

NEUROCRINE BIOSCIENCES INC

Form 10-Q

July 30, 2009

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

**FORM 10-Q**

**(Mark One)**

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

**For the quarterly period ended June 30, 2009**

**OR**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission file number 0-22705**

**NEUROCRINE BIOSCIENCES, INC.**

(Exact name of registrant as specified in its charter)

**DELAWARE**

(State or other jurisdiction of  
incorporation or organization)

**33-0525145**

(IRS Employer Identification No.)

**12780 EL CAMINO REAL, SAN DIEGO,  
CALIFORNIA**

(Address of principal executive office)

**92130**

(Zip Code)

**(858) 617-7600**

(Registrant's telephone number, including area code)

**Not Applicable**

(Former name, former address and former fiscal year, if changed since last report)

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 for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes ☒ No ☐

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

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

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

Smaller reporting company ☐

(Do not check if a  
smaller reporting  
company)

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

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The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 39,089,868 as of July 24, 2009.

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**Table of Contents****PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS**

**NEUROCRINE BIOSCIENCES, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(in thousands, except for share information)  
(unaudited)

	<b>June 30, 2009</b>	<b>December 31, 2008</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 38,615	\$ 68,467
Short-term investments, available-for-sale	14,152	12,006
Receivables under collaborative agreements	3	39
Other current assets	1,014	911
Total current assets	53,784	81,423
Property and equipment, net	4,183	6,191
Long-term investments	21,242	21,057
Restricted cash	6,414	6,409
Other non-current assets	1,246	3,102
Total assets	\$ 86,869	\$ 118,182
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,752	\$ 1,599
Accrued liabilities	10,104	10,905
Current portion of deferred revenues	2,921	2,936
Current portion of cease-use liability	15,414	7,870
Current portion of deferred gain on sale of real estate	2,826	2,784
Total current liabilities	33,017	26,094
Deferred revenues	10,216	11,676
Deferred gain on sale of real estate	31,436	32,867
Deferred rent	756	110
Cease-use liability	2,750	7,527
Other liabilities	1,346	3,134
Total liabilities	79,521	81,408
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; no shares issued and outstanding		
Common stock, \$0.001 par value; 110,000,000 shares authorized; issued and outstanding shares were 39,089,868 as of June 30, 2009 and 38,598,789 as of December 31, 2008	39	39
Additional paid-in capital	744,479	741,568

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Accumulated other comprehensive gain (loss)	1,038	(1,570)
Accumulated deficit	(738,208)	(703,263)
Total stockholders' equity	7,348	36,774
Total liabilities and stockholders' equity	\$ 86,869	\$ 118,182

See accompanying notes to the condensed consolidated financial statements.

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(unaudited)**

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
Revenues:				
Sponsored research and development	\$ 3	\$ 4	\$ 20	\$ 16
License fees and milestones	730	730	1,460	2,460
Grant revenue				9
Total revenues	733	734	1,480	2,485
Operating expenses:				
Research and development	10,808	16,186	21,656	30,413
General and administrative	4,827	4,665	9,022	12,951
Cease use expense	941		5,769	
Total operating expenses	16,576	20,851	36,447	43,364
Loss from operations	(15,843)	(20,117)	(34,967)	(40,879)
Other income and (expense):				
Gain on sale/disposal of assets	21	164	162	198
Deferred gain on real estate	694		1,389	
Gain (loss) on auction rate securities	230		(1,218)	
Interest income	176	919	530	2,627
Interest expense		(1,914)		(3,835)
Other expense, net	(558)	(23)	(841)	(159)
Total other income (expense) net	563	(854)	22	(1,169)
Net loss	\$ (15,280)	\$ (20,971)	\$ (34,945)	\$ (42,048)
Net loss per common share:				
Basic and diluted	\$ (0.39)	\$ (0.55)	\$ (0.90)	\$ (1.10)
Shares used in the calculation of net loss per common share:				
Basic and diluted	39,046	38,421	38,858	38,376

See accompanying notes to the condensed consolidated financial statements.

**Table of Contents****NEUROCRINE BIOSCIENCES, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(in thousands)****(unaudited)**

	<b>Six Months Ended June 30,</b>	
	<b>2009</b>	<b>2008</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (34,945)	\$ (42,048)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,850	4,067
Gain on sale of assets	(162)	(198)
Fair value adjustment for auction rate security rights	407	
Loss (gain) on sale of investments	1,064	(148)
Fair value adjustment for auction rate securities	812	
Cease-use expense	5,769	
Deferred gain on sale of real estate	(1,389)	
Deferred revenues	(1,475)	(1,469)
Deferred rent	646	
Share-based compensation expense	2,911	4,436
Amortization of premiums/discounts on short term-investments	(3)	14
Change in operating assets and liabilities:		
Accounts receivable and other current assets	(67)	1,835
Other non-current assets	1,999	121
Accounts payable and accrued liabilities	(648)	(9,519)
Cease-use liability	(3,002)	
Other non-current liabilities	(1,788)	(255)
Net cash used in operating activities	(28,021)	(43,164)
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchases of investments	(15,346)	(19,056)
Sales/maturities of investments	13,200	56,187
Deposits and restricted cash	(5)	(157)
Proceeds from sales of property and equipment	345	450
Purchases of property and equipment, net	(25)	(1,155)
Net cash (used in) provided by investing activities	(1,831)	36,269
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Issuance of common stock		33
Principal payments on debt		(885)
Net cash used in financing activities		(852)
Net decrease in cash and cash equivalents	(29,852)	(7,747)
Cash and cash equivalents at beginning of the period	68,467	99,664
Cash and cash equivalents at end of the period	\$ 38,615	\$ 91,917



See accompanying notes to the condensed consolidated financial statements.

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**NEUROCRINE BIOSCIENCES, INC.**

**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(unaudited)**

**1. BASIS OF PRESENTATION**

The condensed consolidated financial statements included herein are unaudited. These statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions of the Securities and Exchange Commission (SEC) on Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, these financial statements include all adjustments (consisting of normal recurring adjustments) necessary for a fair presentation of the financial position, results of operations, and cash flows for the periods presented. The results of operations for the interim period shown in this report are not necessarily indicative of results expected for the full year. These financial statements should be read in conjunction with the Management's Discussion and Analysis of Financial Condition and Results of Operations, Quantitative and Qualitative Disclosures About Market Risk and the financial statements and notes thereto for the year ended December 31, 2008 and the three months ended March 31, 2009 included in the Company's Annual Report on Form 10-K for the year ended December 31, 2008 and the Company's Quarterly Report on Form 10-Q for the three months ended March 31, 2009, respectively, filed with the SEC. Certain reclassifications have been made to previously reported amounts to conform to the current period presentation. Further, in connection with preparation of the condensed consolidated financial statements and in accordance with recently issued Statement of Financial Accounting Standards (SFAS) No. 165

Subsequent Events (SFAS 165), the Company evaluated subsequent events after the balance sheet date of June 30, 2009 through July 30, 2009.

The terms "Company" and "Neurocrine" are used in this report to refer collectively to Neurocrine Biosciences, Inc. and its subsidiaries.

**2. ORGANIZATION AND SUMMARY OF BUSINESS**

Neurocrine Biosciences, Inc. discovers, develops and intends to commercialize drugs for the treatment of neurological and endocrine-related diseases and disorders. The Company's product candidates address some of the largest pharmaceutical markets in the world, including endometriosis, anxiety, depression, pain, diabetes, benign prostatic hyperplasia, irritable bowel syndrome, and other neurological and endocrine-related diseases and disorders. The Company currently has eight programs in various stages of research and development, including five programs in clinical development. While the Company independently develops many of its own product candidates, Neurocrine is in collaborations with pharmaceutical companies for two of its programs. The Company's lead clinical development program, elagolix, is a drug candidate for the treatment of endometriosis.

**3. IMPACT OF RECENTLY ISSUED ACCOUNTING STANDARDS**

In June 2009, the Financial Accounting Standards Board (FASB) issued SFAS No. 168, "The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles", a replacement of FASB 162. The FASB Accounting Standards Codification (Codification) will become the source of authoritative U.S. generally accepted accounting principles (GAAP) recognized by the FASB to be applied by nongovernmental entities. Rules and interpretive releases of the SEC under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. On the effective date of this Statement, the Codification will supersede all then-existing non-SEC accounting and reporting standards. All other non-grandfathered non-SEC accounting literature not included in the Codification will become nonauthoritative. SFAS 168 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The Company does not expect the adoption of SFAS 168 to have a material effect on its consolidated results of operations or financial condition.

