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

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**FORM 10-Q**

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

For the quarterly period ended June 30, 2004

or

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

Commission File Number: 000-50768

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**ACADIA PHARMACEUTICALS INC.**

(Exact Name of Registrant as Specified in Its Charter)

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**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)

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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 30, 2004:

<u>Class</u>	<u>Number of Shares Outstanding</u>
Common Stock, \$0.0001 par value	16,865,917

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ACADIA PHARMACEUTICALS INC.

FORM 10-Q

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## PART I. FINANCIAL INFORMATION

**ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**ACADIA PHARMACEUTICALS INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2004	December 31, 2003
	(unaudited)	
<b>Assets</b>		
Cash and cash equivalents	\$ 8,156,500	\$ 6,308,100
Investment securities, available-for-sale	40,636,200	20,905,900
Prepaid expenses and other current assets	1,465,400	1,058,200
	<hr/>	<hr/>
Total current assets	50,258,100	28,272,200
Property and equipment, net	2,760,700	3,117,000
Other assets	284,700	303,800
	<hr/>	<hr/>
	\$ 53,303,500	\$ 31,693,000
	<hr/>	<hr/>
<b>Liabilities and Stockholders' Equity (Deficit)</b>		
Accounts payable	\$ 1,984,600	\$ 1,532,700
Accrued expenses	2,989,800	2,130,900
Deferred revenue	1,986,900	1,320,000
Current portion of long-term debt	2,604,100	3,242,300
	<hr/>	<hr/>
Total current liabilities	9,565,400	8,225,900
	<hr/>	<hr/>
Long-term debt, less current portion	946,300	1,624,100
	<hr/>	<hr/>
<b>Commitments</b>		
Convertible preferred stock, \$0.01 par value; no shares and 21,169,067 shares authorized at June 30, 2004 and December 31, 2003, respectively; no shares and 9,900,913 shares issued and outstanding at June 30, 2004, and December 31, 2003, respectively	—	74,514,000
	<hr/>	<hr/>
<b>Stockholders' equity (deficit)</b>		
Preferred stock, \$0.0001 par value; 5,000,000 shares and no shares authorized at June 30, 2004 and December 31, 2003, respectively; no shares issued and outstanding at June 30, 2004 and December 31, 2003	—	—
Common stock, \$0.0001 par value; 75,000,000 shares and 30,000,000 shares authorized at June 30, 2004 and December 31, 2003, respectively; 16,865,417 and 1,462,062 shares issued and outstanding at June 30, 2004 and December 31, 2003, respectively	1,700	300
Additional paid-in capital	126,626,000	18,193,600
Accumulated deficit	(80,733,600)	(68,365,900)
Unearned stock-based compensation	(3,422,900)	(2,923,100)
Accumulated other comprehensive income	320,600	424,100
	<hr/>	<hr/>
Total stockholders' equity (deficit)	42,791,800	(52,671,000)
	<hr/>	<hr/>
	\$ 53,303,500	\$ 31,693,000
	<hr/>	<hr/>

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,	
	2004	2003	2004	2003
<b>Revenues</b>				
Collaborative revenues—related party	\$ 1,015,700	\$ 1,352,100	\$ 1,939,600	\$ 2,330,100
Other collaborative research revenues	—	929,200	—	1,800,800
<b>Total revenues</b>	<b>1,015,700</b>	<b>2,281,300</b>	<b>1,939,600</b>	<b>4,130,900</b>
<b>Operating expenses</b>				
Research and development(1)	5,406,600	4,323,600	11,155,900	8,454,300
General and administrative(1)	879,900	643,600	1,791,300	1,389,800
Stock-based compensation	614,500	218,000	1,309,700	443,000
<b>Total operating expenses</b>	<b>6,901,000</b>	<b>5,185,200</b>	<b>14,256,900</b>	<b>10,287,100</b>
Loss from operations	(5,885,300)	(2,903,900)	(12,317,300)	(6,156,200)
Interest income	117,400	111,800	204,500	162,200
Interest expense	(118,600)	(184,500)	(254,900)	(393,000)
<b>Net loss</b>	<b>\$ (5,886,500)</b>	<b>\$ (2,976,600)</b>	<b>\$ (12,367,700)</b>	<b>\$ (6,387,000)</b>
Participation of preferred stock	(3,109,900)	(2,594,400)	(8,586,500)	(5,566,800)
<b>Net loss available to common stockholders</b>	<b>(2,776,600)</b>	<b>(382,200)</b>	<b>(3,781,200)</b>	<b>(820,200)</b>
<b>Net loss per common share, basic and diluted</b>	<b>\$ (0.42)</b>	<b>\$ (0.26)</b>	<b>\$ (0.94)</b>	<b>\$ (0.56)</b>
<b>Weighted average common shares outstanding, basic and diluted</b>	<b>6,552,366</b>	<b>1,458,794</b>	<b>4,023,717</b>	<b>1,457,961</b>
<b>Net loss available to participating preferred stockholders</b>	<b>\$ (3,109,900)</b>	<b>\$ (2,594,400)</b>	<b>\$ (8,586,500)</b>	<b>\$ (5,566,800)</b>
<b>Net loss per participating preferred share, basic and diluted</b>	<b>\$ (0.31)</b>	<b>\$ (0.27)</b>	<b>\$ (0.87)</b>	<b>\$ (0.71)</b>
<b>Weighted average participating preferred shares outstanding, basic and diluted</b>	<b>9,900,913</b>	<b>9,715,727</b>	<b>9,900,913</b>	<b>7,853,073</b>
(1) Excludes stock-based compensation as follows:				
Research and development	\$ 279,400	\$ 129,400	\$ 686,200	\$ 255,100
General and administrative	335,100	88,600	623,500	187,900
	<b>\$ 614,500</b>	<b>\$ 218,000</b>	<b>\$ 1,309,700</b>	<b>\$ 443,000</b>

