ACADIA PHARMACEUTICALS INC Form 10-Q August 07, 2008 Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2008

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

ACADIA PHARMACEUTICALS INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware (State of Incorporation)

06-1376651 (I.R.S. Employer

Identification No.)

3911 Sorrento Valley Boulevard

San Diego, California (Address of Principal Executive Offices) 92121 (Zip Code)

(858) 558-2871

(Registrant s Telephone Number, Including Area Code)

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

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

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

(Do not check if a smaller reporting company)

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

Total shares of common stock outstanding as of the close of business on July 31, 2008:

Class
Common Stock, \$0.0001 par value

Number of Shares Outstanding 37,130,389

ACADIA PHARMACEUTICALS INC.

FORM 10-Q

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PART I. FINANCIAL INFORMATION

$\frac{\textbf{ITEM 1.}}{\textbf{ACADIA PHARMACEUTICALS INC.}}$

CONDENSED CONSOLIDATED BALANCE SHEETS

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

(Unaudited)

	J	fune 30, 2008	cember 31, 2007(1)
Assets			
Cash and cash equivalents	\$	20,285	\$ 16,987
Investment securities, available-for-sale		69,336	109,871
Prepaid expenses, receivables and other current assets		3,486	4,395
Total current assets		93,107	131,253
Property and equipment, net		2,712	3,048
Other assets		261	283
Total assets	\$	96,080	\$ 134,584
Liabilities and Stockholders Equity			
Accounts payable	\$	3,217	\$ 2,590
Accrued expenses		9,620	15,012
Deferred revenue		170	707
Current portion of long-term debt		882	978
Total current liabilities		13,889	19,287
Other long-term liabilities		257	207
Long-term debt, less current portion		730	1,156
Total liabilities		14,876	20,650
Commitments (Note 8)		1,,070	20,000
Stockholders equity			
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized at June 30, 2008 and December 31, 2007; no shares issued and outstanding at June 30, 2008 and December 31, 2007			
Common stock, \$0.0001 par value; 75,000,000 shares authorized at June 30, 2008 and December 31, 2007; 37,130,389 shares and 37,035,389 shares issued and outstanding at June 30, 2008 and December 31, 2007, respectively		4	4
Additional paid-in capital		345,416	343,293
Accumulated deficit		(264,523)	(229,856)
Accumulated other comprehensive income		307	493
Accumulated outer completionsive meonic		307	773
Total stockholders equity		81,204	113,934

Total liabilities and stockholders equity

\$ 96,080 \$ 134,584

(1) The condensed consolidated balance sheet at December 31, 2007 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

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

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ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(Unaudited)

	Three Mon June 2008		Six Months Ended June 30, 2008 2007		
Revenues					
Collaborative revenues	\$ 177	\$ 2,055	\$ 983	\$ 4,015	
Operating expenses					
Research and development (includes stock-based compensation of \$380, \$705, \$795 and					
\$1,609, respectively)	16,036	11,495	31,207	23,756	
General and administrative (includes stock-based compensation of \$431, \$377, \$852 and					
\$747, respectively)	3,184	3,163	6,454	6,316	
Total operating expenses	19,220	14,658	37,661	30,072	
Loss from operations	(19,043)	(12,603)	(36,678)	(26,057)	
Interest income	802	1,920	2,109	2,884	
Interest expense	(46)	(70)	(98)	(134)	
Net loss	\$ (18,287)	\$ (10,753)	\$ (34,667)	\$ (23,307)	
Net loss per common share, basic and diluted	\$ (0.49)	\$ (0.29)	\$ (0.94)	\$ (0.70)	
Weighted average common shares outstanding, basic and diluted	37,102	36,894	37,077	33,455	

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

ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(Unaudited)

		ths Ended ae 30,
	2008	2007
Cash flows from operating activities		
Net loss	\$ (34,667)	\$ (23,30
Adjustments to reconcile net loss to net cash used in operating activities:		_
Depreciation and amortization	554	54
Stock-based compensation	1,647	2,35
Amortization of investment premium/discount Other	124	(5)
Changes in operating assets and liabilities:		(.)
Prepaid expenses, receivables and other current assets	984	(49
Other assets	22	(4)
Accounts payable	586	(1,1)
Accrued expenses	(5,514)	(4,9)
Deferred revenue	(537)	(10
Other long-term liabilities	47	(28
outer rong term nationales	.,	(2)
Net cash used in operating activities	(36,754)	(27,9)
Cash flows from investing activities		
Purchases of investment securities	(47,576)	(114,20
Maturities of investment securities	87,739	68,34
Purchases of property and equipment	(152)	(19
Net cash provided by (used in) investing activities	40,011	(46,03
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	476	97,9
Proceeds from issuance of long-term debt		69
Repayments of long-term debt	(522)	(58
Net cash provided by (used in) financing activities	(46)	98,08
Effect of exchange rate changes on cash	87	3
Net increase in cash and cash equivalents	3,298	24,13
Cash and cash equivalents		
Beginning of period	16,987	15,48
End of period	\$ 20,285	\$ 39,63
Supplemental schedule of noncash investing and financing activities		
Unrealized gain (loss) on investment securities The accompanying notes are an integral part of these condensed consoli	\$ (248) idated financial statements.	\$

ACADIA PHARMACEUTICALS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2008

(Unaudited)

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of ACADIA Pharmaceuticals Inc. (together with its wholly owned subsidiaries, ACADIA Pharmaceuticals AB and ACADIA Pharmaceuticals A/S, the Company) should be read in conjunction with the audited financial statements and notes thereto as of and for the year ended December 31, 2007 included in the Company s Annual Report on Form 10-K (Annual Report) filed with the Securities and Exchange Commission (the SEC). The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying financial statements do not include all of the information and notes required by GAAP for complete financial statements. In the opinion of management, the accompanying financial statements reflect all adjustments (consisting of normal recurring adjustments) that are necessary for a fair statement of the financial position, results of operations and cash flows for the interim periods presented. Interim results are not necessarily indicative of results for a full year.