In May 2009, the FASB issued SFAS 165 "Subsequent Events". SFAS 165 is intended to establish general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. It requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for selecting that date, that is, whether that date represents the date the financial

statements were issued or were available to be issued. SFAS 165 is effective for interim or annual financial periods ending after June 15, 2009. The adoption of SFAS 165 did not have a material effect on the Company's consolidated results of operations or financial condition.

In April 2009, the FASB issued several pronouncements related to fair value measurement, recording and disclosure in financial reporting.

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FASB Staff Position No. 107-1 and Accounting Principles Board (APB) 28-1, Interim Disclosures about Fair Value of Financial Instruments, were issued to outline the required financial statement disclosures relating to fair value of financial instruments during interim reporting periods. FASB Staff Position No. 157-4, Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly, was issued to provide additional guidance in evaluating the fair value of a financial instrument when the volume and level of activity for the asset or liability has significantly decreased. FASB Staff Position No. 115-2 and FASB Staff Position No. 124-2, Recognition and Presentation of Other-Than-Temporary Impairments, were issued to provide additional guidance on presenting impairment losses on securities.

All of the fair value measurement pronouncements were effective for interim and annual reporting periods ending after June 15, 2009. The adoption of these new pronouncements did not have a material effect on the Company's consolidated results of operations or financial condition.

**4. USE OF ESTIMATES**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States 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.

**5. INVESTMENTS AVAILABLE FOR SALE**

Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in comprehensive income. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest income. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income or expense. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

The following is a summary of investments classified as available-for-sale securities (in thousands):

	<b>Amortized Cost</b>	<b>Gross Unrealized Gains<sup>(1)</sup></b>	<b>Gross Unrealized Losses<sup>(1)</sup></b>	<b>Aggregate Estimated Fair Value</b>
<b>June 30, 2009</b>				
Certificates of deposit	\$ 14,160	\$	\$ (8)	\$ 14,152
Auction rate securities	5,258	1,404		6,662
Total available-for-sale securities	\$ 19,418	\$ 1,404	\$ (8)	\$ 20,814
<b>December 31, 2008</b>				
Securities of government-sponsored enterprises	\$ 9,919	\$ 80	\$	\$ 9,999
Corporate debt securities	2,039		(32)	2,007
Auction rate securities	6,689			6,689
Total available-for-sale securities	\$ 18,647	\$ 80	\$ (32)	\$ 18,695

(1) Unrealized gains and losses are included in other comprehensive loss.



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The amortized cost and estimated fair value of debt securities classified as available-for-sale by contractual maturity at June 30, 2009 and December 31, 2008 are presented below (in thousands):

	Maturing in less than 12 months		Maturing in more than 12 Months	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
<b>June 30, 2009</b>				
Certificates of deposit	\$ 14,160	\$ 14,152	\$	\$
Auction rate securities classified as available-for-sale			5,258	6,662
Total available-for-sale securities	\$ 14,160	\$ 14,152	\$ 5,258	\$ 6,662
<b>December 31, 2008</b>				
Securities of government-sponsored enterprises	\$ 9,919	\$ 9,999	\$	\$
Corporate debt securities	2,039	2,007		
Auction rate securities classified as available-for-sale			6,689	6,689
Total available-for-sale securities	\$ 11,958	\$ 12,006	\$ 6,689	\$ 6,689

The following table presents certain information related to sales and maturities of investments (in thousands):

	6 months ended June 30, 2009	6 months Ended June 30, 2008
Proceeds from sales/maturities of available-for-sale securities	\$ 13,200	\$ 56,187
Gross realized gains on sales of available-for-sale securities <sup>(1)</sup>		9
Gross realized losses on sales of available-for-sale securities <sup>(1)</sup>		(10)
Gains reclassified out of accumulated other comprehensive loss into earnings		9
Losses reclassified out of accumulated other comprehensive loss into earnings		(14)
Net unrealized holding gain(loss) on available-for-sale securities included in accumulated other comprehensive income	1,396	48
Gains from trading securities held	6	
Gains(losses) included in earnings from transfers of securities from available-for-sale to trading		

(1) The cost basis used in calculating gains and losses on sales of available-for-sale securities is

determined using  
the specific  
identification  
method.

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The following table presents information about investments in an unrealized loss position (in thousands):

	Less Than 12 Months		12 Months or Greater		Total	
	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses
<b>June 30, 2009</b>						
Certificates of deposit <sup>(1)</sup>	\$ 10,800	\$ (10)	\$	\$	\$ 10,800	\$ (10)
Total	\$ 10,800	\$ (10)	\$	\$	\$ 10,800	\$ (10)
<b>December 31, 2008</b>						
Corporate debt securities	\$ 2,007	\$ (32)	\$	\$	\$ 2,007	\$ (32)
Total	\$ 2,007	\$ (32)	\$	\$	\$ 2,007	\$ (32)

- (1) The Company holds 45 certificates of deposit ( CDs ) at June 30, 2009 that are in an unrealized loss position due to valuations assigned based on market data. All of the Company's CD holdings are all fully guaranteed by the Federal Deposit Insurance Corporation. The Company has the ability and intent to hold these CDs until a recovery of fair value, which may be at maturity, and therefore does not consider these investments to be other-than-temporarily impaired at June 30, 2009.

#### 6. AUCTION RATE SECURITIES

The Company's long-term investments at June 30, 2009 included (at par value) \$22.6 million of auction rate securities, \$14.6 million of which are maintained by UBS AG (UBS) and \$8.0 million of which are maintained by Citigroup (Citi). With the liquidity issues experienced in global credit and capital markets, these auction rate securities have experienced multiple failed auctions as the amount of securities submitted for sale has exceeded the amount of purchase orders, and as a result, these affected securities are currently not liquid. However, the Company now earns a higher interest rate according to the terms of these securities. All of the Company's auction rate securities are secured



by student loans, which are backed by the full faith and credit of the federal government (up to approximately 98% of the value of the student loan). All of these securities continue to pay interest according to their stated terms (generally 120 basis points over the ninety-one day United States Treasury bill rate) with interest rates resetting every 7 to 28 days. While it is not the Company's intent to hold these securities until their stated ultimate maturity dates, these investments are scheduled to ultimately mature between 2030 and 2047.

The valuation of the Company's auction rate securities investment portfolio is subject to uncertainties that are difficult to predict. The fair values of these securities are estimated utilizing a discounted cash flow analysis as of June 30, 2009. The significant assumptions of this valuation model were discount margins ranging from 191 to 491 basis points which are based on industry recognized student loan sector indices, an additional required rate of return of 150 basis points and an estimated term to liquidity of 5.5 to 7.5 years. Other items this analysis considers are the collateralization underlying the security investments, the creditworthiness of the counterparty, and the timing of expected future cash flows. These securities were also compared, when possible, to other observable market data with similar characteristics as the securities held by the Company. Although the auction rate security investments continue to pay interest according to their stated terms, based on valuation models of the individual securities.

During the fourth quarter of 2008, UBS extended an offer of Auction Rate Securities Rights (ARS Rights) to holders of illiquid auction rate securities that were maintained by UBS as of February 13, 2008. The ARS Rights provide the holder with the ability to sell the auction rate securities, along with the ARS Rights, to UBS at the par value of the auction rate securities, during an applicable exercise period. The ARS Rights grant UBS the sole discretion and right to sell or otherwise dispose of auction rate securities at any time up until July 2, 2012, without any prior notification of the holder, so long as the holder receives a payment of par upon any sale or disposition. The ARS Rights are not transferable, not tradeable, and will not be quoted or listed on any securities exchange or any other trading network. The offer period for the ARS Rights closed on November 14, 2008 and ARS Rights were issued by UBS during the fourth quarter of 2008.

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The Company elected to participate in the ARS Rights program for all of its outstanding auction rate securities maintained by UBS. The Company has \$14.6 million (at par value) of auction rate securities that are maintained by UBS. Under the terms of the ARS Rights offer, the applicable exercise period begins on June 30, 2010 and ends July 2, 2012. Additionally, the Company is eligible for a loan of up to 75% of the market value of the auction rate securities, should a loan be needed. It is the Company's intention to sell the auction rate securities and ARS Rights to UBS on June 30, 2010.