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,	
	2004	2003
<b>Cash flows from operating activities</b>		
Net loss	\$ (12,367,700)	\$ (6,387,000)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	643,000	655,500
Stock-based compensation	1,309,700	443,000
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(423,100)	34,400
Other assets	12,500	82,400
Accounts payable	474,700	(57,000)
Accrued expenses	880,100	103,900
Deferred revenue	667,000	1,403,300
Net cash used in operating activities	(8,803,800)	(3,721,500)
<b>Cash flows from investing activities</b>		
Purchases of investment securities	(28,886,000)	(24,654,400)
Maturities of investment securities	9,110,000	7,150,000
Purchases of property and equipment	(300,400)	(451,100)
Net cash used in investing activities	(20,076,400)	(17,955,500)
<b>Cash flows from financing activities</b>		
Proceeds from issuance of common stock, net of issuance costs	31,110,300	12,200
Proceeds from issuance of preferred stock, net of issuance costs	—	28,004,700
Proceeds from issuance of long-term debt	1,296,300	—
Repayments of long-term debt	(1,651,800)	(1,464,000)
Net cash provided by financing activities	30,754,800	26,552,900
Effect of exchange rate changes on cash	(26,200)	(4,600)
Net increase in cash and cash equivalents	1,848,400	4,871,300
<b>Cash and cash equivalents</b>		
Beginning of period	6,308,100	4,453,600
End of period	\$ 8,156,500	\$ 9,324,900
<b>Supplemental schedule of noncash investing and financing activities</b>		
Unrealized gain (loss) on investment securities	\$ (45,700)	\$ 12,300
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, 2004  
(Unaudited)**

**1. Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements of ACADIA Pharmaceuticals Inc. (together with its wholly owned subsidiary 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, 2003 included in the Company's Prospectus filed pursuant to Rule 424(b) of the Securities Act of 1933, as amended, with the Securities and Exchange Commission (the "SEC") on May 26, 2004. 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 presentation 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 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. The Company computed its net income (loss) per common share using the two class method; therefore, the right of preferred stockholders to participate in the Company's net income (loss) was excluded from net income (loss) available to common stockholders up to the completion of the Company's initial public offering on June 2, 2004, at which time all outstanding preferred stock was reclassified or converted into common stock. For the 2003 financial reporting periods, 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 at the end of the applicable financial reporting period. For the 2004 financial reporting periods, the Company allocated net income (loss) to the preferred stock 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 available to common stockholders.

The basic and diluted net loss per common share amounts for the three and six months ended June 30, 2004, presented in the statements of operations, include the effect, on a weighted average basis, of the 5.0 million shares of common stock issued in the Company's initial public offering that closed on June 2, 2004 and the approximately 9.9 million shares of common stock issued upon conversion or reclassification of the Company's preferred stock in conjunction with the initial public offering.

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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,	
	2004	2003	2004	2003
	(unaudited)		(unaudited)	
Antidilutive options to purchase common stock	1,686,102	1,092,234	1,742,095	1,067,916
Antidilutive warrants to purchase common stock	74,073	74,073	74,073	74,073
Restricted common stock	273,609	—	182,406	—
	<u>2,033,784</u>	<u>1,166,307</u>	<u>1,998,574</u>	<u>1,141,989</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.

For purposes of determining compensation expense, the fair value of each option grant is estimated on the grant date using the Black-Scholes option pricing model with the following assumptions used for grants during the periods (the 70% volatility assumption was used to determine compensation expense as of June 2, 2004, the date of the initial public offering):

	Three Months Ended June 30		Six Months Ended June 30,	
	2004	2003	2004	2003
	(unaudited)		—	
Dividend yield	0.0%	0.0%	0.0%	0.0%
Volatility	70.0%	0.0%	70.0%	0.0%
Risk-free interest rate	3.0%	3.0%	3.0%	3.0%
Expected life (in years)	5	5	5	5