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

2. Earnings (Loss) Per Share

Basic earnings (loss) per common share is computed by dividing net income (loss) by the weighted average number of common shares outstanding for the period. Diluted earnings (loss) per common share is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period increased to include potential dilutive common shares that were outstanding during the period. The effect of outstanding stock options, restricted vesting common stock and warrants, when dilutive, is reflected in diluted earnings (loss) per common share by application of the treasury stock method. The Company has excluded all outstanding stock options, restricted vesting common stock and warrants from the calculation of diluted net loss per common share because all such securities are antidilutive for all periods presented.

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

		Three Months Ended June 30,		onths Ended Six Months Ended 90, June 30		
	2008	2008 2007		2007		
	(unaud	ited)	d) (unaud			
Antidilutive options to purchase common stock	3,293	2,833	3,134	2,831		
Antidilutive warrants to purchase common stock	1,393	1,393	1,393	1,393		
Restricted vesting common stock		7		10		
	4,686	4,233	4,527	4,234		

3. Stock-Based Compensation

During the three and six months ended June 30, 2008 and the three and six months ended June 30, 2007, the Company recorded stock-based compensation expense related to employee and non-employee stock option awards and its employee stock purchase plan (the Purchase Plan) of \$811,000, \$1.6 million, \$1.1 million and \$2.4 million, respectively. The Company adopted Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), *Share-Based Payment* (SFAS No. 123(R)), using the modified prospective method on January 1, 2006. The Company continues to account for compensation expense for options granted to non-employees other than directors in accordance with Emerging Issues Task Force, Issue No. 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with

Selling Goods or Services. At June 30, 2008, total unrecognized estimated compensation cost related to non-vested stock options granted prior to that date and existing Purchase Plan rights was \$6.4 million, which is expected to be recognized over a weighted-average period of 2.4 years.

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The value of each employee stock option and Purchase Plan right is estimated on the grant date under the fair value method using the Black-Scholes option pricing model. All option expense is amortized over the requisite service period of the awards, which are generally the vesting periods. The following assumptions were used to estimate the fair value of employee stock options:

	Six Month June	
	2008	2007
	(unaud	lited)
Expected volatility	68%-74%	64%-68%
Risk-free interest rate	2-3%	5%
Expected forfeiture rate	5-6%	6%
Expected dividend yield	0%	0%
Expected life of options in years	5.5-5.7	5.4-5.5

The following assumptions were used to estimate fair value for the latest offering under the Purchase Plan that commenced June 1, 2008: expected volatility of 50 to 76 percent; risk-free interest rate of 2 to 3 percent; dividend yield of 0 percent; and expected life in years of 0.5 to 2.0

4. Comprehensive Loss

Comprehensive loss consisted of the following (in thousands):

	Three Mon June		Six Months Ended June 30,		
	2008 2007		2008	2007	
	(unau	dited)	(unaudited)		
Net loss	\$ (18,287)	\$ (10,753)	\$ (34,667)	\$ (23,307)	
Unrealized gain (loss) on investment securities, net of tax	(382)	61	(248)	55	
Foreign currency translation gain, net of tax	22	26	62	18	
Total comprehensive loss	\$ (18,647)	\$ (10,666)	\$ (34,853)	\$ (23,234)	

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	June 30, 2008	Dec	ember 31, 2007	
	(ur	audite	udited)	
Accrued clinical and research services	\$ 6,283	\$	10,650	
Accrued compensation and benefits	2,567		3,410	
Other	770		952	
Total	\$ 9,620	\$	15,012	

6. Segment Information

Management has determined that the Company operates in one business segment. All revenues for the three and six months ended June 30, 2008 and 2007 were generated in the United States. Information regarding long-lived assets by geographic area as of the dates indicated were as follows (in thousands):

	June 30, 2008		nber 31 007
	(una	nudited)	
United States	\$ 1,805	\$	2,090
Europe	907		958
Total	\$ 2,712	\$	3,048

7. Fair Value Measurements

The Company adopted SFAS No. 157, Fair-Value Measurements, or SFAS 157, effective January 1, 2008. SFAS 157 is applicable for all financial assets and liabilities and any other assets and liabilities that are recognized or disclosed at fair value on a recurring basis. SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair-value measurements. SFAS 157 requires fair value measurements be classified and disclosed in one of the following three categories:

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

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

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

As of June 30, 2008, the Company held \$88.1 million of cash equivalents and available-for-sale investment securities consisting of high quality, marketable debt instruments of corporations, financial institutions, and government agencies and a money market fund wholly-backed by U.S. Treasury collateral. The Company has adopted an investment policy and established guidelines relating to credit quality, diversification and maturities of its investments to preserve principal and maintain liquidity. All investment securities have a credit rating of at least AA or A1+/P1 as determined by Moody s Investors Service and/or Standard & Poor s. The Company does not have any direct investments in auction-rate securities or securities that are collateralized by assets that include mortgages or subprime debt. The Company s investment portfolio has not been adversely impacted by the recent disruption in the credit markets. However, if there is continued and expanded disruption in the credit markets, there can be no assurance that the Company s investment portfolio will not be adversely affected in the future.