The Company has elected to measure the ARS Rights under the fair value option of SFAS 159, "The Fair Value Option for Financial Assets and Financial Liabilities—Including an amendment to FASB Statement No. 115" (SFAS 159) to mitigate volatility in reported earnings due to their linkage to the auction rate securities. The ARS Rights were valued in a similar fashion to the auction rate securities as described above. Simultaneously, due to the ARS Rights granted by UBS, the Company made a one-time election to transfer the related auction rate security holdings from available-for-sale securities to trading securities. The Company anticipates that any changes in the fair value of the ARS Rights will be offset by the changes in the fair value of the related auction rate securities with no material net impact to the consolidated statement of operations. The ARS Rights will continue to be measured at fair value under SFAS 159 until the earlier of their maturity or exercise. At June 30, 2009, the Company valued these ARS Rights at \$1.9 million.

These ARS Rights together with the auction rate securities held at UBS (fair value of \$12.6 million as of June 30, 2009) are carried as long-term investments on the condensed consolidated balance sheet at June 30, 2009. In addition to the election of the fair value option for the ARS Rights, the Company made a one-time election in the fourth quarter of 2008 to transfer the related auction rate security holdings from available-for-sale securities to trading securities. This enabled the changes in the fair value of the ARS Rights to be offset by the changes in the fair value of the related auction rate securities with no material net impact to the condensed consolidated statement of operations.

The Company's remaining auction rate securities that are maintained by Citi continue to be treated as available-for-sale investments. These auction rate securities have a par value of \$8.0 million. During the first three months of 2009, certain ratings agencies downgraded these auction rate securities and the Company recognized an other-than-temporary impairment of \$1.5 million in the consolidated statement of operations for the three months ended March 31, 2009. During the second quarter of 2009, global credit markets improved and credit spreads narrowed resulting in an increase in the fair value of the investments of approximately \$1.4 million which was recorded as an unrealized gain in other comprehensive income as of June 30, 2009. At June 30, 2009, the Company valued these long-term investments at \$6.7 million.

At present, in the event the Company needs to access the funds that are in an illiquid state, the Company may not be able to do so without the possible loss of principal until a future auction for these investments is successful, another secondary market evolves for these securities, they are redeemed by the issuer or they mature. If the Company is unable to sell these securities in the market or they are not redeemed, the Company could be required to hold them to maturity.

Changes to estimates and assumptions used in estimating the fair value of the auction rate securities and related ARS Rights may provide materially different values. In addition, actual market exchanges, if any, may occur at materially different amounts. For example, a reduction of the expected term to redemption assumption by approximately two years for the auction rate securities and related ARS Rights would yield a net increase in the valuation of these investments of \$0.3 million. Other factors that may impact the valuation of the Company's auction rate securities and related ARS Rights include changes to credit ratings of the securities as well as to the underlying assets supporting those securities, rates of default of the underlying assets, underlying collateral value, discount rates, counterparty risk and ongoing strength and quality of market credit and liquidity.

## **7. FAIR VALUE MEASUREMENTS**

The Company adopted SFAS No. 157, "Fair Value Measurements" (SFAS 157) on January 1, 2008. SFAS 157, among other things, defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. SFAS 157 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a

market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, SFAS 157 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

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Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Assets measured at fair value as of June 30, 2009 and December 31, 2008 are classified below based on the three fair value hierarchy tiers described above (in millions):

		<b>Fair Value Measurements Using</b>		
		<b>Quoted Prices in Active Markets for Identical Assets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
	<b>Carrying Value</b>			
<b>June 30, 2009:</b>				
Cash and money market funds	\$ 45.0	\$ 45.0	\$	\$
Certificates of Deposit <sup>(1)</sup>	14.2	14.2		
Auction rate securities <sup>(2)</sup>	19.3			19.3
ARS Rights (Note 6)	1.9			1.9
Total	\$ 80.4	\$ 59.2	\$	\$ 21.2
<b>December 31, 2008:</b>				
Cash and money market funds	\$ 64.9	\$ 64.9	\$	\$
Commercial Paper <sup>(1)</sup>	10.0	10.0		
Corporate debt securities <sup>(1)</sup>	2.0	2.0		
Securities of government-sponsored enterprises <sup>(1)</sup>	10.0	10.0		
Auction rate securities <sup>(2)</sup>	18.7			18.7
ARS Rights (Note 6)	2.4			2.4
Total	\$ 108.0	\$ 86.9	\$	\$ 21.1

Activity for assets measured at fair value during the six month period ended June 30, 2009 using significant unobservable inputs. (Level 3) is presented in the table below (in millions):

	<b>Fair Value Measurements Using Significant Unobservable Inputs (Level 3)</b>
Beginning balance as of December 31, 2008	\$ 21.1
Transfers into Level 3	
Purchases, sales, issuances, and settlements (net)	

Total unrealized gains included in other comprehensive income	1.4
Total unrealized losses (net) included in other expense	(1.3)
Ending balance as of June 30, 2009	\$ 21.2

(1) Securities are classified as available-for-sale.

(2) The Company transferred a portion of its auction rate securities from available-for-sale to trading in the fourth quarter of 2008. The fair value of these auction rate securities was estimated based on the following:

- (i) the underlying structure of each security;
- (ii) the present value of future principal and interest payments discounted at rates considered to reflect current market conditions;
- (iii) consideration of the probabilities of default, auction failure, or repurchase at par for each period;
- (iv) the expected term to liquidity;
- and (v) its market required rate of return.

#### 8. IMPAIRMENT OF LONG-LIVED ASSETS

In accordance with SFAS 144, Accounting for the Impairment or Disposal of Long-Lived Assets, if indicators of impairment exist, the Company assesses the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If the carrying amount is not recoverable, the Company measures the amount of any impairment by comparing the carrying value of

the asset to the present value of the expected future cash flows associated with the use of the asset. The Company has determined that no impairment exists on its long-lived assets.

**Table of Contents****9. SHARE-BASED COMPENSATION**

The Company's net loss for the three months ended June 30, 2009 and 2008 included \$1.0 million and \$2.2 million, respectively, of compensation expense related to the Company's share-based compensation awards. The Company's net loss for the six months ended June 30, 2009 and 2008 included \$2.9 million and \$4.4 million, respectively, of compensation expense related to the Company's share-based compensation awards. As of June 30, 2009, total unrecognized estimated compensation cost related to non-vested stock options and non-vested restricted stock units (RSUs) granted prior to that date was \$1.4 million and \$3.2 million, respectively, which is expected to be recognized over a weighted average period of approximately 1.0 and 1.4 years, respectively. The compensation expense related to the Company's share-based compensation arrangements is recorded as components of general and administrative expense and research and development expense. The following is a summary of the components of the Company's compensation expense related to share-based compensation (in millions):

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
General and administrative	\$0.7	\$1.2	\$1.6	\$2.5
Research and development	0.3	1.0	1.3	1.9

There were no stock option exercises for the six months ended June 30, 2009. Cash received from stock option exercises for the six months ended June 30, 2008 was \$33,000. The Company issued approximately 0.5 million shares of common stock pursuant to the vesting of RSUs and distributions of stock awards from the Company's deferred compensation plan during the six months ended June 30, 2009.

***Stock Option Assumptions***

The exercise price of all options granted during the six month period ended June 30, 2009 and 2008 was equal to the closing price of the Company's common stock on the date of grant. The estimated fair value of each option award granted was determined on the date of grant using the Black-Scholes option valuation model. The following weighted-average assumptions were used for option grants during the three and six months ended June 30, 2009 and 2008:

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
Risk-free interest rate	2.34 %	3.36 %	2.34 %	2.65 %
Expected volatility of common stock	83.26 %	67.99 %	83.26 %	68.60 %
Dividend yield	0.0 %	0.0 %	0.0 %	0.0 %
Expected option term	5.35 years	4.75 years	5.35 years	4.75 years

The Company estimates forfeiture rates for options based on past behavior for similar options with further consideration given to the class of employees to whom the options were granted.

**10. RESTRUCTURING CHARGES**

In May 2009, the Company announced a restructuring program to implement cost containment measures and to focus research and development efforts. As a result, the Company reduced its research and development and general and administrative staff in San Diego by approximately 65 employees and incurred a net restructuring charge of approximately \$2.9 million (of which \$2.2 million was classified as research and development expense and \$0.7 million classified as general and administrative expense), which was comprised of salary continuation, outplacement services, and other miscellaneous costs related to this reduction in force. Substantially all of these expenses were paid in cash during the second quarter of 2009. During the first quarter of 2008, the Company also recorded a net charge of \$2.1 million (primarily all general and administrative expense) for severance related to certain executives and other personnel departing the Company.