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Pro forma information follows for the periods:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
	(unaudited)		(unaudited)	
Net loss, as reported	\$ (5,886,500)	\$ (2,976,600)	\$ (12,367,700)	\$ (6,387,000)
Add: Total stock-based employee compensation costs included in the determination of net loss	662,700	201,900	1,292,700	430,000
Deduct: Total stock-based employee compensation costs that would have been included in net loss if the fair value method had been applied	(740,100)	(233,400)	(1,409,300)	(502,200)
Pro forma net loss	\$ (5,963,900)	\$ (3,008,100)	\$ (12,484,300)	\$ (6,459,200)
Participation of preferred stock	(3,131,400)	(2,621,800)	(8,641,100)	(5,629,700)
Pro forma net loss available to common stockholders	\$ (2,832,500)	\$ (386,300)	\$ (12,484,300)	\$ (829,500)
Actual net loss per common share, basic and diluted	\$ (0.42)	\$ (0.26)	\$ (0.94)	\$ (0.56)
Pro forma net loss per common share, basic and diluted	\$ (0.43)	\$ (0.26)	\$ (0.96)	\$ (0.57)
Pro forma net loss available to participating preferred stockholders	\$ (3,131,400)	\$ (2,621,800)	\$ (8,641,100)	\$ (5,629,700)
Actual net loss per participating preferred share, basic and diluted	\$ (0.31)	\$ (0.27)	\$ (0.87)	\$ (0.71)
Pro forma net loss per participating preferred share, basic and diluted	\$ (0.32)	\$ (0.27)	\$ (0.87)	\$ (0.72)



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### 4. Comprehensive Loss

For the three and six months ended June 30, 2004 and 2003, comprehensive loss consisted of the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
	(unaudited)		(unaudited)	
Net loss	\$(5,886,500)	\$(2,976,600)	\$ (12,367,700)	\$ (6,387,000)
Unrealized gain (loss) on investment securities	(58,100)	11,900	(45,700)	12,300
Foreign currency translation gain (loss)	(500)	27,800	(57,800)	35,200
<b>Total comprehensive loss</b>	<b>\$(5,945,100)</b>	<b>\$(2,936,900)</b>	<b>\$ (12,471,200)</b>	<b>\$(6,339,500)</b>

### 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, 2004 and 2003 were generated in the United States. Information regarding long-lived assets by geographic area as of the dates indicated is as follows:

	June 30, 2004	December 31 2003
	(unaudited)	
United States	\$ 1,574,300	\$ 1,660,300
Denmark	1,471,100	1,760,500
<b>Total</b>	<b>\$ 3,045,400</b>	<b>\$ 3,420,800</b>

### 6. Development Agreement With The Stanley Medical Research Institute

On May 3, 2004, the Company entered into a development agreement with The Stanley Medical Research Institute, or SMRI, a leading nonprofit organization that supports research on the treatment of schizophrenia. The development term is for three years and may be extended for additional one-year periods by written agreement of the parties. Under this agreement, the Company is entitled to receive up to \$5 million in funding to support the further development of one of the Company's drug candidates for the treatment of schizophrenia. Assuming the successful development and commercialization of this drug candidate, the Company is required to pay to SMRI royalties on product sales up to a specified level. SMRI may terminate this agreement in selected instances, including if the Company enters into a strategic alliance covering the drug candidate or does not reasonably progress its development. Upon signing this agreement, the Company received \$1 million from SMRI and issued a \$1 million convertible promissory note to SMRI bearing interest at 9% per annum (the "SMRI Note"). Upon the closing of the Company's initial public offering, the SMRI Note and accrued interest were automatically converted into 143,914 shares of the Company's common stock at the initial public offering price of \$7.00 per share. As of June 30, 2004, no revenues have been recognized under this development agreement.

### 7. Convertible Preferred Stock and Stockholders' Equity

#### *Initial Public Offering*

On June 2, 2004, the Company completed the initial public offering of 5.0 million shares of its common stock for proceeds of \$31.0 million, net of underwriting discounts and commissions and offering expenses.

#### *Convertible Preferred Stock*

Each outstanding share of the Company's Series A, B, D, E and F Preferred Stock was reclassified and each outstanding share of the Company's Series C Preferred Stock was converted into one share of its common stock upon the closing of the initial public offering.

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*Stock Split*

On May 25, 2004, the Company effected a 1-for-2 reverse stock split of its outstanding preferred and common stock. The condensed consolidated financial statements give retroactive effect to the reverse stock split for all periods presented.

**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, 2003 included with our prospectus filed pursuant to Rule 424(b) of the Securities Act of 1933, as amended, with the Securities and Exchange Commission (the "SEC") on May 26, 2004 (the "Prospectus"). 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, 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 SEC reports, including this Quarterly Report.

**Overview**

**Background**

We are a biopharmaceutical company focused on the discovery, development and commercialization of small molecule drugs for the treatment of central nervous system disorders. We currently have five drug programs in clinical and preclinical development. Our three clinical programs are ACP-103 for treatment-induced dysfunction in Parkinson's disease currently in Phase II clinical trials, and ACP-104 and ACP-103, both for the treatment of schizophrenia and expected to enter into Phase II clinical trials in 2004. We have retained worldwide commercialization rights to these drug candidates. We also have two preclinical programs for the development of drug candidates for neuropathic pain and glaucoma 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, 2004, we had an accumulated deficit of \$80.7 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 May 25, 2004, we effected a 1-for-2 reverse stock split of our outstanding preferred and common stock. On June 2, 2004, we completed the initial public offering of 5.0 million shares of our common stock at \$7.00 per share for proceeds to us of \$31.0 million, net of underwriting discounts and commissions and offering expenses of \$4.0 million. In connection with the closing of our initial public offering, all outstanding shares of our Series A, B, D, E and F Preferred stock were reclassified into shares of our common stock and all outstanding shares of our Series C Preferred Stock were automatically converted into shares of our common stock.

