materially affect our balance sheet and results of operations.

Stock-based Compensation

We account for employee stock options using the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations, and provide pro forma disclosures of net income (loss) as if a fair value method had been applied in measuring compensation expense. Stock compensation expense, which is a non-cash charge, is measured as the excess, if any, of the fair value of our underlying common stock at the date of grant over the amount an employee must pay to acquire such stock. This compensation cost is amortized over the related vesting periods, generally four years, using an accelerated method.

[Table of Contents](#)

In December 2004, the FASB issued SFAS No. 123 (revised 2004), Share-Based Payment, or SFAS 123(R), which requires that compensation costs relating to share-based payment transactions be recognized in financial statements. We are required to implement SFAS 123(R) in the first quarter of 2006. We are currently evaluating the requirements of SFAS 123(R) and we have not yet fully determined the impact on our consolidated financial statements.

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 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 June 30, 2005 and 2004

Revenues

Revenues increased to \$2.5 million for the three months ended June 30, 2005 from \$1.0 million for the three months ended June 30, 2004. This increase was primarily due to \$923,000 in revenues recognized under our collaboration agreement with Sepracor, which commenced in January 2005, and \$500,000 in revenues earned pursuant to our agreement with SMRI during the three months ended June 30, 2005. Revenues from our collaboration agreements with Allergan totaled \$1.1 million and \$1.0 million for the three months ended June 30, 2005 and 2004, respectively.

Research and Development Expenses

Research and development expenses increased to \$6.6 million for the three months ended June 30, 2005 from \$5.4 million for the three months ended June 30, 2004. This increase was primarily due to \$455,000 in increased fees paid to external service providers, and increased costs associated with our internal research and development activities, including \$402,000 in increased salaries and related personnel costs, and increased equipment, facility and other costs. External service costs totaled \$2.1 million, or 32 percent of our research and development expenses, for the three months ended June 30, 2005, compared to \$1.6 million, or 30 percent of our research and development expenses, for the comparable period in 2004. The increase in external service costs for the three months ended June 30, 2005 relative to the comparable period of 2004 was primarily attributable to increased clinical development expenses associated with ACP-103 and ACP-104. We expect that our research and development costs will increase significantly in future periods as we continue to pursue the clinical development of our lead drug candidates and expand our discovery and development pipeline.

General and Administrative Expenses

General and administrative expenses increased to \$2.1 million for the three months ended June 30, 2005 from \$880,000 for the three months ended June 30, 2004. The increase in general and administrative expenses was primarily due to \$555,000 in increased professional fees and insurance costs, largely associated with operating as a public company, and \$415,000 in increased salaries and related personnel costs. We anticipate increases in general and administrative expenses in future periods as we continue to expand our administrative organization and incur additional costs associated with operating as a public company and to support the future operations and growth of our organization.

[Table of Contents](#)

Stock-Based Compensation Expenses

Stock-based compensation expenses totaled \$395,000 for the three months ended June 30, 2005, compared to \$615,000 for the three months ended June 30, 2004. The decrease in stock-based compensation expenses resulted largely from a decrease in the amortization of deferred stock-based compensation associated with employee stock options.

Interest Income

Interest income increased to \$494,000 for the three months ended June 30, 2005 from \$117,000 for the three months ended June 30, 2004. The increase in interest income was primarily due to higher average levels of cash and investment securities and, to a lesser extent, increased yields on our investment portfolio.

Interest Expense

Interest expense decreased to \$38,000 for the three months ended June 30, 2005 from \$119,000 for the three months ended June 30, 2004. The decrease in interest expense was primarily due to repayments under our loan agreements.

Comparison of the Six Months Ended June 30, 2005 and 2004

Revenues

Revenues increased to \$4.8 million for the six months ended June 30, 2005 from \$1.9 million for the comparable period of 2004. This increase was primarily due to \$1.7 million in revenues recognized under our collaboration agreement with Sepracor, which commenced in January 2005, and \$1.0 million in revenues earned pursuant to our agreement with SMRI during the six months ended June 30, 2005. Revenues from our collaboration agreements with Allergan totaled \$2.1 million and \$1.9 million for the six months ended June 30, 2005 and 2004, respectively.

Research and Development Expenses

Research and development expenses increased to \$12.7 million for the six months ended June 30, 2005 from \$11.2 million for the comparable period of 2004. This increase was primarily due to increased costs associated with our internal research and development activities, including \$1.1 million in increased salaries and related personnel costs and \$299,000 in increased equipment and facilities expenses, as well as \$119,000 in increased external service costs. External service costs totaled \$3.4 million, or 27 percent of our research and development expenses, for the six months ended June 30, 2005 compared to \$3.3 million, or 29 percent of our research and development expenses, for the comparable period in 2004.