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As of June 30, 2009, the Company had a remaining balance of approximately \$1.5 million of accrued restructuring expenses included in the condensed consolidated balance sheet. This liability will be paid over the remaining contractual period of certain severance agreements. The changes to the accrued liability for the first six months of 2009 are as follows (in thousands):

		<b>Six Months Ended June 30, 2009</b>
Accrual balance as of January 1, 2009	\$	1,578
Charge for 2009 restructuring		2,900
Payments		(3,018)
Adjustments		(8)
Accrual balance as of June 30, 2009	\$	1,452

**11. REAL ESTATE**

Effective December 10, 2008, the Company entered into a First Amendment to Lease (Lease Amendment) with DMH Campus Investors, LLC (DMH). The Company and DMH are parties to a lease agreement, dated December 4, 2007, pursuant to which the Company leases its corporate headquarters, located at 12790 El Camino Real (Front Building) and 12780 El Camino Real (Rear Building) in San Diego, California (Lease). The Lease Amendment provides for the renovation of the Front Building in a manner that facilitates multiple tenant usage and establishes a mechanism for the Company to terminate its use of the Front Building. The Company will continue to occupy the Rear Building.

During the fourth quarter of 2008, the Company vacated the Front Building. In accordance with SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities (SFAS 146), a liability of \$15.7 million was recorded for estimated lease termination costs (cease-use liability). Estimated lease termination costs include future minimum lease payments, taxes, insurance, construction, and maintenance costs from the cease-use date to the end of the remaining lease term net of estimated sublease rental income. During the first six months of 2009, the Company adjusted the liability in response to the declining economic conditions in San Diego, by extending the expected period to lease the Front Building. In addition, certain other period costs such as leasing commissions and legal fees will be borne by the Company in the event of the sublease of the Front Building. If estimated net sublease rental income were to change by 10% in either direction, the Company's estimated lease termination costs would increase or decrease by approximately \$1.7 million. The changes to the accrued liability for the first six months of 2009 are as follows (in millions):

		<b>Six Months Ended June 30, 2009</b>
Accrued lease termination costs at January 1, 2009	\$	15.4
Lease termination costs accrued during the period		5.8
Cash payments for lease termination costs during the period		(3.0)
Accrued lease termination costs at June 30, 2009		18.2
Less current portion of accrued lease termination costs		15.4

Non-current portion of accrued lease termination costs	\$	2.8
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In accordance with SFAS No. 98, Accounting for Leases: Sale-Leaseback Transactions Involving Real Estate, Sales-Type Leases of Real Estate, Definition of the Lease Term, and Initial Direct Costs of Direct Financing Leases (SFAS 98) and SFAS No. 66, Accounting for Sales of Real Estate (SFAS 66) the Company initially deferred the gain on the sale of the building and related vacant parcel due to a repurchase right. The Company initially established a long-term liability of \$108.7 million upon the close of the transaction, essentially the gross proceeds from the real estate sale. The lease amendment terminated this repurchase right and the Company removed from its balance sheet the long-term liability of \$108.7 million and the related previously conveyed real estate related assets of \$69.6 million during the fourth quarter of 2008. Additionally, the Company began to recognize the deferred gain of \$39.1 million on the sale of the real estate over the remaining term of the lease. During the first six months of 2009, the Company recognized \$1.4 million of the deferred gain and will recognize the balance of the deferred gain over the remaining lease term.

## 12. LOSS PER COMMON SHARE

The Company computes net loss per share in accordance with SFAS No. 128, Earnings Per Share (SFAS 128). Under the provisions of SFAS 128, basic net loss per share is computed by dividing the net loss for the period by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss for the period by the weighted average number of common and common equivalent shares outstanding during the period. Additionally, potentially dilutive securities, composed of incremental common shares issuable upon the exercise of stock options and warrants, are excluded from historical diluted loss per share because of their anti-dilutive effect. Potentially dilutive securities totaled 8,000 and 0.1 million for the

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three months ended June 30, 2009 and 2008, respectively, and 8,000 and 0.1 million for the six months ended June 30, 2009 and 2008, respectively.

### **13. COMPREHENSIVE LOSS**

Comprehensive loss is calculated in accordance with SFAS No. 130, Comprehensive Income (SFAS 130). SFAS 130 requires the disclosure of all components of comprehensive loss, including net loss and changes in equity during a period from transactions and other events and circumstances generated from non-owner sources. The Company's components of comprehensive loss consist of the net loss and unrealized gains and losses on available-for-sale investments. For the three months ended June 30, 2009 and 2008, comprehensive loss was \$12.8 million and \$21.1 million, respectively. For the six months ended June 30, 2009 and 2008, comprehensive loss was \$32.3 million and \$43.3 million, respectively.

### **14. REVENUE RECOGNITION**

Revenues under collaborative research agreements and grants are recognized as research costs are incurred over the period specified in the related agreement or as the services are performed. These agreements are on a best-efforts basis, do not require scientific achievement as a performance obligation and provide for payment to be made when costs are incurred or the services are performed. All fees are nonrefundable to the collaborators. Upfront, nonrefundable payments for license fees, grants, and advance payments for sponsored research revenues received in excess of amounts earned are classified as deferred revenue and recognized as income over the contract or development period. Estimating the duration of the development period includes continual assessment of development stages and regulatory requirements. Milestone payments are recognized as revenue upon achievement of pre-defined scientific events, which require substantive effort, and for which achievement of the milestone was not readily assured at the inception of the agreement.

### **15. RESEARCH AND DEVELOPMENT**

Research and development (R&D) expenses are recognized as incurred and include related salaries, contractor fees, clinical trial costs, facilities costs, administrative expenses and allocations of certain other costs. These expenses result from the Company's independent R&D efforts as well as efforts associated with collaborations and in-licensing arrangements. In addition, the Company funds R&D at other companies and research institutions under agreements, which are generally cancelable. The Company reviews and accrues clinical trial expenses based on work performed, a method that relies on estimates of total costs incurred based on patient enrollment, completion of patient studies and other events. The Company follows this method since reasonably dependable estimates of the costs applicable to various stages of a research agreement or clinical trial can be made. Accrued clinical costs are subject to revisions as trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

### **16. INCOME TAXES**

On July 13, 2006, the FASB issued FASB Interpretation No. 48 (FIN 48), Accounting for Uncertainty in Income Taxes, an interpretation of FASB No. 109. Under FIN 48, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

The Company adopted the provisions of FIN 48 on January 1, 2007. There were no unrecognized tax benefits as of the date of adoption. As a result of the implementation of FIN 48, the Company did not recognize an increase in the liability for unrecognized tax benefits. There are no unrecognized tax benefits included in the balance sheet that would, if recognized, affect the effective tax rate.

The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties on the Company's balance sheets at December 31, 2008 and at June 30, 2009, and has not recognized interest and/or penalties in the statement of operations for the first six months of 2009.

The Company is subject to taxation in the United States and various state jurisdictions. The Company's tax years for 1993 and forward are subject to examination by the United States and California tax authorities due to the

carryforward of unutilized net operating losses and R&D credits.

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At January 1, 2009, the Company had net deferred tax assets of \$69.3 million. Due to uncertainties surrounding the Company's ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset the net deferred tax assets. Additionally, the future utilization of the Company's net operating loss and research and development credit carryforwards to offset future taxable income may be subject to a substantial annual limitation, pursuant to Internal Revenue Code Sections 382 and 383, as a result of ownership changes that may have occurred previously or that could occur in the future. Although the Company determined that an ownership change had not occurred through January 31, 2007, it is possible that an ownership change occurred subsequent to that date. The Company has not completed an update of its Section 382 analysis subsequent to January 31, 2007. Until this analysis has been updated, the Company has removed the deferred tax assets for net operating losses of \$227.2 million and research and development credits of \$38.8 million generated through 2008 from its deferred tax asset schedule and has recorded a corresponding decrease to its valuation allowance. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact the Company's effective tax rate.