The Company s cash equivalents and available-for-sale investment securities are classified within Level 1 or Level 2 of the fair value hierarchy. These investment securities are valued using quoted market prices, broker or dealer quotations, or other observable inputs. The fair value measurements of the Company s cash equivalents and available-for-sale investment securities are identified in the following hierarchy in connection with our adoption of SFAS 157 (in thousands):

Fair Value Measurements at

		ran value Measurements at				
	Reporting Date using					
		Quoted Prices				
		in Active				
		Markets	Significant			
		for	Other	Significant		
	June 30, 2008	Identical Assets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)		
Money market fund, wholly-backed by U.S. Treasury collateral	\$ 13,688	\$ 13,688	\$	\$		
U.S. government agency securities	2,255	2,255				
Government sponsored enterprises	14,037		14,037			
Corporate debt securities	6,063		6,063			
Commercial paper	47,289		47,289			
Asset-backed securities	4,754		4,754			
	\$ 88,086	\$ 15,943	\$ 72,143	\$		

In February 2008, the Financial Accounting Standards Board, or FASB, issued FASB Staff Position 157-2, or FSP 157-2, which delays the effective date of SFAS 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis, until fiscal years beginning after November 15, 2008 and interim periods within those years. The partial adoption of SFAS 157 effective January 1, 2008 for financial assets and liabilities recognized at fair value on a recurring basis, in accordance with FSP 157-2, did not impact the Company s consolidated financial position or valuation of cash equivalents or investment securities.

The Company adopted SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, or SFAS 159, effective January 1, 2008. SFAS 159 permits companies to elect to measure certain financial instruments and certain other items at fair value. The standard requires that unrealized gains and losses on items for which the fair value option has been elected be reported in earnings. The adoption of SFAS 159 did not impact the Company s consolidated financial position, results of operations or cash flows.

8. Commitments

The Company has entered into agreements with contract research organizations and other external service providers for services in connection with the development of its drug candidates. The Company was contractually obligated for up to approximately \$34.6 million of future services under these agreements as of June 30, 2008. The nature of the work being conducted under the Company s agreements with contract research organizations is such that, in most cases, the services may be stopped with short notice. In such event, the Company would not be liable for the full amount of the contract. The Company s actual contractual obligations may vary depending upon several factors, including the progress of the underlying studies.

9. Recent Accounting Pronouncements

In December 2007, the FASB ratified EITF No. 07-1, *Accounting for Collaborative Arrangements*, or EITF 07-1. EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 also establishes the appropriate income statement presentation and classification for joint operating activities and payments between participants, as well as the sufficiency of the disclosures related to these arrangements. EITF 07-1 is effective for fiscal years beginning after December 15, 2008, and would be applied retrospectively as a change in accounting principle for collaborative arrangements existing at the effective date. The Company is currently evaluating the potential impact of EITF 07-1 on its consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations*, or SFAS 141(R). SFAS 141(R) will require an acquiring company to measure all assets acquired and liabilities assumed, including contingent considerations and all contractual contingencies, at fair value as of the acquisition date. In addition, an acquiring company is required to capitalize in-process research and development and either amortize it over the life of the product, or write it off if the project is abandoned or impaired. SFAS 141(R) is effective for fiscal years beginning after December 15, 2008.

In December 2007, the FASB issued SFAS No. 160, *Interests in Consolidated Financial Statements an amendment of ARB No. 51*, or SFAS 160. SFAS 160 impacts the accounting for minority interest in the consolidated financial statements of filers. The statement requires the reclassification of minority interest to the equity section of the balance sheet and the results from operations attributed to minority interest to be included in net income. The amount of consolidated net income attributable to the parent filer and to the minority interest would be clearly identified and presented on the face of the consolidated statements of operations. SFAS 160 is effective for fiscal years beginning after December 15, 2008.

10. Subsequent Events

On August 5, 2008, the Company announced a strategic restructuring designed to focus resources on its most advanced product candidates and provide additional financial flexibility and strength. The Company is focused on developing a portfolio of its four most advanced product candidates, consisting of two internal compounds as well as two partnered compounds that are funded by Allergan.

In connection with the restructuring, the Company plans to reduce its total workforce by about 50 percent to 65 employees. The Company estimates that it will record charges of between approximately \$2.0 to \$2.5 million during the third quarter of 2008 in connection with the restructuring. The Company anticipates that its internal operating expenses will be reduced significantly following the restructuring.

On August 4, 2008, the Company entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited that provides the Company with access, at its discretion, to up to \$60 million in capital during the next three years through the sale of newly-issued shares of

the Company s common stock. The funds that can be raised under the CEFF over the three-year

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period will depend on the then-current price of the Company s common stock and the number of shares actually sold, which may not exceed an aggregate of approximately 7 million shares. The Company is not obligated to utilize any of the funds available under the CEFF and there are no minimum commitments or minimum use penalties.

The Company may access capital under the CEFF in tranches of up to a maximum of between 2.0 and 3.5 percent of its market capitalization at the time of the draw down of each tranche, subject to certain conditions, including a minimum share price threshold. Kingsbridge may purchase shares of common stock under the CEFF at discounts ranging from 6 percent to 12 percent, depending on the average market price of the Company s common stock during the applicable pricing period. In connection with the CEFF, the Company issued a warrant to Kingsbridge to purchase 350,000 shares of common stock at an exercise price of \$3.915 per share, which represented a 25 percent premium over the average of the closing price of its common stock for the five days preceding the signing of the CEFF. The Company has agreed to file a registration statement with respect to the resale of shares issuable pursuant to the CEFF and underlying the warrant.

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, 2007 included with our annual report on Form 10-K (Annual Report) filed with the SEC. Past operating results are not necessarily indicative of results that may occur in future periods.

This Quarterly Report contains forward-looking statements. These forward-looking statements involve a number of risks and uncertainties. Such forward-looking statements include statements about our strategies, objectives, expectations, discoveries, collaborations, clinical trials, internal programs, and other statements that are not historical facts, including statements which may be preceded by the words intends, may, will, plans, expects, anticipates, projects, predicts, estimates, aims, believes, hopes, potential or similar words. For such statements, we clair of the Private Securities Litigation Reform Act of 1995. Readers of this Quarterly Report are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date on which they are made. We undertake no obligation to update publicly or revise any forward-looking statements. Actual events or results may differ materially from our expectations. Important factors that could cause actual results to differ materially from those stated or implied by our forward-looking statements include, but are not limited to, the risk factors identified in our filings with the SEC, including this Quarterly Report.