On May 3, 2004, we entered into an three-year development agreement with The Stanley Medical Research Institute, or SMRI, a leading nonprofit organization that supports research on the treatment of schizophrenia. Under this development agreement, we are entitled to receive up to \$5 million in funding to support the further development of ACP-104. Assuming the successful development and commercialization of this drug candidate, we are required to pay SMRI royalties on sales of ACP-104 up to a specified level. SMRI may terminate this agreement in selected instances, including if we enter into a strategic alliance covering ACP-104 or do not reasonably progress its development. In connection with this agreement, we issued a \$1 million convertible promissory note to SMRI bearing interest at 9% per annum. Upon the closing of our initial public offering, the principal and accrued interest under the note were automatically converted into 143,914 shares of our common stock.

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### **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. To date, we have entered into three separate collaboration agreements with Allergan and one with Amgen. We have also entered into a technology license agreement with Aventis and smaller scale collaboration agreements with other parties. As of June 30, 2004, we had received \$30.1 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 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 expect to receive a minimum of approximately \$12.0 million in research funding and other fees through March 2006, of which \$6.6 million had been received as of June 30, 2004. Our collaboration agreements with Allergan also allow for potential additional levels of research funding as determined by the parties. In addition, we may receive milestone payments and royalties on product sales, if any, under each of our three collaboration agreements with Allergan. The research term of our collaboration with Amgen was completed in late 2003. Each of our collaboration agreements is subject to early termination by the collaborator upon specified events, including if we have a change in control or breach the agreement. Upon the conclusion of the research term under each agreement, our collaborator may terminate the agreement by notice.

### **Research and Development Expenses**

Our research and development expenses consist primarily of salaries and related personnel expenses, fees paid to external service providers, laboratory supplies and costs for facilities and equipment. We charge all research and development expenses to operations as incurred. Our research and development activities are primarily focused on the preclinical and clinical development of our most advanced programs. We are responsible for all costs incurred in the preclinical and clinical development of ACP-103 for both schizophrenia and treatment-induced dysfunction in Parkinson's disease patients and ACP-104 for schizophrenia, as well as the research costs associated with other drug programs. We are not responsible for, nor have we incurred, preclinical or clinical development expenses in the drug programs that we are pursuing under our collaboration agreements, including our two preclinical programs that we are developing in collaboration with Allergan.

We use our internal research and development resources, including our employees and discovery infrastructure, across several projects and many of our costs are not attributable to a specific project but are directed to broadly applicable research projects. Accordingly, we do not account for 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 substantial majority of 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, 2004 and 2003.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
	(in thousands)			
Costs of external service providers:				
ACP-103	\$ 1,127	\$ 925	\$ 2,511	\$ 1,692
ACP-104	114	118	164	119
Other	404	161	654	416
Subtotal	1,645	1,204	3,329	2,227
Unallocated internal costs	3,762	3,120	7,827	6,227
Total research and development	\$ 5,407	\$ 4,324	\$ 11,156	\$ 8,454

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

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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, as well as continue and expand our research programs. 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 Prospectus, 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, upfront payments, future milestone payments, and royalties.

Upfront, nonrefundable payments under collaboration agreements are recognized ratably over the term of the agreement. 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. 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. 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 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 and the invoices received from our external service providers. In the case of clinical trials, 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, the number of clinical trials and related research service agreements has been relatively limited and 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 be a material change in our accrual, which could also materially affect our 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

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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.

### **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 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, 2004 and 2003***

##### *Revenues*

Revenues decreased to \$1.0 million for the three months ended June 30, 2004 from \$2.3 million for the three months ended June 30, 2003. Revenues from our collaboration agreements with Allergan, a stockholder, totaled \$1.0 million and \$1.4 million for the three months ended June 30, 2004 and 2003, respectively, and are reflected as “collaborative revenues—related party” in our consolidated financial statements. Revenues decreased primarily due to the completion of the research term of our collaboration agreement with Amgen in late 2003, which had contributed \$929,000 in revenues for the three months ended June 30, 2003.

##### *Research and Development Expenses*

Research and development expenses increased to \$5.4 million for the three months ended June 30, 2004 from \$4.3 million for the three months ended June 30, 2003. This increase was primarily due to \$441,000 in increased fees paid to external service providers and increased costs associated with our internal research and development activities, including \$306,000 in increased salaries and related personnel costs, \$193,000 in increased laboratory supplies, and increased facility and equipment costs. The increase in external service costs for the three months ended June 30, 2004 relative to the comparable period of 2003 was primarily attributable to increased clinical development expenses associated with ACP-103 as well as increased patent and other external costs. We expect that fees paid to external service providers will continue to increase as we develop our drug candidates.