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

*The following Management's Discussion and Analysis of Financial Condition and Results of Operations section contains forward-looking statements, which involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below in Part II, Item 1A under the caption Risk Factors. The interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the Financial Statements and Notes thereto for the year ended December 31, 2008 and the three months ended March 31, 2009 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, which are contained in our Annual Report on Form 10-K for the year ended December 31, 2008 and our Quarterly Report on Form 10-Q for the three months ended March 31, 2009, respectively.*

### **OVERVIEW**

We discover, develop and intend to commercialize drugs for the treatment of neurological and endocrine-related diseases and disorders. Our product candidates address some of the largest pharmaceutical markets in the world, including endometriosis, anxiety, depression, pain, diabetes, irritable bowel syndrome, insomnia, and other neurological and endocrine related diseases and disorders. To date, we have not generated any revenues from the sale of products. We have funded our operations primarily through private and public offerings of our common stock and payments received under research and development agreements. We are developing certain products with corporate collaborators and intend to rely on existing and future collaborators to meet funding requirements. We expect to generate future net losses due to increases in operating expenses as product candidates are advanced through the various stages of clinical development. As of June 30, 2009, we had an accumulated deficit of \$738.2 million and expect to incur operating losses in the near future, which may be greater than losses in prior years. We currently have eight programs in various stages of research and development, including five programs in clinical development. While we independently develop many of our product candidates, we are in a collaboration for two of our programs.

In May 2009, we announced a restructuring program to implement cost containment measures and to focus research and development efforts. As a result, we reduced our research and development and general and administrative staff in San Diego by approximately 65 employees and incurred a net restructuring charge of approximately \$2.9 million. Restructuring charges are comprised of salary continuation, outplacement services, and other miscellaneous costs related to this reduction in force. Substantially all of these expenses were paid in cash during the second quarter of 2009. We expect this restructuring to save approximately \$12.0 million per annum through a reduction of personnel-related and other research and development costs.

### **CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

Our discussion and analysis of our financial condition and results of operations is based upon financial statements that we have prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosures. On an on-going basis, we evaluate these estimates, including those related to revenues under collaborative research agreements and grants, clinical trial

accruals (research and development expense), debt, share-based compensation, investments, and fixed assets. Estimates are based on historical experience, information received from third parties and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ

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from these estimates under different assumptions or conditions. The items in our financial statements requiring significant estimates and judgments are as follows:

Revenues under collaborative research and development agreements are recognized as costs are incurred over the period specified in the related agreement or as the services are performed. These agreements are on a best-efforts basis, do not require scientific achievement as a performance obligation, and provide for payment to be made when costs are incurred or the services are performed. All fees are nonrefundable to the collaborators. Upfront, nonrefundable payments for license fees, grants, and advance payments for sponsored research revenues received in excess of amounts earned are classified as deferred revenue and recognized as income over the contract or development period. Estimating the duration of the development period includes continual assessment of development stages and regulatory requirements. Milestone payments are recognized as revenue upon achievement of pre-defined scientific events, which requires substantive effort, and for which achievement of the milestone was not readily assured at the inception of the agreement.

Research and development (R&D) expenses include related salaries, contractor fees, facilities costs, administrative expenses and allocations of corporate costs. All such costs are charged to R&D expense as incurred. These expenses result from our independent R&D efforts as well as efforts associated with collaborations, grants and in-licensing arrangements. In addition, we fund R&D and clinical trials at other companies and research institutions under agreements, which are generally cancelable. We review and accrue clinical trials expense based on work performed, a method that relies on estimates of total costs incurred based on patient enrollment, completion of studies and other events. We follow this method since reasonably dependable estimates of the costs applicable to various stages of a research agreement or clinical trial can be made. Accrued clinical costs are subject to revisions as trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. Historically, revisions have not resulted in material changes to R&D costs; however a modification in the protocol of a clinical trial or cancellation of a trial could result in a charge to our results of operations.

In accordance with Statement of Financial Accounting Standards (SFAS) No. 144 (SFAS 144), Accounting for the Impairment or Disposal of Long-Lived Assets, if indicators of impairment exist, we assess the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, we measure the amount of such impairment by comparing the carrying value of the asset to the estimated fair value of the asset, which is generally determined based on the present value of the expected future cash flows. We have determined that no impairment exists on our long-lived assets.

We grant stock options to purchase our common stock to our employees and directors under the 2003 Incentive Stock Plan, as amended (the 2003 Plan) and grant stock options to certain employees pursuant to Employment Commencement Nonstatutory Stock Option Agreements. We also grant certain employees stock bonuses and RSUs under the 2003 Plan. Additionally, we have outstanding options that were granted under option plans from which we no longer make grants. The benefits provided under all of these plans are subject to the provisions of revised SFAS No. 123, Share-Based Payment (SFAS 123R). Share-based compensation expense recognized under SFAS 123R for the three months ended June 30, 2009 and 2008 was \$1.0 million and \$2.2 million, respectively. Share-based compensation expense recognized under SFAS 123R for the six months ended June 30, 2009 and 2008 was \$2.9 million and \$4.4 million, respectively.

Stock option awards and RSUs generally vest over a three to four year period and expense is ratably recognized over those same time periods. However, due to certain retirement provisions in our stock plans, share-based compensation expense may be recognized over a shorter period of time, and in some cases the entire share-based compensation expense may be recognized upon grant of the share-based compensation award. Employees who are age 55 or older and have five or more years of service with us are entitled to accelerated vesting of certain unvested share-based compensation awards upon retirement. This retirement provision leads to variability in the quarterly expense amounts recognized under SFAS 123R, and therefore individual share-based compensation awards may impact earnings disproportionately in any individual fiscal quarter.

The determination of fair value of stock-based payment awards on the date of grant using the Black-Scholes model is affected by our stock price, as well as the input of other subjective assumptions. These assumptions include, but are

not limited to, the expected term of stock options and our expected stock price volatility over the term of the awards. Our stock options have characteristics significantly different from those of traded options, and changes in the assumptions can materially affect the fair value estimates.

SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. If actual forfeitures vary from our estimates, we will recognize the difference in compensation expense in the period the actual forfeitures occur or when options vest.



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**THREE MONTHS ENDED JUNE 30, 2009 AND 2008**

Revenues were \$0.7 million for the three months ended June 30, 2009 compared with \$0.7 million for the respective period last year. During the second quarters of both 2009 and 2008, we recognized \$0.7 million in revenue under our collaboration agreement with Dainippon Sumitomo Pharma Co. Ltd (DSP) from amortization of up-front licensing fees.

Research and development expenses decreased to \$10.8 million for the second quarter of 2009 compared with \$16.2 million for the respective period in 2008. Laboratory costs decreased by \$0.6 million in the second quarter of 2009 compared to the same period in 2008 and external development costs decreased by \$4.5 million compared to the same period last year. External development spending in our elagolix and pro drug programs decreased by \$3.5 million and \$1.1 million, respectively, in the second quarter of 2009 compared with the same period in 2008. Research and development expenses for the second quarter of 2009 also included severance expenses of \$2.2 million, which were offset entirely by other personnel cost reductions during the quarter.

General and administrative expenses were \$4.8 million for the second quarter of 2009 compared with \$4.7 million during the same period last year. General and administrative expenses for the second quarter of 2009 also included severance costs of \$0.7 million which were almost entirely offset by cost savings from related expense management efforts.

During the second quarter of 2009, we recognized additional cease-use expense under SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities (SFAS 146) of \$0.9 million due to the timing of tenant occupancy for the Front Building. See Note 11, Real Estate to the accompanying financial statements.

Other income (expense) was \$(0.9) million during the second quarter of 2008 compared to \$0.6 million for the second quarter of 2009. The change resulted primarily from rental payments made during the second quarter of 2008 under our sale-leaseback agreement which were recorded as interest expense under sale-leaseback accounting rules. These rental payments are components of operating expense during 2009. Additionally, we recognized \$0.7 million in deferred gains on real estate and \$0.2 million in gains on our auction rate securities in the second quarter of 2009.

Our net loss for the second quarter of 2009 was \$15.3 million, or \$0.39 per share, compared to \$21.0 million, or \$0.55 per share, for the same period in 2008. This decrease in net loss primarily resulted from expense management efforts during the second quarter of 2009.

**SIX MONTHS ENDED JUNE 30, 2009 AND 2008**

Revenues were \$1.5 million for the six months ended June 30, 2009 compared with \$2.5 million for the respective period last year. During the six months ended June 30, 2008, we recognized a \$1.0 million milestone from GSK related to clinical advancements of our CRF program. During both six month periods ended June 30, 2009 and 2008, we recognized \$1.5 million in revenue under our collaboration agreement with DSP from amortization of up-front licensing fees.