Overview

Background

We are a biopharmaceutical company focused on the development and commercialization of small molecule drugs for the treatment of central nervous system disorders. Our most advanced product candidate is pimavanserin, currently in Phase III development for the treatment of Parkinson's disease psychosis, or PDP. We also have reported positive results from a Phase II trial with pimavanserin as a co-therapy in schizophrenia and from a proof-of-concept clinical study with pimavanserin for the treatment of sleep maintenance insomnia in healthy older adults. We have retained worldwide commercialization rights to pimavanserin. We also have a chronic pain program in Phase II development and a glaucoma program in Phase I studies in collaboration with Allergan, Inc. In addition to our clinical programs, we are developing ACP-106, currently in IND-track development. All of the product candidates in our pipeline emanate from discoveries made using our proprietary drug discovery platform.

We have incurred substantial operating losses since our inception due in large part to expenditures for our research and development activities. At June 30, 2008, we had an accumulated deficit of \$264.5 million. We expect our operating losses to continue for at least the next several years as we pursue the clinical development of our drug candidates and expand our product pipeline.

Recent Developments

In June 2008, we reported top-line results from a Phase IIb clinical trial in our program with ACP-104 as a treatment for patients with schizophrenia. The study did not meet its primary endpoint of antipsychotic efficacy or any of the secondary endpoints. Although we are continuing to analyze the results from this study, we currently do not anticipate conducting further studies with ACP-104.

On August 5, 2008, we announced a strategic restructuring designed to focus resources on our most advanced product candidates and provide additional financial flexibility and strength. We are focused on developing a portfolio of our four most advanced product candidates, consisting of two internal compounds as well as two partnered compounds that are funded by Allergan. Our top priority continues to be advancing our Phase III program with pimavanserin for PDP. Through our collaborations with Allergan, we are advancing a Phase II program in chronic pain and a Phase I program in glaucoma. In addition, we intend to complete IND-enabling studies to advance a fourth product candidate, ACP-106, into the clinic in 2009. While we have significantly reduced spending on earlier-stage programs, we have maintained core discovery capabilities to support our advanced clinical programs and collaborations and to provide opportunities to introduce additional clinical programs in the future.

In connection with the restructuring, we plan to reduce our total workforce by about 50 percent to 65 employees. We estimate that we will record charges of between approximately \$2.0 to \$2.5 million during the third quarter of 2008 in connection with the restructuring. We anticipate that our internal operating expenses will be reduced significantly following the restructuring and that cash used in our operating activities during 2009 will be below its 2008 level.

On August 4, 2008, we entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited that provides us with access, at our discretion, to up to \$60 million of capital during the next three years through the sale of newly-issued shares of our common stock. The funds that can be raised under the CEFF will depend on the then-current price of our common stock and the number of shares actually sold, which may not exceed an aggregate of approximately 7 million shares. We are not obligated to utilize any of the funds available under the CEFF and there are no minimum commitments or minimum use penalties.

We may access capital under the CEFF in tranches of up to a maximum of between 2.0 and 3.5 percent of our market capitalization at the time of the draw down of each tranche, subject to certain conditions, including a minimum share price threshold. Kingsbridge may purchase shares of common stock under the CEFF at discounts ranging from 6 percent to 12 percent, depending on the average market price of our common stock during the applicable pricing period.

Revenues

We have not generated any revenues from product sales to date, and we do not expect to generate revenues from product sales for at least the next several years, if at all. Our revenues to date have been generated substantially from research and milestone payments under our collaboration agreements. We have entered into three separate collaboration agreements with Allergan. We also entered into a collaboration agreement with Sepracor and a development agreement with The Stanley Medical Research Institute (SMRI), the terms of which ended in January 2008 and May 2007, respectively, as well as smaller scale research and license agreements with other parties. As of June 30, 2008, we had received an aggregate of \$58.5 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 primarily of payments under our current agreements with Allergan and any additional collaborations, including any upfront payments upon execution of new agreements, research funding throughout the research term of our agreements with these parties, and milestone payments contingent upon achievement of agreed-upon objectives.

Pursuant to our March 2003 collaboration agreement with Allergan, we had received an aggregate of \$14.8 million in payments as of June 30, 2008, consisting of upfront fees, and research funding and related fees. This collaboration originally provided for a three-year research term, which has been extended by the parties through March 2009. While we will receive additional research funding during this extended term, we have had, and anticipate we will have, a reduced level of research activities and related research funding under this collaboration during the extension. We are also a party to two other collaboration agreements with Allergan, under which we are currently pursuing the clinical development of drug candidates in the areas of neuropathic pain and glaucoma. We are eligible to receive milestone payments and royalties on product sales, if any, under each of our three collaboration agreements with Allergan. Each of our collaboration agreements with Allergan is subject to early termination by the collaborator upon specified events, including if we breach the agreement or, in the case of one of our agreements, if we have a change in control. Upon the conclusion of the research term under each agreement, Allergan may terminate the agreement by notice.

Pursuant to a three-year collaboration agreement with Sepracor, the term of which ended in January 2008, we received \$6.7 million in research funding. In connection with this agreement, Sepracor also purchased an aggregate of \$20 million of our common stock in two \$10 million tranches. We recognized the premium from these stock purchases as revenue as the related research activities were performed over the research term. Pursuant to a development agreement with SMRI, the term of which ended in May 2007, we received an aggregate of \$5 million in funding to support the development of ACP-104.