General and Administrative Expenses

General and administrative expenses increased to \$3.7 million for the six months ended June 30, 2005 from \$1.8 million for the comparable period of 2004. This increase was primarily due to \$884,000 in increased professional fees and insurance costs largely associated with operating as a public company, and \$749,000 in increased salaries and related personnel costs.

Stock-Based Compensation Expenses

Stock-based compensation expense totaled \$766,000 for the six months ended June 30, 2005, compared to \$1.3 million for the comparable period of 2004. The decrease in stock-based compensation expense resulted largely from a decrease in the amortization of deferred stock-based compensation associated with employee stock options.

[Table of Contents](#)

Interest Income

Interest income increased to \$755,000 for the six months ended June 30, 2005 from \$205,000 for the comparable period in 2004. The increase in interest income was primarily due to higher average levels of cash and investment securities and increased yields on our investment portfolio.

Interest Expense

Interest expense decreased to \$88,000 for the six months ended June 30, 2005 from \$255,000 for the comparable period in 2004. The decrease in interest expense was primarily due to repayments under our loan agreements.

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 June 30, 2005, we had received \$156.1 million in net proceeds from sales of our equity securities, including \$6.9 million in debt we had retired through the issuance of our stock, \$40.7 million in payments from collaboration agreements, \$19.5 million in debt financing, and \$6.9 million in interest income.

At June 30, 2005, we had approximately \$69.0 million in cash, cash equivalents and investment securities compared to \$35.9 million at December 31, 2004. We have invested a substantial portion of our available cash in investment securities consisting of high quality, marketable debt instruments of corporations, financial institutions and government agencies. 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 decreased to \$7.0 million for the six months ended June 30, 2005 compared to \$8.8 million for the six months ended June 30, 2004. This decrease was primarily due to an increase of \$3.8 million in deferred revenue from our collaboration agreements during the six months ended June 30, 2005, compared to an increase of \$667,000 during the comparable period in 2004, and a decrease in our net loss, partially offset by a decrease in accrued expenses. The increase in deferred revenue during the six months ended June 30, 2005 was largely attributable to payments from our collaboration with Sepracor, including a portion of the premium amount of \$3.1 million resulting from Sepracor's purchase of \$10 million of our common stock in January 2005.

Net cash used in investing activities other than purchases and maturities of investment securities reflects our purchases of property and equipment. From inception through June 30, 2005, we purchased \$10.6 million in property and equipment, the majority of which we have funded through equipment financing agreements and other debt facilities.

Net cash provided by financing activities totaled \$40.6 million for the six months ended June 30, 2005, compared to \$30.8 million for the six months ended June 30, 2004. The net cash provided by financing activities in the six months ended June 30, 2005 was primarily due to \$41.4 million in net proceeds received from sales of our equity securities, including \$34.0 million received from the sale of common stock and warrants to purchase common stock in our private placement and \$6.9 million resulting from the purchase of common stock by Sepracor, which amount does not include the premium amount of \$3.1 million received in connection with this stock purchase, partially offset by repayments of our long-term debt. Sepracor has agreed to purchase an additional \$10 million of our common stock in January 2006 at a 25 percent premium to the then 30-day trailing average closing price, subject to specified closing conditions set forth in a stock purchase agreement entered into by the parties. The net cash provided by financing activities for the six months ended June 30, 2004 was primarily due to net proceeds of approximately \$31.1 million raised in our initial public offering, offset by net repayments of our long-term debt.

[Table of Contents](#)

We have entered into equipment financing agreements from time to time, which we have utilized to fund the majority of our property and equipment acquisitions. The agreements contain interest rates ranging from 7.93 to 9.58 percent per annum. At June 30, 2005, we had \$1.7 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 June 30, 2005.

The following table summarizes our contractual obligations at June 30, 2005:

	<u>Total</u>	<u>Less than 1 Year</u>	<u>1 - 3 Years (2006-2009)</u>	<u>4 - 5 Years (2009-2010)</u>	<u>After 5 Years</u>
Operating leases	\$ 10,367,600	\$ 1,304,800	\$ 2,756,900	\$ 1,823,400	\$ 4,482,500
Long-term debt	1,843,400	962,300	881,100	—	—
Total	\$ 12,211,000	\$ 2,267,100	\$ 3,638,000	\$ 1,823,400	\$ 4,482,500

We have consumed substantial amounts of capital since our inception and expect to use between \$26 and \$30 million of our cash resources to fund operations during 2005. Although we believe our existing cash resources and the anticipated payments from existing agreements with our collaborators will be sufficient to fund our anticipated cash requirements through at least mid-2007, 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;
- 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;
- 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 additional 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.