Research and development expenses decreased to \$21.7 million for the first half of 2009 compared with \$30.4 million for the respective period in 2008. This decrease in research and development expenses is primarily due to cost savings related to our recent restructurings. The decrease in staff levels reduced personnel costs in the first six months of 2009 which were essentially offset by severance costs of \$2.2 million during the first six months of 2009. Additionally, laboratory costs decreased by \$0.8 million in the first half of 2009 compared to the same period in 2008. External development costs decreased by \$6.6 million to \$4.4 million in the first half of 2009 compared to \$11.0 million in the same period last year. External development spending in our elagolix and pro drug programs decreased by \$5.3 million and \$1.1 million, respectively, in the first six months of 2009 compared to the same period in 2008. Other non-personnel cost management efforts have resulted in approximately \$1.0 million of year to date savings over the prior six month period.

General and administrative expenses were \$9.0 million for the six months ended June 30, 2009 compared with \$13.0 million during the same period last year. We incurred a \$2.2 million restructuring charge in the first half of 2008 compared to a \$0.7 million charge in the first half of 2009. Additionally, other non-personnel cost reductions resulted in savings of approximately \$1.2 million compared with the prior year period.

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During the six months ended June 30, 2009, we recognized additional cease-use expense under SFAS 146 of \$5.8 million due to an estimated increase in construction costs, and a change in assumptions on the timing of tenant occupancy and rental rates for the Front Building. See Note 11, Real Estate to the accompanying financial statements.

Other income (expense) was \$(1.2) million during the first six months of 2008 compared to \$22,000 for the first six months of 2009. The change resulted primarily from rental payments made in 2008 under our facilities sale-leaseback agreement that were recorded as interest expense under sale-leaseback accounting rules. The rental payments are components of operating expense during 2009. Additionally, we recognized \$1.4 million in deferred gains on real estate during the first six months of 2009, which was partially offset by a net recognized loss on auction rate securities of \$1.2 million during the same period.

Net loss for the first half of 2009 was \$34.9 million, or \$0.90 per share, compared to \$42.0 million, or \$1.10 per share, for the same period in 2008. This decrease in net loss was primarily due to a reduction in expenses as a result of our restructuring programs implemented in the fourth quarter of 2007 and second quarter of 2009.

To date, our revenues have been derived primarily from funded research and development, achievements of milestones under corporate collaborations, and licensing of product candidates. The nature and amount of these revenues from period to period may lead to substantial fluctuations in our of quarterly revenues and earnings. Accordingly, results and earnings for one period are not predictive of future periods. Collaborations, including grant revenue, accounted for 100% of our revenue for the three and six months ended June 30, 2009 and 2008.

We expect to incur operating losses for the foreseeable future because of the expenses we expect to incur related to progressing programs through our pipeline.

### **LIQUIDITY AND CAPITAL RESOURCES**

At June 30, 2009, our cash, cash equivalents, and investments totaled \$74.0 million compared with \$101.5 million at December 31, 2008. The decrease in cash and investment balances at June 30, 2009 resulted primarily from our net loss of \$34.9 million, which includes various non-cash expenditures.

Our long-term investments at June 30, 2009 included (at par value) \$22.6 million of auction rate securities. With the liquidity issues experienced in global credit and capital markets, these auction rate securities have experienced multiple failed auctions as the amount of securities submitted for sale has exceeded the amount of purchase orders, and as a result, these affected securities are currently not liquid. All of our auction rate securities are secured by student loans, which are backed by the full faith and credit of the federal government (up to approximately 98% of the value of the student loan). All of these securities continue to pay interest according to their stated terms (generally 120 basis points over the ninety-one day United States Treasury bill rate) with interest rates resetting every 7 to 28 days. While it is not our intent to hold these securities until their stated ultimate maturity dates, these investments are scheduled to ultimately mature between 2030 and 2047.

The valuation of our auction rate securities investment portfolio is subject to uncertainties that are difficult to predict. The fair values of these securities were estimated utilizing a discounted cash flow analysis as of June 30, 2009. The significant assumptions of this valuation model were discount margins ranging from 191 to 491 basis points which are based on industry recognized student loan sector indices, an additional liquidity discount of 150 basis points and an estimated term to liquidity of 5.5 to 7.5 years. Other items this analysis considers are the collateralization underlying the security investments, the creditworthiness of the counterparty, and the timing of expected future cash flows. These securities were also compared, when possible, to other observable market data with similar characteristics as the securities held by us. Although the auction rate security investments continue to pay interest according to their stated terms, based on valuation models of the individual securities, we have recognized in the consolidated statement of operations for the six months ended June 30, 2009 a loss of approximately \$1.3 million in other expense, net for auction rate securities that we have concluded that an other-than-temporary impairment exists.

During the fourth quarter of 2008, UBS AG (UBS) extended an offer of Auction Rate Securities Rights (ARS Rights) to holders of illiquid auction rate securities that were maintained by UBS as of February 13, 2008. The ARS Rights provide the holder with the ability to sell the auction rate securities, along with the ARS Rights, to UBS at the par value of the auction rate securities, during an applicable exercise period. The ARS Rights grant UBS the sole discretion and right to sell or otherwise dispose of auction rate securities at any time up until July 2, 2012, without any prior notification of the holder, so long as the holder receives a payment of par upon any sale or disposition. The ARS

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exchange or any other trading network. The offer period for the ARS Rights closed on November 14, 2008 and ARS Rights were issued by UBS during the fourth quarter of 2008.

We have elected to participate in the ARS Rights program for all of our outstanding auction rate securities maintained by UBS. We have \$14.6 million (at par value) of auction rate securities that are maintained by UBS. Under the terms of the ARS Rights offer, our applicable exercise period begins on June 30, 2010 and ends July 2, 2012. Additionally, we are eligible for a loan of up to 75% of the market value of the auction rate securities, should a loan be needed. It is our intention to sell the auction rate securities and ARS Rights to UBS on June 30, 2010.

We elected to measure the ARS Rights under the fair value option of SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities* including an amendment of FASB Statement No. 115 (SFAS 159), to mitigate volatility in reported earnings due to their linkage to the auction rate securities. Simultaneously, due to the ARS Rights granted by UBS, we made a one-time election to transfer the related auction rate security holdings from available-for-sale securities to trading securities. We anticipate that any changes in the fair value of the ARS Rights will be offset by the changes in the fair value of the related auction rate securities with no material net impact to the consolidated statement of operations. The ARS Rights will continue to be measured at fair value under SFAS 159 until the earlier of their maturity or exercise. At June 30, 2009, we valued these ARS Rights at \$1.9 million.

These ARS Rights together with the auction rate securities held at UBS (fair value of \$12.6 million as of June 30, 2009) are carried as short-term investments on the condensed consolidated balance sheet at June 30, 2009. In addition to the election of the fair value option for the ARS Rights, we made a one-time election in the fourth quarter of 2008 to transfer the related auction rate security holdings from available-for-sale securities to trading securities. This enabled the changes in the fair value of the ARS Rights to be offset by the changes in the fair value of the related auction rate securities with no material net impact to our condensed consolidated statement of operations.

Our remaining auction rate securities that are not maintained by UBS continue to be treated as available-for-sale investments. These auction rate securities have a par value of \$8.0 million. During the three months ended March 31, 2009, certain ratings agencies downgraded these auction rate securities and we recognized an other-than-temporary impairment of \$1.5 million in the consolidated statement of operations for the three months ended March 31, 2009. During the second quarter of 2009, global credit markets improved and credit spreads narrowed resulting in an increase in the fair value of these investments of approximately \$1.4 million which was recorded as an unrealized gain in other comprehensive income as of June 30, 2009. At June 30, 2009, we valued these investments at \$6.7 million and they are carried as long-term investments on our condensed consolidated balance sheet at June 30, 2009.

Changes to estimates and assumptions used in estimating the fair value of the auction rate securities and related ARS Rights may provide materially different values. In addition, actual market exchanges, if any, may occur at materially different amounts. For example, a reduction of the expected term to redemption assumption by approximately two years for the auction rate securities and related ARS Rights would yield a net increase in the valuation of these investments of \$0.3 million. Other factors that may impact the valuation of our auction rate securities and related ARS Rights include changes to credit ratings of the securities as well as to the underlying assets supporting those securities, rates of default of the underlying assets, underlying collateral value, discount rates, counterparty risk and ongoing strength and quality of market credit and liquidity.

At present, in the event we need to access the funds that are in an illiquid state, we may not be able to do so without the possible loss of principal, until a future auction for these investments is successful, another secondary market evolves for these securities, they are redeemed by the issuer or they mature. If we are unable to sell these securities in the market or they are not redeemed, we could be required to hold them to maturity. We do not currently anticipate a need to access these funds for operational purposes in 2009, nor the outstanding auction rate securities with UBS prior to June 30, 2010, the beginning of the ARS Rights exercise period. We will continue to monitor and evaluate these investments on an ongoing basis for impairment.