Research and Development Expenses

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

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We use our internal research and development resources, including our employees and discovery infrastructure, across several projects and many of our costs are not attributable to a specific project but are directed to broadly applicable research activities. Accordingly, we do not report our internal research and development costs on a project basis. We use external service providers to manufacture our drug candidates to be used in clinical trials and for the majority of the services performed in connection with the preclinical and clinical development of our drug candidates. To the extent that external expenses are not attributable to a specific project, they are included in other external costs. The following table summarizes our research and development expenses for the three and six months ended June 30, 2008 and 2007 (in thousands):

	Three Months Ended June 30,			ths Ended e 30,
	2008 2007		2008	2007
External costs:	(unai	ıdited)	(unaudited)	
Pimavanserin	\$ 6,668	\$ 2,428	\$ 12,744	\$ 5,012
ACP-104	1,253	1,347	2,633	3,266
Other	1,000	323	1,374	670
Subtotal	8,921	4,098	16,751	8,948
Internal costs	6,735	6,692	13,661	13,199
Stock-based compensation	380	705	795	1,609
Total research and development	\$ 16,036	\$ 11,495	\$ 31,207	\$ 23,756

At this time, due to the risks inherent in the clinical trial process and given the stage of development of our programs, we are unable to estimate with any certainty the costs we will incur in the continued development of our drug candidates for potential commercialization. Due to these same factors, we are unable to determine the anticipated completion dates for our current research and development programs. Clinical development timelines, probability of success, and development costs vary widely. While our current focus is primarily on advancing the clinical development of pimavanserin, we anticipate that we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success of each drug candidate, as well as an ongoing assessment of each drug candidate s commercial potential. We cannot forecast with any degree of certainty which drug candidates will be subject to future collaborative or licensing arrangements, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. As a result, we cannot be certain when and to what extent we will receive cash inflows from the commercialization of our drug candidates.

We expect our external research and development expenses to be substantial and to increase as we continue the development of our clinical 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.

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries and other costs for employees serving in executive, finance, business development, and business operations functions, as well as professional fees associated with legal and accounting services, and costs associated with patents and patent applications for our intellectual property.

Critical Accounting Policies and Estimates

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

Revenue Recognition

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

Upfront, non-refundable payments under collaboration agreements are recorded as deferred revenue once received and recognized ratably over the term of the agreement. Non-refundable payments for research funding are generally recognized as revenues over the period as the related research activities are performed. Revenues from non-refundable milestones are recognized when the earnings process is complete and the payment is reasonably assured. Non-refundable milestone payments related to arrangements under which we have continuing performance obligations are recognized as revenue upon achievement of the milestone, provided that (i) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement and (ii) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with the triggering event. Revenues from non-refundable license fees are recognized upon receipt of the payment if the license has stand-alone value, we do not have ongoing involvement or obligations, and the fair value of any undelivered items can be determined.

Accrued Expenses

We are required to estimate accrued expenses as part of our process of preparing financial statements. Examples of areas in which subjective judgments may be required include costs associated with services provided by contract organizations for preclinical development, manufacturing of clinical materials, and clinical trials. We accrue for costs incurred as the services are being provided by monitoring the status of the trials or services provided, and the invoices received from our external service providers. In the case of clinical trials, a portion of the estimated cost normally relates to the projected cost to treat a patient in our trials and we recognize this cost over the estimated term of the study based on the number of patients enrolled in the trial on an ongoing basis, beginning with patient enrollment. As actual costs become known to us, we adjust our accruals. To date, our estimates have not differed significantly from the actual costs incurred. However, we expect to expand the level of our clinical trials and related services in the future. As a result, we anticipate that our estimated accruals for clinical services will be more material to our operations in future periods. Subsequent changes in estimates may result in a material change in our accruals, which could also materially affect our balance sheet and results of operations.

Stock-based Compensation

Effective January 1, 2006, we adopted the fair value recognition provisions of Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), Share-Based Payment (SFAS No. 123(R)), which is a revision of SFAS No. 123, Accounting for Stock-Based Compensation (SFAS No. 123), using the modified prospective transition method. Under that transition method, compensation cost recognized for the three and six months ended June 30, 2008 and 2007 included (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, excluding stock options granted prior to December 31, 2003, which were valued using the minimum value method, and for which the related compensation cost will continue to be determined by using the intrinsic value method under Accounting Principles Board (APB) Opinion No. 25, and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123(R).

The value of each employee stock option and each employee stock purchase plan right is estimated on the grant date under the fair value method using the Black-Scholes option pricing model. For options granted prior to January 1, 2006, we amortize the fair value on an accelerated basis. For options granted after January 1, 2006, we amortize the fair value on a straight-line basis. All options are amortized over the requisite service period of the awards, which is generally the vesting period. At June 30, 2008, total unrecognized estimated compensation cost related to non-vested stock options granted prior to that date and employee stock purchase plan rights existing on that date were \$6.4 million, which is expected to be recognized over a weighted-average period of 2.4 years.

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

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Results of Operations

Fluctuations in Operating Results

Our results of operations have fluctuated significantly from period to period in the past and are likely to continue to do so in the future. We anticipate that our quarterly and annual results of operations will be impacted for the foreseeable future by several factors, including the timing and amount of payments received pursuant to our current and future collaborations, and the progress and timing of expenditures related to our discovery and development efforts. Due to these fluctuations, we believe that the period-to-period comparisons of our operating results are not a good indication of our future performance.

Comparison of the Three Months Ended June 30, 2008 and 2007

Revenues

Revenues totaled \$177,000 for the three months ended June 30, 2008 compared to \$2.1 million for the three months ended June 30, 2007. The decrease in revenues was primarily due to completion of the terms of our agreements with Sepracor and SMRI in January 2008 and May 2007, respectively, as well as lower revenues from our collaborations with Allergan. Revenues from our agreements with Allergan totaled \$177,000 for the three months ended June 30, 2008 compared to \$666,000 for the three months ended June 30, 2007. Revenues from our agreements with Sepracor and SMRI totaled \$827,000 and \$250,000, respectively, for the three months ended June 30, 2007.