##### *General and Administrative Expenses*

General and administrative expenses increased to \$880,000 for the three months ended June 30, 2004 from \$644,000 for the three months ended June 30, 2003. The increase in general and administrative expenses was primarily due to increased legal and other professional fees. We anticipate increases in general and administrative expenses in future periods as we expand our administrative organization and incur additional costs for insurance and professional fees associated with operating as a public company and to support the future growth of our research and development organization.

##### *Stock-Based Compensation Expenses*

Stock-based compensation expense totaled \$615,000 for the three months ended June 30, 2004, compared to \$218,000 for the three months ended June 30, 2003. The increase in stock-based compensation expense resulted from an increase in the amortization of deferred stock-based compensation associated with employee stock options and compensation expense from the valuation of options granted to consultants. We estimate that the remaining unearned stock-based compensation of \$3.4 million at June 30, 2004 will be recognized as expense in future years as follows: \$1.1 million for the remainder of 2004, \$1.3 million in 2005, \$669,000 in 2006, \$265,000 in 2007 and \$31,000 thereafter.

#### ***Comparison of the Six Months Ended June 30, 2004 and 2003***

##### *Revenues*

Revenues decreased to \$1.9 million for the six months ended June 30, 2004 from \$4.1 million for the six months ended June 30, 2003. Revenues from our collaboration agreements with Allergan totaled \$1.9 million and \$2.3 million for the six months ended June 30, 2004 and 2003, respectively. Revenues decreased primarily due to the completion of the research term of our collaboration agreement with Amgen in late 2003, which had contributed \$1.8 million in revenues for the six months ended June 30, 2003.

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### *Research and Development Expenses*

Research and development expenses increased to \$11.2 million for the six months ended June 30, 2004 from \$8.5 million for the six months ended June 30, 2003. This increase was primarily due to \$1.1 million in increased fees paid to external service providers and increased costs associated with our internal research and development activities, including \$636,000 in increased salaries and related personnel costs, \$520,000 in increased laboratory supplies, and increased facility and equipment costs. The increase in external service costs for the six months ended June 30, 2004 relative to the comparable period of 2003 was primarily attributable to increased clinical development expenses associated with ACP-103.

### *General and Administrative Expenses*

General and administrative expenses increased to \$1.8 million for the six months ended June 30, 2004 from \$1.4 million for the six months ended June 30, 2003. The increase in general and administrative expenses was primarily due to increased legal and other professional fees and, to a lesser degree, increased personnel expenses.

### *Stock-Based Compensation Expenses*

Stock-based compensation expense totaled \$1.3 million for the six months ended June 30, 2004, compared to \$443,000 for the six months ended June 30, 2003. The increase in stock-based compensation expense resulted from an increase in the amortization of deferred stock-based compensation associated with employee stock options and compensation expense from the valuation of options granted to consultants. We recorded deferred stock-based compensation totaling \$1.8 million and \$158,000 for the six months ended June 30, 2004 and 2003, respectively, in connection with the grant of stock options to employees.

## **Liquidity and Capital Resources**

Since inception, we have funded our operations primarily through sales of our equity securities, payments under our collaboration agreements, debt financing and interest income. As of June 30, 2004, we had received \$107.2 million in net proceeds from sales of our equity securities, including \$6.0 million from Allergan. In addition, as of June 30, 2004, we had retired \$6.9 million in debt and related accrued interest through the issuance of our common stock. From inception to June 30, 2004, we received \$30.1 million in payments from collaboration agreements, \$18.6 million in debt financing, and \$5.7 million in interest income.

At June 30, 2004, we had approximately \$48.8 million in cash, cash equivalents and investment securities compared to \$27.2 million at December 31, 2003. We have invested a substantial portion of our available cash funds in investment securities consisting of high quality, marketable debt instruments of corporations, government agencies and financial institutions. We have established guidelines relating to diversification and maturities of our investments to preserve principal and maintain liquidity.

Net cash used in operating activities increased to \$8.8 million for the six months ended June 30, 2004 compared to \$3.7 million for the six months ended June 30, 2003. The increase in net cash used in operations during the six months ended June 30, 2004 was primarily due to an increase in our net loss, partially offset by increased non-cash, stock-based compensation expense. Included in accounts payable and accrued expenses at June 30, 2004 were approximately \$730,000 in accrued offering costs associated with our initial public offering.

Net cash used in investing activities (excluding purchases and maturities of investment securities) reflects our purchases of property and equipment. From inception through June 30, 2004, we purchased \$9.8 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 \$30.8 million for the six months ended June 30, 2004 compared to \$26.6 million for the six months ended June 30, 2003. The net cash provided by financing activities in the six months ended June 30, 2004 was primarily due to net proceeds of approximately \$31.0 million raised in our initial public offering. The net cash provided by financing activities in the six months ended June 30, 2003 was primarily due to net proceeds of \$28.0 million from the issuance of our Series F preferred stock.