RISK FACTORS

You should consider carefully the following information about the risks described below, together with the other information contained in this report and in our other public filings in evaluating our business. 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 June 30, 2005, we had an accumulated deficit of approximately \$105.9 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. All of our revenues for the three and six months ended June 30, 2005 were from our agreements with Allergan, Sepracor and SMRI. We anticipate that collaborations with pharmaceutical companies will continue to be our primary source of revenues for the next several years, which provide us with research funding and potential milestone payments and royalties. We cannot be certain that the milestones required to trigger payments 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 clinical products 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.

All of our drug candidates are at an early stage of development and the historical rate of failures for drug candidates is extremely high. Our three Phase II-stage clinical programs are ACP-103 as an adjunctive therapy for schizophrenia, ACP-103 for treatment-induced dysfunctions in Parkinson's disease, and ACP-104 for the treatment of schizophrenia.

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

[Table of Contents](#)

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 Phase I and Phase II clinical trials, those results are not necessarily predictive of results of future trials. Of the large number of drugs in development, only a small percentage result in the submission of a new drug application to the FDA and even fewer are approved for commercialization.

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

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

- demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;
- manufacturing sufficient quantities of a drug candidate;
- obtaining approval of an Investigation New Drug Application, or IND, from the FDA;
- obtaining institutional review board approval to conduct a clinical trial at a prospective site; and
- insufficient 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 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 in our clinical trials, the commercial prospects for our drug candidates 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 year ended December 31, 2004, we used \$20.7 million in cash, cash equivalents and investment securities to fund our operating activities. We expect to use between \$26 and \$30 million of our cash resources to fund operations during 2005. Although we believe our existing cash resources and anticipated payments from existing agreements with our collaborators will be sufficient to fund our anticipated cash requirements through at least mid-2007, 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;

[Table of Contents](#)

- 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; 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 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.

We depend on collaborations with third parties to develop and commercialize selected drug candidates and to provide the majority 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, commercialization and regulatory expertise for selected drug candidates. All of our revenues for the three and six months ended June 30, 2005 were from our agreements with Allergan, Sepracor and SMRI. We expect that nearly all of our revenues for the foreseeable future will be generated by collaborations, although 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;

[Table of Contents](#)

- 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 programs related to this field that are independent from our collaboration project in this therapeutic area. In addition, our collaboration with Sepracor includes an option to pursue a combination drug to treat sleep disorders. Sepracor currently markets a therapeutic product to treat sleep disorders and is engaged in other research programs related to this field that are independent from our development program 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.

Our preclinical development 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 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 successfully complete the clinical trials of our drug candidates, they may fail for other reasons.

Even if we successfully complete the clinical trials of our drug candidates, they 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 our 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 1 percent of patients treated with clozapine. As a result, patients being treated with clozapine are subject to weekly or bi-weekly blood monitoring. In addition, one of the other side effects of clozapine is the occurrence of seizures, which is found in approximately 5 percent of users. 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.

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

[Table of Contents](#)

and retain highly skilled chemists, biologists, pharmacologists and development personnel, especially in the fields of central nervous system disorders, including neuropsychiatric and pain disorders. In addition, 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.

Although we have employment agreements with key members of management, all of our employees are “at will” employees, which means that any employee may quit at any time and we may terminate any employee at any time. We do not carry “key person” insurance covering members of senior management.

We do not know whether our drug discovery platform will lead to the discovery or development of commercially viable 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 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 and collaborators 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 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, reporting systems and procedures in at least two countries and to attract and retain sufficient numbers of talented employees. In addition, we may have to develop sales, marketing and distribution capabilities if we decide to market any drug that we may successfully develop without partnering with third parties. 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.