Net cash used in operating activities during the first half of 2009 was \$28.0 million compared with \$43.2 million during the same period last year. Net loss for the first six months of 2009 was \$34.9 million compared to \$42.0 million for the same period in 2008. This decrease in net loss was primarily due to a reduction in expenses as a result of our restructuring programs and expense management efforts.

Net cash used in investing activities during the first six months of 2009 was \$1.8 million compared to net cash provided by investing activities of \$36.3 million for the first six months of 2008. The fluctuation in net cash provided by investing activities

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resulted primarily from the timing differences in investment purchases, sales and maturities, and the fluctuation of our portfolio mix between cash equivalents and short-term investment holdings.

No cash was utilized in financing activities during the first six months of 2009 compared to \$0.9 million used in 2008 related to cash payments made on outstanding debt obligations.

The terms of our facility lease agreement require that we maintain \$50.0 million in cash and investments at all times, or increase our security deposit by \$5.0 million.

We believe that our existing capital resources, together with interest income and future payments due under our strategic alliances, will be sufficient to satisfy our current and projected funding requirements for at least the next 12 months. However, we cannot guarantee that these capital resources and payments will be sufficient to conduct all of our research and development programs as planned. The amount and timing of expenditures will vary depending upon a number of factors, including progress of our research and development programs.

We will require additional funding to continue our research and product development programs, to conduct preclinical studies and clinical trials, for operating expenses, to pursue regulatory approvals for our product candidates, for the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims, if any, the cost of product in-licensing and any possible acquisitions, and we may require additional funding to establish manufacturing and marketing capabilities in the future. We intend to seek additional funding through strategic alliances, and may seek additional funding through public or private sales of our securities, including equity securities. In addition, we have financed capital purchases and may continue to pursue opportunities to obtain additional debt financing in the future. However, additional equity or debt financing might not be available on reasonable terms, if at all, and any additional equity financings will be dilutive to our stockholders. Recently, the credit markets and the financial services industry have been experiencing a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the United States federal government. These events have generally made equity and debt financing more difficult to obtain. If adequate funds are not available, we may be required to curtail significantly one or more of our research or development programs or obtain funds through arrangements with collaborators or others. This may require us to relinquish rights to certain of our technologies or product candidates. To the extent that we are unable to obtain third-party funding for such expenses, we expect that increased expenses will result in increased losses from operations. We cannot assure you that we will be successful in the development of our product candidates, or that, if successful, any products marketed will generate sufficient revenues to enable us to earn a profit.

### **INTEREST RATE RISK**

We are exposed to interest rate risk on our short and long term investments. 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 seek to invest in highly liquid and high quality government and other debt securities. To minimize our exposure due to adverse shifts in interest rates, we invest in short-term securities and ensure that the maximum initial average maturity of our investments does not exceed 36 months. If a 10% change in interest rates had occurred on June 30, 2009, this change would not have had a material effect on the fair value of our investment portfolio as of that date. Due to the short holding period of our investments and the nature of our investments, we have concluded that we do not have a material financial market interest rate risk exposure.

### **NEW ACCOUNTING PRONONCEMENTS**

In June 2009, the Financial Accounting Standards Board (FASB) issued SFAS 168, The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles, a replacement of FASB 162. The FASB Accounting Standards Codification (Codification) will become the source of authoritative U.S. generally accepted accounting principles (GAAP) recognized by the FASB to be applied by nongovernmental entities. Rules and interpretive releases of the Securities and Exchange Commission (SEC) under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. On the effective date of this Statement, the Codification will supersede all then-existing non-SEC accounting and reporting standards. All other nongrandfathered non-SEC accounting literature not included in the Codification will become nonauthoritative. SFAS 168 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. We do not expect the

adoption of SFAS 168 to have a material impact on our consolidated results of operation or financial condition.

In May 2009, the FASB issued SFAS 165, Subsequent Events (SFAS 165). SFAS 165 is intended to establish general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are

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available to be issued. It requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for selecting that date, that is, whether that date represents the date the financial statements were issued or were available to be issued. SFAS 165 is effective for interim or annual financial periods ending after June 15, 2009. The adoption of SFAS 165 did not have a material effect on our consolidated results of operations or financial condition.

In April 2009, the FASB issued several pronouncements related to fair value measurement, recording and disclosure in financial reporting.

FASB Staff Position No. 107-1 and Accounting Principles Board (APB) 28-1, *Interim Disclosures about Fair Value of Financial Instruments*, were issued to outline the required financial statement disclosures relating to fair value of financial instruments during interim reporting periods. FASB Staff Position No. 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly*, was issued to provide additional guidance in evaluating the fair value of a financial instrument when the volume and level of activity for the asset or liability has significantly decreased. FASB Staff Position No. 115-2 and FASB Staff Position No. 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments*, were issued to provide additional guidance on presenting impairment losses on securities.

The adoption of these new fair value measurement pronouncements did not have a material effect on our consolidated results of operations or financial condition.

### **FORWARD-LOOKING STATEMENTS**

This Quarterly Report on Form 10-Q and the information incorporated herein by reference contain forward-looking statements that involve a number of risks and uncertainties. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, these forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements.

Forward-looking statements can be identified by the use of forward-looking words such as *believes, expects, hopes, may, will, plan, intends, estimates, could, should, would, continue, seeks, proforma*, similar words (including their use in the negative), or by discussions of future matters such as the development or regulatory approval of new products, technology enhancements, possible changes in legislation and other statements that are not historical. These statements include but are not limited to statements under the captions *Risk Factors*, and

*Management's Discussion and Analysis of Financial Condition and Results of Operations* as well as other sections in this report. You should be aware that the occurrence of any of the events discussed under the heading in Part II titled

*Item 1A. Risk Factors* and elsewhere in this report could substantially harm our business, results of operations and financial condition and that if any of these events occurs, the trading price of our common stock could decline and you could lose all or a part of the value of your shares of our common stock.

The cautionary statements made in this report are intended to be applicable to all related forward-looking statements wherever they may appear in this report. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. Except as required by law, we assume no obligation to update our forward-looking statements, even if new information becomes available in the future.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

A discussion of our exposure to, and management of, market risk appears in Part I, Item 2 of this Quarterly Report on Form 10-Q under the heading *Interest Rate Risk*.

### **ITEM 4. CONTROLS AND PROCEDURES**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the timelines specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance,





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management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), 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 of the end of the quarter covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

There has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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**PART II: OTHER INFORMATION**

**ITEM 1A. RISK FACTORS**

The following Risk Factors do not reflect any material changes to the Risk Factors set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008, other than the revisions to the risk factors set forth below with an asterisk (\*) next to the title. The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report and those we may make from time to time. If any of the following risks actually occur, our business, operating results, prospects or financial condition could be harmed. Additional risks not presently known to us, or that we currently deem immaterial, may also affect our business operations.

**Risks Related to Our Company**

***We depend on continuing our current collaborations and developing additional collaborations to develop and commercialize our product candidates.***

Our strategy for fully developing and commercializing our products is dependent upon maintaining our current arrangements and establishing new arrangements with research collaborators, corporate collaborators and others, particularly as it relates to our GnRH and urocortin 2 programs. We have active collaboration agreements with GlaxoSmithKline and Dainippon Sumitomo Pharma Co. Ltd. and previously have had collaborations with Pfizer, Wyeth, Johnson & Johnson, Novartis, Taisho and Eli Lilly and Company. We historically have been dependent upon these corporate collaborators to provide adequate funding for a number of our programs. Under these arrangements, our corporate collaborators are typically responsible for:

selecting compounds for subsequent development as drug candidates;

conducting preclinical studies and clinical trials and obtaining required regulatory approvals for these drug candidates; and

manufacturing and commercializing any resulting drugs.

Because we expect to continue to rely heavily on corporate collaborators, the development and commercialization of our programs would be substantially delayed if one or more of our current or future collaborators:

failed to select a compound that we have discovered for subsequent development into marketable products;

failed to gain the requisite regulatory approvals of these products;

did not successfully commercialize products that we originate;

did not conduct its collaborative activities in a timely manner;

did not devote sufficient time and resources to our partnered programs or potential products;

terminated its alliance with us;

developed, either alone or with others, products that may compete with our products;

disputed our respective allocations of rights to any products or technology developed during our collaborations;  
or

merged with a third party that wants to terminate the collaboration.