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 12.58% per annum. At June 30, 2004, we had \$1.9 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, 2004. In May 2002, we also

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issued a secured promissory note to a lender for \$5.0 million, which we utilized to finance equipment, leasehold improvements and other working capital needs. We had an outstanding balance of \$1.6 million under this promissory note at June 30, 2004. This note accrues interest at a rate of 10.73% per annum and is collateralized by substantially all personal property of the Company, excluding its intellectual property.

In June 2004, we entered into an agreement to lease a new facility in Scandinavia. The lease is expected to commence in June 2005 and will require us to pay annual rent of approximately \$945,000 for a ten-year period.

The following table summarizes our long-term contractual obligations at June 30, 2004:

	<u>Total</u>	<u>Less than 1 Year</u>	<u>1 - 3 Years (2005-2007)</u>	<u>4 - 5 Years (2008-2009)</u>	<u>Thereafter</u>
Operating leases	\$ 11,294,200	\$ 697,000	\$ 3,495,800	\$ 1,893,700	\$ 5,207,700
Long-term debt	3,550,400	1,611,100	1,290,500	463,700	185,100
<b>Total</b>	<b>\$ 14,844,600</b>	<b>\$ 2,308,100</b>	<b>\$ 4,786,300</b>	<b>\$ 2,357,400</b>	<b>\$ 5,392,800</b>

We have consumed substantial amounts of capital since our inception. Although we believe our existing cash resources plus the anticipated payments from existing collaboration agreements will be sufficient to fund our anticipated cash requirements through 2005, 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; 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 Quarterly 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. For the year ended December 31, 2003, we had a net loss of \$14.1 million. For the six months ended June 30, 2004, we had a net loss of \$12.4 million. As of June 30, 2004, we had an accumulated deficit of approximately \$80.7 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. Our primary source of revenues in 2003 was from research and milestone payments under our collaboration agreements with Allergan and Amgen. In 2003, we received 67% of our revenues from collaborations with Allergan and 32% of our revenues from our collaboration with Amgen. For the six-month period ended June 30, 2004, we received all of our revenues from our collaborations with Allergan, as the research term of our collaboration with Amgen was completed in late 2003. We anticipate that our 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 revenues 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 most advanced clinical program, ACP-103 for treatment-induced dysfunction in Parkinson's disease, is in early Phase II clinical trials. Our other two early clinical programs, ACP-104 and ACP-103, each for the treatment of schizophrenia, are expected to start Phase II clinical trials in 2004.

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.

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 our 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 Investigational New Drug application 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 described above 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, 2003 and the six months ended June 30, 2004, we used \$13.2 million and \$9.5 million, respectively, in cash, cash equivalents and investment securities to fund our activities. Although we believe our existing cash resources and anticipated payments from existing collaboration agreements will be sufficient to fund our anticipated cash requirements through 2005, 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; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory clearances to market our drug candidates.

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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. Further, 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. We received approximately 99% of our revenues for the year ended December 31, 2003 from our collaborations with Allergan and Amgen. For the six months ended June 30, 2004, we received all of our revenues from our collaborations with Allergan. We expect that a similar percentage of our revenues for the foreseeable future will be generated by collaborations.

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 potential 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 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 a collaboration agreement;
- disagreements with respect to ownership of intellectual property rights;
- unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities, or to permit public disclosure of these activities;
- delay of a collaborator's development or commercialization efforts with respect to our drug candidates; or
- termination or non-renewal of the collaboration.

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

In addition, in each of our collaborations, we generally have agreed not to conduct independently, or with any third party, any research that is 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.

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We have collaborations with Allergan for the development of drug candidates related to neuropathic pain and 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. Competing products, either developed by our collaborators or to which our collaborators have rights, may result in their withdrawal of support for our drug candidates.

***We rely on third parties to coordinate 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 coordinate 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 regulatory obligations or meet 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 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. We cannot estimate these costs or delays with certainty but do not expect them to be material.

***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; 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;

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- 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 likely 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% of the patients. 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% 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 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 that will be safe, well tolerated and effective in humans. 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 in-license, 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.

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***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 clinical 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 Danish subsidiary with our activities in California, which could have an adverse impact on our operations.***

Our subsidiary in Denmark, ACADIA Pharmaceuticals A/S, employs approximately 36% 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 California. The additional administrative expense required to monitor and coordinate activities in both Denmark 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 Danish 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;
- 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 two third-party manufacturers to produce ACP-103 and ACP-104 for us. While we believe that there are numerous 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 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.

***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 in-license 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, California 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 one patent 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;

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- we may not have been the first to file patent applications for our drug candidates or the technologies we rely upon;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- any or all of our pending patent applications may not result in issued patents;
- we may not seek or obtain patent protection in all countries that will eventually provide a significant business opportunity;
- any patents issued to us or our collaborators may not provide a basis for commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties;
- our proprietary technologies may not be patentable;
- others may design around our patent claims to produce competitive products which fall outside of the scope of our patents; or
- others may identify prior art which could invalidate our patents.

Even if we 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 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. 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, in-licensed technology 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 and/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 a method of use patent application for ACP-104, but a competitor could use ACP-104, and patent its method of use, for a treatment not covered by our patent application.