We have recently consolidated our chemistry operations in a single research and development facility located in Malmo, Sweden. We have incurred and are likely to incur additional costs in setting up and adjusting to operations in a new country with a new Swedish subsidiary. Our subsidiary in Sweden, ACADIA Pharmaceuticals AB, employs approximately 30 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 expense required to follow and coordinate activities in both Europe and California could divert management resources from other important endeavors and, in turn, delay any development and commercialization efforts. In addition, currency fluctuations involving our Swedish operations may cause foreign currency translation 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 ACP-103 and ACP-104 and the preclinical and clinical development of our other drug candidates;
- whether we generate revenues by achieving specified research or commercialization milestones under any agreements or otherwise receive 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 during these periods 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; 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 an indication 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 ACP-103 and ACP-104 for us. While we believe that there are alternative sources available to manufacture our drug candidates, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without delays or additional expenditures. We cannot estimate these delays or costs with certainty but do not expect them to be material.

Our manufacturers 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 obtaining regulatory

[Table of Contents](#)

approval of drug candidates or the ultimate launch of our products 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 premarket 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 profitability or our market value, or in ways with which our stockholders may not agree. We may use our cash resources for corporate purposes that do not yield a significant return or any return at all for our stockholders, which may cause our stock price to decline.

We will incur increased 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, or SOA, and rules adopted or proposed by the SEC and by the Nasdaq Stock Market, will result in increased costs to us as we evaluate the implications of any new rules and respond to their requirements. Although we are not required to issue an evaluation of our internal control over financial reporting under Section 404 of SOA until March 2006, at the earliest, preparations for the issuance of this report have already resulted in increased costs to us, which will increase further. 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. The 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 same or similar 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, our board committees and as executive officers. We cannot predict or estimate the amount of the additional costs we may incur or the timing of such costs to comply with these rules and regulations.

Changes in stock option accounting treatment may adversely affect our results of operations.

Changes in stock option accounting treatment commencing January 1, 2006 will require us to account for employee stock options as compensation expense in our financial statements. In December 2004, the Financial Accounting Standards Board, or FASB, issued SFAS No. 123 (revised 2004), Share-Based Payment, or SFAS 123(R), which requires that compensation costs relating to share-based payment transactions be recognized in financial statements. We are required to implement SFAS 123(R) in our first quarter of 2006. We are currently evaluating the requirements of SFAS 123(R) and we have not yet fully determined the impact on our consolidated financial statements. However, implementation of SFAS 123(R) could materially and adversely affect our reported results of operations and our timing to achieve profitability.

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 other non-technical 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 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 the event of an earthquake, 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.

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 several patent applications with respect to ACP-104 and ACP-103, we have not been issued any patents with respect to ACP-104, and have been issued only two patents with respect to ACP-103.

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;

[Table of Contents](#)

- 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. In particular, we are aware of claims that have been allowed by, and are pending before, the United States Patent and Trademark Office that, if issued as currently drafted, would encompass the chemical structure of ACP-103. While we do not believe that these pending claims would be valid if issued in their current form, there can be no assurance that a court would find these claims invalid or that the text or substance of these claims will not be modified upon further prosecution of the application. If valid, these claims could limit our rights with respect to ACP-103.

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 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-desmethylclozapine, 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 for ACP-104. 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 will not prevent a potential competitor from making ACP-104.

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 other than Mark Brann, Ph.D., our founder, President and CSO.

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 office), which proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, reexamination and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

In addition, changes in or different interpretations of patent laws in the United States and foreign countries may permit others to use our discoveries or to develop and commercialize our technology and products without providing any compensation to us. 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.

[Table of Contents](#)

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 treatment-induced dysfunctions in Parkinson's disease would compete with off-label use of Seroquel, marketed by Astra-Zeneca, and 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, Seroquel, marketed by Astra-Zeneca, and clozapine. In the area of neuropathic pain, our potential products would compete with Neurontin and Lyrica (pregabalin), marketed by Pfizer, and Cymbalta, marketed by Eli Lilly, as well as a variety of generic or proprietary opioids. Our potential products for the treatment of glaucoma would compete with Xalatan, marketed by Pfizer, and Lumigan and Alphagan, marketed by Allergan.

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

- identifying and validating targets;
- screening compounds against targets;
- preclinical studies and clinical trials of potential pharmaceutical products; and
- obtaining FDA and other regulatory approvals.

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

[Table of Contents](#)

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.

The market prices for securities of biotechnology companies in general, and early-stage 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 ACP-103, ACP-104, and our neuropathic pain collaboration;
- 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 foreign countries; or
- economic and political factors, including 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.

[Table of Contents](#)

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

Our directors, executive officers and holders of five percent or more of our outstanding common stock, as of April 20, 2005, and their affiliates beneficially owned approximately 47.5 percent of our common stock, based on their beneficial ownership at that time. 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 directors, 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 our interests or the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders.