Research and Development Expenses

Research and development expenses increased to \$16.0 million for the three months ended June 30, 2008, including \$380,000 in stock-based compensation, compared to \$11.5 million for the three months ended June 30, 2007, including \$705,000 in stock-based compensation. Excluding stock-based compensation, the increase in research and development expenses was primarily attributable to \$4.8 million in increased external costs, largely reflecting increased clinical development activity associated with our proprietary clinical programs. External costs totaled \$8.9 million, or 56 percent of our research and development expenses, for the three months ended June 30, 2008, compared to \$4.1 million or 36 percent of our research and development expenses, for the comparable period in 2007.

General and Administrative Expenses

General and administrative expenses totaled \$3.2 million for the three months ended June 30, 2008, including \$431,000 in stock-based compensation, compared to \$3.2 million for the three months ended June 30, 2007, including \$377,000 in stock-based compensation. General and administrative expenses for the three months ended June 30, 2008 were comparable to expenses for the three months ended June 30, 2007 as increased personnel and other administrative costs were offset by decreased professional fees.

Interest Income

Interest income decreased to \$802,000 for the three months ended June 30, 2008 from \$1.9 million for the three months ended June 30, 2007. The decrease in interest income was due to lower average levels of cash and investment securities and decreased yields on our investment security portfolio during the three months ended June 30, 2008.

Comparison of the Six Months Ended June 30, 2008 and 2007

Revenues

Revenues totaled \$983,000 for the six months ended June 30, 2008 compared to \$4.0 million for the comparable period of 2007. The decrease in revenues was primarily due to completion of the terms of our agreements with Sepracor and SMRI in January 2008 and May 2007, respectively, as well as lower revenues from our collaborations with Allergan. Revenues from our agreement with Sepracor totaled \$91,000 for the six months ended June 30, 2008 compared to \$1.7 million for the six months ended June 30, 2007. Revenues from our collaborations with Allergan totaled \$504,000 for the six months ended June 30, 2008 compared to \$987,000 for the six months ended June 30, 2007. Revenues from our agreement with SMRI totaled \$1.0 million for the six months ended June 30, 2007.

Research and Development Expenses

Research and development expenses increased to \$31.2 million for the six months ended June 30, 2008, including \$795,000 in stock-based compensation, compared to \$23.8 million for the six months ended June 30, 2007, including \$1.6 million in stock-based compensation, largely reflecting increased clinical development activity associated with our proprietary clinical programs. Excluding stock-based compensation, the increase in research and development expenses was primarily attributable to \$7.9 million in increased external costs, and increased costs associated with our research and development organization, including \$640,000 in increased

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salaries and related personnel costs. External costs totaled \$16.8 million, or 54 percent of our research and development expenses, for the six months ended June 30, 2008, compared to \$8.9 million or 38 percent of our research and development expenses, for the comparable period of 2007.

General and Administrative Expenses

General and administrative expenses totaled \$6.5 million for the six months ended June 30, 2008, including \$852,000 in stock-based compensation, compared to \$6.3 million for the six months ended June 30, 2007, including \$747,000 in stock-based compensation. Excluding stock-based compensation, general and administrative expenses for the six months ended June 30, 2008 were comparable to expenses for the six months ended June 30, 2007 as increased personnel and other administrative costs were offset by decreased professional fees.

Interest Income

Interest income decreased to \$2.1 million for the six months ended June 30, 2008 from \$2.9 million for the six months ended June 30, 2007. The decrease in interest income was primarily due to decreased yields on our investment portfolio during the six months ended June 30, 2008.

Liquidity and Capital Resources

Since inception, we have funded our operations primarily through sales of our equity securities, payments received under our collaboration agreements, debt financings, and interest income. As of June 30, 2008, we had received \$324.7 million in net proceeds from sales of our equity securities, including \$6.9 million in debt we had retired through the issuance of our common stock, \$58.5 million in payments from collaboration agreements, \$22.4 million in debt financing, and \$20.8 million in interest income.

At June 30, 2008, we had approximately \$89.6 million in cash, cash equivalents and investment securities compared to \$126.9 million at December 31, 2007. We have invested a substantial portion of our available cash in investment securities consisting of high quality, marketable debt instruments of corporations, financial institutions, and government agencies. We have adopted an investment policy and established guidelines relating to credit quality, diversification and maturities of our investments to preserve principal and maintain liquidity. All investment securities have a credit rating of at least AA or A1+/P1 as determined by Moody s Investors Service and/or Standard & Poor s. We do not have any direct investments in auction-rate securities or securities that are collateralized by assets that include mortgages or subprime debt. Our investment portfolio has not been adversely impacted by the recent disruption in the credit markets. However, if there is continued and expanded disruption in the credit markets, there can be no assurance that our investment portfolio will not be adversely affected in the future.

We adopted SFAS 157 as of January 1, 2008, as discussed in Note 7 to the Condensed Consolidated Financial Statements. SFAS 157 is applicable for all financial assets and liabilities and any other assets and liabilities that are recognized or disclosed at fair value on a recurring basis. SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair-value measurements. Our cash equivalents and investment securities held at June 30, 2008 are classified within Level 1 or Level 2 of the fair value hierarchy. These investments are valued using quoted market prices, broker or dealer quotations, or other observable inputs. The partial adoption of SFAS 157, in accordance with FSP 157-2, did not impact our consolidated financial position or valuation of cash equivalents or investment securities.

Net cash used in operating activities increased to \$36.8 million for the six months ended June 30, 2008 compared to \$27.9 million for the six months ended June 30, 2007. This increase was primarily due to an increase in our net loss, offset by changes in operating assets and liabilities. These changes included a decrease of \$1.0 million in prepaid expenses, receivables and other current assets during the six months ended June 30, 2008, compared to an increase of \$495,000 in the comparable period of 2007, and an aggregate decrease of \$4.9 million in accounts payable and accrued expenses during the six months ended June 30, 2008, compared to an aggregate decrease of \$6.1 million in the comparable period of 2007.