***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 Dr. Brann.

***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. 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. 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.

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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, or complexity and novelty of the product and requires substantial resources. Even if regulatory approval is obtained, it may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion and/or marketing of such products, and requirements for post-approval studies, including additional research and development and clinical trials. These limitations may limit the size of the market for the product or result in the incurrence of additional costs. Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues from the particular drug candidate.

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

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

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

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

For example, our potential product for treatment-induced dysfunction in Parkinson's disease will compete with off-label use of Seroquel, marketed by Astra-Zeneca, and the generic drug clozapine. Our potential products for the treatment of schizophrenia will compete with Zyprexa, marketed by Eli Lilly, Risperdal, marketed by Johnson & Johnson, and clozapine. In the area of neuropathic pain, our potential products will compete with Neurontin, marketed by Pfizer, and Pregabalin, currently submitted for U.S. regulatory approval by Pfizer, as well as a variety of generic or proprietary opioids. Our potential products for the treatment of glaucoma will 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;

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- 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 effect on our business.

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

Our research and development activities involve the controlled use of potentially harmful hazardous materials, including volatile solvents, biological materials such as blood from patients that has the potential to transmit disease, chemicals that cause cancer and various radioactive compounds. Our operations also produce hazardous waste products. We face the risk of contamination or injury from the use, storage, handling or disposal of these materials. We are subject to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations could be significant, and current or future environmental regulations may impair our research, development or production efforts. If one of our employees were accidentally injured from the use, storage, handling or disposal of these materials, the medical costs related to his or her treatment would be covered by our workers' compensation insurance policy. However, we do not carry specific biological or hazardous waste insurance coverage and our general liability insurance policy specifically excludes coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be subject to criminal sanctions or fines or 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 and ACP-104;
- 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;

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- 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 genetic testing 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.

***Our management has broad discretion over the use of the proceeds from the initial public offering of our common stock, and we may not use these proceeds effectively, which could adversely affect our results of operations.***

Our management has significant flexibility in applying the net proceeds of our initial public offering of common stock and could use these proceeds for corporate purposes that do not increase our profitability or our market value, or in ways with which our stockholders may not agree. Investors rely on the judgment of our management regarding the application of these proceeds. We may use the net proceeds 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.

***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.***

Following completion of our initial public offering, our directors, executive officers and holders of 5% or more of our outstanding common stock and their affiliates beneficially owned approximately 41% of our common stock, based on their beneficial ownership at March 31, 2004 and participation in the initial public offering. 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. The holders of most of our outstanding capital stock have agreed with the underwriters of the initial public offering to be bound by a lock-up agreement that prohibits these holders from selling or transferring their stock, other than in specific circumstances, before November 22, 2004. However, Banc of America Securities LLC, on behalf of the underwriters, at its discretion can waive the restrictions of the lock-up agreement at an earlier time without prior notice or announcement. We have been advised that Banc of America, in evaluating whether to waive the restrictions in a lock-up agreement, may consider a number of factors with a view toward maintaining an orderly market for, and minimizing volatility in the market price of, our common stock. These factors include, among others, the number of shares involved, the then recent trading volume and prices of our common stock, the length of time before the lock-up expires and the reasons for, and the timing of, the request. In addition, after the lock-up expires, at least 11,536,321 shares of our common stock will become freely tradable, and holders of at least 10,003,289 shares of our common stock will have rights to cause us to file a registration statement on their behalf or include their shares in registration statements that we may file on our behalf or on behalf of other stockholders.

***We may incur increased costs as a result of recently enacted and proposed changes in laws and regulations relating to corporate governance matters.***

Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted or proposed by the Securities and Exchange Commission 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. 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 or 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.

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### ***Anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us more complicated and 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% 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% 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% change in interest rates were to have occurred on December 31, 2003, 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 a wholly owned subsidiary in Denmark, ACADIA Pharmaceuticals A/S, which exposes us to foreign exchange risk. The functional currency of our subsidiary is the Danish local currency, the Danish kroner. Accordingly, all assets and liabilities of our subsidiary 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 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 Vice President and 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 Vice President and 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 and 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 Vice President and 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 2. CHANGES IN SECURITIES, USE OF PROCEEDS AND ISSUER PURCHASES OF EQUITY SECURITIES**

(c) During the three month period ended June 30, 2004, we issued and sold 15,312 shares of our common stock that were not registered under the Securities Act of 1933, as amended (the "Securities Act"), to our employees upon the exercise of options for cash consideration with an aggregate exercise price of \$22,938. During the same period, we granted options to purchase 10,625 shares of common stock at a weighted average exercise price of \$4.47 per share. No underwriters were involved in the foregoing stock or option issuances. The issuance of these options was exempt from registration under the Securities Act in reliance on Rule 701 promulgated under the Securities Act as transactions by an issuer under compensatory benefit plans and contracts relating to compensation within the parameters required by Rule 701.