These issues and possible disagreements with current or future corporate collaborators could lead to delays in the collaborative research, development or commercialization of many of our product candidates. Furthermore, disagreements with these parties could require or result in litigation or arbitration, which would be time-consuming and expensive. If any of these issues arise, it may delay the development and commercialization of drug candidates

and, ultimately, our generation of product revenues.

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***Our clinical trials may fail to demonstrate the safety and efficacy of our product candidates, which could prevent or significantly delay their regulatory approval.***

Before obtaining regulatory approval for the sale of any of our potential products, we must subject these product candidates to extensive preclinical and clinical testing to demonstrate their safety and efficacy for humans. Clinical trials are expensive, time-consuming and may take years to complete.

In connection with the clinical trials of our product candidates, we face the risks that:

- the product candidate may not prove to be effective;
- we may discover that a product candidate may cause harmful side effects;
- the results may not replicate the results of earlier, smaller trials;
- we or the FDA or similar foreign regulatory authorities may suspend the trials;
- the results may not be statistically significant;
- patient recruitment may be slower than expected;
- patients may drop out of the trials; and
- regulatory requirements may change.

For example, there is uncertainty regarding future development of indiplon as described below under the risk factor entitled *There is uncertainty regarding future development of our product candidate, indiplon, and we may not be able to meet the requirements to receive regulatory approvals for it.*

In addition, late stage clinical trials are often conducted with patients having the most advanced stages of disease. During the course of treatment, these patients can die or suffer other adverse medical effects for reasons that may not be related to the pharmaceutical agent being tested but which can nevertheless adversely affect clinical trial results. Any failure or substantial delay in completing clinical trials for our product candidates may severely harm our business.

***If we cannot raise additional funding, we may be unable to complete development of our product candidates.***

We may require additional funding to continue our research and product development programs, to conduct preclinical studies and clinical trials, for operating expenses and to pursue regulatory approvals for product candidates, for the costs involved in filing and prosecuting patent application and enforcing or defending patent claims, if any, as well as costs associated with litigation matters, product in-licensing and any possible acquisitions, and we may require additional funding to establish manufacturing and marketing capabilities in the future. We believe that our existing capital resources, together with investment income, and future payments due under our strategic alliances, will be sufficient to satisfy our current and projected funding requirements for at least the next 12 months. However, these resources might be insufficient to conduct research and development programs as planned. If we cannot obtain adequate funds, we may be required to curtail significantly one or more of our research and development programs or obtain funds through additional arrangements with corporate collaborators or others that may require us to relinquish rights to some of our technologies or product candidates.

Our future capital requirements will depend on many factors, including:

- continued scientific progress in our research and development programs;
- the magnitude of our research and development programs;
- progress with preclinical testing and clinical trials;
- the time and costs involved in obtaining regulatory approvals;

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the costs involved in filing and pursuing patent applications and enforcing patent claims;  
 competing technological and market developments;  
 the establishment of additional strategic alliances;  
 the cost of commercialization activities and arrangements, including manufacturing of our product candidates;  
 and  
 the cost of product in-licensing and any possible acquisitions.

We intend to seek additional funding through strategic alliances, and may seek additional funding through public or private sales of our securities, including equity securities. For example, we have an effective shelf registration statement on file with the Securities and Exchange Commission which allows us to issue shares of our common stock from time to time for an aggregate initial offering price of up to \$150 million. In addition, we have previously financed capital purchases and may continue to pursue opportunities to obtain additional debt financing in the future. Recently, the credit markets and the financial services industry have been experiencing a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the United States federal government. These events have generally made equity and debt financing more difficult to obtain. Accordingly, additional equity or debt financing might not be available on reasonable terms, if at all. Any additional equity financings will be dilutive to our stockholders and any additional debt financings may involve operating covenants that restrict our business.

***\*Our restructuring activities could result in management distractions, operational disruptions and other difficulties.***

In order to focus efforts on our clinical programs, we initiated restructuring activities in an effort to reduce operating costs, including a work force reduction announced in May 2009. Employees whose positions were eliminated in connection with this reduction may seek future employment with our competitors. Although all employees are required to sign a confidentiality agreement with us at the time of hire, we cannot assure you that the confidential nature of our proprietary information will be maintained in the course of such future employment. We cannot assure you that we will not 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 previous or future restructuring plans. In addition, if we continue to reduce our workforce, it may adversely impact our ability to respond rapidly to any new growth opportunities.

We also entered into a December 2008 amendment to our facilities lease, under which our landlord will seek to enter into leases with replacement tenants for portions of the front building of our corporate headquarters, thereby reducing our rent under the lease. Our landlord may not be successful in entering into leases with replacement tenants on favorable terms, or at all. Any additional restructuring efforts could divert the attention of our management away from our operations, harm our reputation and increase our expenses. If we are unable to lease our front building, we will continue to incur significant expense which will limit the resources we can devote to our development programs.

***There is uncertainty regarding future development of our product candidate, indiplon, and we may not be able to meet the requirements to receive regulatory approvals for it.***

On December 12, 2007 we received an action letter from the FDA stating that indiplon 5mg and 10mg capsules are approvable (2007 FDA Approvable Letter). The 2007 FDA Approvable Letter acknowledged that our resubmitted NDA for indiplon 5mg and 10mg capsules had addressed the issues raised in a previous approvable letter, but set forth new requirements. The new requirements set forth in the 2007 FDA Approvable Letter are the following: (i) an objective/subjective clinical trial in the elderly, (ii) a safety study assessing the rates of adverse events occurring with indiplon when compared to a marketed product and (iii) a preclinical study to evaluate indiplon administration during the third trimester of pregnancy. After receipt of the 2007 FDA Approvable Letter, we ceased all indiplon clinical development activities in the United States as well as all pre-commercialization activities. We met with the FDA in July 2008 to discuss the 2007 FDA Approvable Letter and we are awaiting the finalization of the written minutes of this meeting from the FDA.

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The process of preparing and resubmitting the NDA for indiplon would require significant resources and could be time consuming and subject to unanticipated delays and cost. As a result of the 2007 FDA Approvable Letter, there is a significant amount of uncertainty regarding the future development of indiplon. Should the NDA be refiled, the FDA could again refuse to approve the NDA, or could still require additional data analysis or clinical trials, which would require substantial expenditures by us and would further delay the approval process. Even if our indiplon NDA is approved, the FDA may determine that our data do not support elements of the labeling we have requested. In such a case, the labeling actually granted by the FDA could limit the commercial success of the product. The FDA could require Phase IV, or post-marketing, trials to study the long-term effects of indiplon and could withdraw its approval based on the results of those trials. The FDA could also require a Risk Evaluation and Mitigation Strategy (REMS) program for indiplon that could limit the commercial success of the product. We face the risk that for any of the reasons described above, as well as other reasons set forth herein, indiplon may never be approved by the FDA or commercialized anywhere in the world.

If we determine that it is impractical or we are unable to refile the NDA, or the FDA refuses to accept or approve the resubmitted NDA for any reason or we experience a further delay in approval and subsequent commercialization of indiplon, our business and reputation may be harmed and our stock price could decline.

***We have a history of losses and expect to incur losses and negative operating cash flows for the near future, and we may never achieve sustained profitability.***

Since our inception, we have incurred significant net losses, including net losses of \$88.6 million and \$207.3 million for the years ended December 31, 2008 and 2007, respectively. As a result of ongoing operating losses, we had an accumulated deficit of \$703.3 million and \$614.7 million as of December 31, 2008 and 2007, respectively. We do not expect to be profitable for the year ending December 31, 2009 or the foreseeable future.

We have not yet obtained regulatory approvals of any products and, consequently, have not generated revenues from the sale of products. Even if we succeed in developing and commercializing one or more of our drugs, we may not be profitable. We also expect to continue to incur significant operating and capital expenditures as we:

- seek regulatory approvals for our product candidates;
- develop, formulate, manufacture and commercialize our drugs;
- in-license or acquire new product development opportunities;
- implement additional internal systems and infrastructure; and
- hire additional clinical, scientific and marketing personnel.

We also expect to experience negative cash flow for the near future as we fund our operating losses, in-licensing or acquisition opportunities, and capital expenditures. We will need to generate significant revenues to achieve and maintain profitability and positive cash flow. We may not be able to generate these revenues, and we may never achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the market price of our common stock. Even if we become profitable, we cannot assure you that we would be able to sustain or increase profitability on a quarterly or annual basis.