Net cash provided by investing activities has fluctuated significantly from period to period primarily due to the timing of purchases and maturities of investment securities. The increase in net cash provided by investing activities during the six months ended June 30, 2008, relative to the comparable period of 2007, was primarily due to increased maturities of investment securities, net of purchases of investment securities.

Net cash used in financing activities totaled \$46,000 during the six months ended June 30, 2008 compared to net cash provided by financing activities of \$98.1 million during the six months ended June 30, 2007. The decrease was primarily attributable to lower proceeds from the issuance of common stock. Proceeds from the issuance of common stock during the six months ended June 30, 2008 included net proceeds of \$96.1 million raised from our public offering in April 2007.

We have entered into equipment financing agreements from time to time, which we have utilized to fund the majority of our property and equipment purchases. The agreements contain fixed interest rates ranging from 8.47 to 10.41 percent per annum. At June 30, 2008, we had \$1.6 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, 2008.

The following table summarizes our contractual obligations, including interest, at June 30, 2008 (in thousands):

		Less than			After
	Total	1 Year	1-3 Years	4-5 Years	5 Years
Operating leases	\$ 15,473	\$ 2,561	\$ 7,478	\$ 3,066	\$ 2,368
Long-term debt	1,794	1,002	779	13	
Total	\$ 17.267	\$ 3,563	\$ 8,257	\$ 3.079	\$ 2.368

We have also entered into agreements with contract research organizations and other external service providers for services in connection with the development of our drug candidates. We were contractually obligated for up to approximately \$34.6 million of future services under these agreements as of June 30, 2008. The nature of the work being conducted under our agreements with contract research organizations is such that, in most cases, the services may be stopped with short notice. In such event, we would not be liable for the full amount of the contract. Our actual contractual obligations may vary depending upon several factors, including the results of the underlying studies.

We have also entered into certain other agreements that may require us to make payments in the future and currently cannot forecast with any degree of certainty when or if we will be required to make payments under these agreements. Under the terms of one agreement in which we licensed certain intellectual property rights that complement our patent portfolio, if certain conditions are met, we are required to make future payments, including milestones, royalties and sublicensing fees for compounds covered by the agreement.

We have consumed substantial amounts of capital since our inception. In August 2008, we announced a strategic restructuring designed to focus resources on our most advanced product candidates and provide additional financial flexibility and strength. In connection with the restructuring, we plan to reduce our total workforce by about 50 percent to 65 employees. We estimate that we will record charges of between approximately \$2.0 to \$2.5 million during the third quarter of 2008 in connection with the restructuring. We anticipate that our internal operating expenses will be reduced significantly following the restructuring and that cash used in our operating activities during 2009 will be below its 2008 level.

We believe that our existing cash resources and the anticipated payments from our collaborations will be sufficient to fund our cash requirements into the first half of 2010. In August 2008, we entered into a CEFF with Kingsbridge designed to provide us with added financial strength and flexibility. The CEFF provides us with access, at our discretion, to up to \$60 million of capital during the next three years through the sale of newly-issued shares of our common stock. The funds that can be raised under the CEFF will depend on the then-current price of our common stock and the number of shares actually sold, which may not exceed an aggregate of approximately 7 million shares.

We will require significant additional financing in the future to continue to fund our operations. Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

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

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

the ability of our collaborators and us to reach the milestones, and other events or developments, under our collaboration agreements;

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

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

the costs of establishing, or contracting for, sales and marketing capabilities if we obtain regulatory clearances to market our drug candidates.

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through strategic collaborations, private or public sales of our securities, debt financings, or by licensing all or a portion of our drug candidates or technology. We cannot be certain that 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.

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Off-Balance Sheet Arrangements

To date, we have not had any relationships with unconsolidated entities or financial partnerships, such as entities referred to as structured finance or special purpose entities, which are established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

Recent Accounting Pronouncements

In December 2007, the Financial Accounting Standards Board, or FASB, ratified EITF No. 07-1, *Accounting for Collaborative Arrangements*, or EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 also establishes the appropriate income statement presentation and classification for joint operating activities and payments between participants, as well as the sufficiency of the disclosures related to these arrangements. EITF 07-1 is effective for fiscal years beginning after December 15, 2008, and would be applied retrospectively as a change in accounting principle for collaborative arrangements existing at the effective date. We are currently evaluating the potential impact of EITF 07-1 on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations*, or SFAS 141(R). SFAS 141(R) will require an acquiring company to measure all assets acquired and liabilities assumed, including contingent considerations and all contractual contingencies, at fair value as of the acquisition date. In addition, an acquiring company is required to capitalize in-process research and development and either amortize it over the life of the product, or write it off if the project is abandoned or impaired. SFAS 141(R) is effective for fiscal years beginning after December 15, 2008.

In December 2007, the FASB issued SFAS No. 160, *Interests in Consolidated Financial Statements an amendment of ARB No. 51*, or SFAS 160. SFAS 160 impacts the accounting for minority interest in the consolidated financial statements of filers. The statement requires the reclassification of minority interest to the equity section of the balance sheet and the results from operations attributed to minority interest to be included in net income. The amount of consolidated net income attributable to the parent filer and to the minority interest would be clearly identified and presented on the face of the consolidated statements of operations. SFAS 160 is effective for fiscal years beginning after December 15, 2008.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK Interest Rate Risk

We invest our excess cash in investment-grade, interest-bearing securities. The primary objective of our investment activities is to preserve principal and maintain liquidity. To achieve this objective, we invest in highly liquid and high quality marketable debt instruments of corporations, financial institutions, and government agencies with contractual maturity dates of generally less than two years. All investment securities have a credit rating of at least AA or A1+/P1 as determined by Moody s Investors Service and/or Standard & Poor s. We do not have any direct investments in auction-rate securities or securities that are collateralized by assets that include mortgages or subprime debt. If a 10 percent change in interest rates were to have occurred on June 30, 2008, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

Foreign Currency Risk

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

ITEM 4. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC is rules and forms, and that such information is accumulated and communicated to our management, including

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our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As of June 30, 2008, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a 15(e) and 15d 15(e) under the Securities Exchange Act of 1934, as amended. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of June 30, 2008.