In addition, on May 3, 2004, we issued to The Stanley Medical Research Institute a convertible promissory note in the aggregate principal amount of \$1 million. The note bore interest at 9% per annum. The principal and accrued interest under the note automatically converted into 143,914 shares of our common stock upon the closing of our initial public offering at a conversion price of \$7.00 per share, the price per share in our initial public offering. Neither the note nor the shares of our common stock issued upon conversion of the note were registered under the Securities Act. The issuance of these securities was exempt from registration under the Securities Act in reliance on Regulation D promulgated under the Securities Act. No underwriters were involved in the issuance of the note or the shares of our common stock issued upon conversion of the note.

(d) The initial public offering of our common stock, par value \$0.0001 (the "Offering"), was effected through a Registration Statement on Form S-1 (File No. 333-113137) that was declared effective by the Securities and Exchange Commission on May 26, 2004. The Offering commenced on May 26, 2004 and did not terminate before any securities were sold. On June 2, 2004, 5.0 million shares of common stock were sold on our behalf at an initial public offering price of \$7.00 per share, resulting in aggregate proceeds of approximately \$31.0 million, net of underwriting discounts and commissions of approximately \$2.5 million to Banc of America Securities LLC, Piper Jaffray & Co., JMP Securities and Adams Harkness, Inc. (formerly, Adams Harkness & Hill, Inc.) and offering expenses of approximately \$1.5 million.

No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or any person owning ten percent or more of any class of our equity securities or to any other of our affiliates.

There has been no material change in the planned use of proceeds as described in our final Prospectus.

### **ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

On May 25, 2004, we effected a 1-for-2 reverse split of our outstanding common stock and preferred stock. Except where otherwise noted, all share numbers in this Item 4 do not reflect this reverse stock split.

On April 27, 2004, we sent a written consent to our stockholders requesting consent to the taking of the following actions in connection with the initial public offering of our common stock: (1) the approval and adoption of an Amended and Restated Certificate of Incorporation to be filed prior to the effectiveness of our initial public offering to (i) implement a 1-for-2 reverse stock split of our outstanding common stock and preferred stock and (ii) modify certain provisions of the preferred stock to facilitate our initial public offering, (2) the approval and adoption of our Restated Certificate of Incorporation to become effective upon the closing of our initial public offering, (3) the approval and adoption of our Amended and Restated Bylaws to become effective upon the effectiveness of our initial public offering, (4) the approval and adoption of our 2004 Equity Incentive Plan to become effective upon the closing of our initial public offering and reservation of 200,000 shares of common stock (post-split) to be available for issuance thereunder and additional shares to be available under specified circumstances for issuance thereunder, (5) the approval and adoption of our 2004 Employee Stock Purchase Plan to become effective upon the effectiveness of our initial public offering and reservation of 125,000 shares of common stock (post-split) to be available for issuance thereunder and additional shares to be available under specified circumstances for issuance thereunder, and (6) the approval of the form of indemnity agreement between us and each of our directors and executive officers. All such actions were effected pursuant to an action by written consent of our stockholders in compliance with Section 228 of the Delaware General Corporation Law.

Stockholders holding an aggregate of 19,929,548 shares approved the above matters and stockholders holding approximately 3,499,497 shares did not vote with respect to such matters.

**ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K**

**(a) 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	Convertible Promissory Note issued to The Stanley Medical Research Institute on May 3, 2004 (filed as Exhibit 4.4 to Registration Statement File No. 333-113137).
10.1	Form of Indemnity Agreement for directors and officers (filed as Exhibit 10.1 to Registration Statement File No. 333-113137).
10.2	2004 Equity Incentive Plan and forms of agreement thereunder (filed as Exhibit 10.3 to Registration Statement File No. 333-113137).
10.3	2004 Employee Stock Purchase Plan and initial offering thereunder (filed as Exhibit 10.4 to Registration Statement File No. 333-113137).
10.4	Development Agreement, dated May 3, 2004, between the Registrant and The Stanley Medical Research Institute (filed as Exhibit 10.18 to Registration Statement File No. 333-113137).
10.5	General Agreement, dated April 22, 2004, between the Registrant and Medeon Fastigheter AB (filed as Exhibit 10.19 to Registration Statement File No. 333-113137).
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.

**(b) Reports on Form 8-K**

None.



**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.

Date: August 12, 2004

ACADIA Pharmaceuticals Inc.

By: /s/ Uli Hacksell

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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

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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, 2004 of ACADIA Pharmaceuticals Inc.
2. Based on my knowledge, this quarterly 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 quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly 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 quarterly report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this quarterly report based on such evaluation; and
  - c) disclosed in this quarterly 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, 2004

/s/ Uli Hacksell

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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, 2004 of ACADIA Pharmaceuticals Inc.
2. Based on my knowledge, this quarterly 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 quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly 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 quarterly report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this quarterly report based on such evaluation; and
  - c) disclosed in this quarterly 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, 2004

/s/ Thomas H. Aasen

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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, 2004, 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) and 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 and results of operations 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, 2004

/s/ Uli Hacksell

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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, 2004, 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) and 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 and results of operations 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, 2004

/s/ Thomas H. Aasen

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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.