If 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. As of August 1, 2005, holders of at least 10 million shares of our common stock, and holders of approximately 74,000 shares issuable upon the exercise of warrants, have rights to cause us to file a registration statement on their behalf or include those shares in registration statements that we may file on our behalf or on behalf of other stockholders. We have filed a registration statement with respect to approximately 6.5 million shares of our common stock that are owned by stockholders, including approximately 1.3 million shares that may be issued upon the exercise of warrants. Our stock price may decline as a result of the sale of shares of our common stock pursuant to the prospectus included in that registration statement, which was declared effective on June 7, 2005.

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

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

- establish that members of the board of directors may be removed only for cause upon the affirmative vote of stockholders owning at least a majority of our capital stock;
- authorize the issuance of “blank check” preferred stock that could be issued by our board of directors to increase the number of outstanding shares and prevent or delay a takeover attempt;
- limit who may call a special meeting of stockholders;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings;
- prohibit our stockholders from making certain changes to our amended and restated certificate of incorporation or amended and restated bylaws except with 66 ²/₃ percent stockholder approval; and
- provide for a board of directors with staggered terms.

We are also subject to provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15 percent or more of our common stock for five 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 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, government agencies and financial institutions with maturities of less than two years. If a 10 percent change in interest rates were to have occurred on June 30, 2005, 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 in Denmark, each of which exposes 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 these subsidiaries are translated to U.S. dollars based on the 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 in accumulated other comprehensive income as a component of our stockholders' equity (deficit). 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

Prior to the filing of this Quarterly Report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a - 15(e) or 15d - 15(e) of the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Quarterly Report. Disclosure controls and procedures are designed to ensure that information required to be disclosed in our periodic reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Based upon that evaluation, our Chief Executive Officer and our Vice President and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Quarterly Report.

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.

Our management, including our Chief Executive Officer and our Chief Financial Officer, does not expect that its disclosure controls will prevent all errors or potential fraud. A control system, no matter how well conceived and operated, can provide only reasonable and not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their cost. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons or by collusion of two or more people. 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.

PART II. OTHER INFORMATION**Item 4. Submission of Matters to a Vote of Security Holders**

Our 2005 Annual Meeting of Stockholders was held on June 10, 2005.

The following matters were voted on at our 2005 Annual Meeting of Stockholders:

1. The election of three nominees to serve as Class I directors on our board of directors until the 2008 Annual Meeting of Stockholders. The following three Class I directors were elected by the votes indicated:

	<u>For</u>	<u>Withheld</u>
Mary Ann Gray	15,188,189	925
Lester J. Kaplan	15,187,760	1,354
Martien van Osch	15,186,385	2,729

2. The ratification of the appointment of PricewaterhouseCoopers as our independent registered public accounting firm for the fiscal year ending December 31, 2005. This appointment was ratified and approved by the following vote: 15,187,860 votes for and 1,154 votes against, with 100 votes abstaining and 0 broker non-votes.

Item 6. Exhibits

<u>Exhibit Number</u>	<u>Description of Document</u>
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).
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.

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: August 12, 2005

By: /s/ ULI HACKSELL

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)

CERTIFICATION
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Uli Hacksell, Ph.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q for the three months ended June 30, 2005 of ACADIA Pharmaceuticals Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and we have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2005

/s/ ULI HACKSELL

Uli Hacksell, Ph.D.
Chief Executive Officer

CERTIFICATION
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Thomas H. Aasen., certify that:

1. I have reviewed this quarterly report on Form 10-Q for the three months ended June 30, 2005 of ACADIA Pharmaceuticals Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and we have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ THOMAS H. AASEN

Date: August 12, 2005

Thomas H. Aasen
Vice President and Chief Financial Officer

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of ACADIA Pharmaceuticals Inc. (the "Company") on Form 10-Q for the period ending June 30, 2005, as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, Uli Hacksell, Ph.D., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge, that:

- (1) the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Date: August 12, 2005

/s/ Uli Hacksell

Uli Hacksell, Ph.D.
Chief Executive Officer

This certification shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, or the Exchange Act, or otherwise subject to the liability of Section 18 of the Exchange Act. Such certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of ACADIA Pharmaceuticals Inc. (the "Company") on Form 10-Q for the period ending June 30, 2005, as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, Thomas H. Aasen, Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge, that:

- (1) the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Date: August 12, 2005

/s/ Thomas H. Aasen

Thomas H. Aasen
Vice President and Chief Financial Officer

This certification shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, or the Exchange Act, or otherwise subject to the liability of Section 18 of the Exchange Act. Such certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.