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1A. RISK FACTORS

You should consider carefully the following information about the risks described below, together with the other information contained in this Quarterly Report and in our other public filings in evaluating our business. The risk factors set forth below that are marked with an asterisk (*) contain changes to the similarly titled risk factor included in Item 1A to our Annual Report. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.

Risks Related to Our Business

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

We have experienced significant net losses since our inception. As of June 30, 2008, we had an accumulated deficit of approximately \$264.5 million. We expect our annual net losses to continue over the next several years as we advance our programs and incur significant clinical development costs.

We have not received, and do not expect to receive for at least the next several years, any revenues from the commercialization of our drug candidates. Substantially all of our revenues for the six months ended June 30, 2008 and year ended December 31, 2007 were from our collaborations with Allergan and Sepracor as well as our agreements with other parties. We anticipate that collaborations with pharmaceutical companies, which provide us with research funding and potential milestone payments and royalties, will continue to be our primary source of revenues for the next several years. We cannot be certain that the milestones required to trigger payments under our existing collaborations will be reached or that we will secure additional collaboration agreements. To obtain revenues from our drug candidates, we must succeed, either alone or with others, in developing, obtaining regulatory approval for, and manufacturing and marketing drugs with significant market potential. We may never succeed in these activities, and may never generate revenues that are significant enough to achieve profitability.

If we do not realize the expected benefits from the restructuring that we announced in August 2008, our operating results and financial conditions would be negatively impacted.*

In August 2008, we announced a strategic restructuring designed to focus our resources on our most advanced products candidates. If we are unable to realize the expected operational efficiencies from our restructuring, our operating results and financial condition would be adversely affected. Employees whose positions are eliminated in connection with the restructuring may seek future employment with our competitors.

Although each of our employees is required to sign a confidentiality agreement with us at

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the time of hire, we cannot guarantee that the confidential nature of our proprietary information will be maintained in the course of such future employment. We cannot guarantee that we will not have to undertake additional restructuring activities, that any of our restructuring efforts will be successful, or that we will be able to realize the cost savings and other anticipated benefits from our restructuring.

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

Pursuant to the CEFF, Kingsbridge committed to purchase up to the lesser of \$60 million or up to approximately 7 million shares of our common stock over a three-year period, if we elect to use this facility. Kingsbridge will not be obligated to purchase shares under the CEFF unless specified conditions are met, which include a minimum price for our common stock, the effectiveness of a registration statement registering for resale the shares of common stock to be issued in connection with the CEFF, and customary other conditions, such as accuracy of representations and warranties and compliance with applicable laws. Kingsbridge is permitted to terminate the CEFF under certain circumstances. If we are unable to access funds through the CEFF or Kingsbridge terminates the CEFF, we may be unable to access capital on favorable terms.

In connection with the CEFF, we have agreed to file a registration statement with the SEC within 60 days of August 4, 2008 to register the resale of shares of our common stock that may be issued pursuant to the CEFF or upon exercise of the warrant. After the registration statement has been declared effective by the SEC, we are entitled, in certain circumstances, to deliver a blackout notice to Kingsbridge to suspend the use of the prospectus covering the shares of common stock that may be issued in connection with the CEFF and prohibit Kingsbridge from selling shares under that prospectus for a certain period of time. If we deliver a blackout notice in the 15 trading days following the settlement of a draw down, or if the registration statement covering the resale of the shares of common stock to be issued in connection with the CEFF is not effective in circumstances not permitted by our registration rights agreement with Kingsbridge, then we must make a payment to Kingsbridge, or issue Kingsbridge additional shares in lieu of this payment, calculated on the basis of a specified number of shares held by Kingsbridge immediately prior to the blackout period and the change in the market price of our common stock during the period in which the use of the resale registration statement is suspended. If the trading price of our common stock declines during a suspension of the resale registration statement, the blackout or other payment could be significant.

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

Our most advanced drug candidates are in clinical trials, which are long, expensive and unpredictable, and there is a high risk of failure.*

Preclinical testing and clinical trials are long, expensive and unpredictable processes that can be subject to delays. It may take several years to complete the preclinical testing and clinical development necessary to commercialize a drug, and delays or failure can occur at any stage. Interim results of clinical trials do not necessarily predict final results, and success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials even after promising results in earlier trials.

Our drug development programs are at various stages of development and the historical rate of failures for drug candidates is extremely high. In our most advanced program, we are in Phase III development with pimavanserin for the treatment of Parkinson s disease psychosis. We also have completed clinical trials in our program with pimavanserin as a co-therapy for schizophrenia, and in our program with pimavanserin for the treatment of sleep maintenance insomnia. We also have neuropathic pain and glaucoma clinical programs in collaboration with Allergan.

In connection with clinical trials, we face risks that:

a drug candidate may not prove to be efficacious;

patients may die or suffer other adverse effects for reasons that may or may not be related to the drug candidate being tested;

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

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

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

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

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

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

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

manufacturing sufficient quantities of a drug candidate;

obtaining approval of an Investigational New Drug Application (IND) from the FDA;

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

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

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

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

failure to conduct clinical trials in accordance with regulatory requirements;

lower than anticipated retention rate of patients in clinical trials;