

NEUROCRINE BIOSCIENCES INC

Form 10-Q

October 28, 2008

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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 AND EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2008

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES AND 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 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 Act). Yes ☐ No ☒

The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 38,598,123 as of October 24, 2008.

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

	September 30, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 80,125	\$ 99,664
Short-term investments, available-for-sale	16,824	79,721
Receivables under collaborative agreements	163	27
Other current assets	1,698	3,536
Total current assets	98,810	182,948
Property and equipment, net	77,309	82,598
Long term investments	21,255	
Restricted cash	6,441	6,399
Other non-current assets	3,918	4,709
Total assets	\$ 207,733	\$ 276,654
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,988	\$ 3,776
Accrued liabilities	12,785	21,717
Deferred revenues	2,926	2,928
Current portion of long-term debt	276	1,486
Total current liabilities	18,975	29,907
Long-term deferred revenues	12,405	14,595
Leaseback financing obligation	108,745	108,745
Other liabilities	3,961	4,710
Total liabilities	144,086	157,957
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 38,589,790 as of September 30, 2008 and 38,273,979 as of December 31, 2007	39	38
Additional paid-in capital	739,761	733,542
Accumulated other comprehensive loss	(1,744)	(233)
Accumulated deficit	(674,409)	(614,650)

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Total stockholders' equity	63,647	118,697
Total liabilities and stockholders' equity	\$ 207,733	\$ 276,654

See accompanying notes to the condensed consolidated financial statements.

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NEUROCRINE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except loss per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Revenues:				
Sponsored research and development	\$ 32	\$ 13	\$ 48	\$ 120
License fees and milestones	729	500	3,189	500
Grant revenue		27	9	72
Total revenues	761	540	3,246	692
Operating expenses:				
Research and development	12,993	19,795	43,406	57,645
General and administrative	3,472	9,571	16,423	26,695
Total operating expenses	16,465	29,366	59,829	84,340
Loss from operations	(15,704)	(28,826)	(56,583)	(83,648)
Other income and (expense):				
Interest income and other income (expense)	(93)	2,413	2,573	6,869
Interest expense	(1,914)	(827)	(5,749)	(2,545)
Total other (expense) income, net	(2,007)	1,586	(3,176)	4,324
Net loss	\$ (17,711)	\$ (27,240)	\$ (59,759)	\$ (79,324)
Net loss per common share:				
Basic and diluted	\$ (0.46)	\$ (0.72)	\$ (1.56)	\$ (2.09)
Shares used in the calculation of net loss per common share:				
Basic and diluted	38,446	37,990	38,399	37,956

See accompanying notes to the condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2008	2007
CASH FLOW FROM OPERATING ACTIVITIES		
Net loss	\$ (59,759)	\$ (79,324)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	6,037	7,238
Gain on sale and disposal of assets	(84)	(126)
Realized loss on auction rate securities	717	
Deferred revenues	(2,192)	36
Share-based compensation expense	6,187	7,757
Change in operating assets and liabilities:		
Accounts receivable and other current assets	1,702	7,707
Other non-current assets	(13)	(512)
Accounts payable and accrued liabilities	(9,720)	1,667
Other non-current liabilities	(749)	449
Net cash used in operating activities	(57,874)	(55,108)
CASH FLOW FROM INVESTING ACTIVITIES		
Purchases of investments	(36,926)	(50,466)
Sales/maturities of investments	77,132	78,245
Restricted cash	(30)	
Sale of property and equipment	521	126
Purchases of property and equipment	(1,185)	(491)
Net cash provided by investing activities	39,512	27,414
CASH FLOW FROM FINANCING ACTIVITIES		
Issuance of common stock	33	575
Principal payments on debt	(1,210)	(3,512)
Net cash used in financing activities	(1,177)	(2,937)
Net decrease in cash and cash equivalents	(19,539)	(30,631)
Cash and cash equivalents at beginning of the period	99,664	80,981
Cash and cash equivalents at end of the period	\$ 80,125	\$ 50,350

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, 2007 included in the Company's Annual Report on Form 10-K for the year ended December 31, 2007 and the Company's Quarterly Reports on Form 10-Q for the three and six months ended March 31 and June 30, 2008, respectively, filed with the SEC.

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, irritable bowel syndrome, anxiety, depression, pain, diabetes, insomnia 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 February 2007, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities" including an amendment of FASB Statement No. 115 (SFAS 159). SFAS 159 expands the use of fair value accounting but does not affect existing standards which require assets or liabilities to be carried at fair value. Under SFAS 159, a company may elect to use fair value to measure accounts and loans receivable, available-for-sale and held-to-maturity securities, equity method investments, accounts payable, guarantees and issued debt. Other eligible items include firm commitments for financial instruments that otherwise would not be recognized at inception and non-cash warranty obligations where a warrantor is permitted to pay a third party to provide the warranty goods or services. If the use of fair value is elected, any upfront costs and fees related to the item must be recognized in earnings and cannot be deferred, e.g., debt issue costs. The fair value election is irrevocable and generally made on an instrument-by-instrument basis, even if a company has similar instruments that it elects not to measure based on fair value. At the adoption date, unrealized gains and losses on existing items for which fair value has been elected are reported as a cumulative adjustment to beginning retained earnings. Subsequent to the adoption of SFAS 159, changes in fair value are recognized in earnings. SFAS 159 is effective for fiscal years beginning after November 15, 2007 and was adopted by the Company January 1, 2008. The adoption of SFAS 159 did not have a material impact on the Company's consolidated results of operations and financial condition as the fair value option was not elected for any of the Company's financial assets or financial liabilities.

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" (SFAS 157). SFAS 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors' requests for expanded information about the extent to which a company measures assets and liabilities at fair value, the information used to

measure fair value, and the effect of fair value measurements on earnings. SFAS 157 applies whenever other standards require (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and was adopted by the Company January 1, 2008. The adoption of SFAS 157 did not have a material impact on the Company's consolidated results of operations and financial condition.

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In June 2007, the FASB ratified Emerging Issues Task Force (EITF) Issue No. 07-3, Accounting for Non-Refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities (EITF No. 07-3), which requires nonrefundable advance payments for goods and services that will be used or rendered for future research and development activities to be deferred and capitalized. These amounts will be recognized as expense in the period that the related goods are delivered or the related services are performed. EITF No. 07-3 is effective for fiscal years beginning after December 15, 2007. The Company adopted the provisions of EITF No. 07-3 on January 1, 2008 and the adoption of EITF No. 07-3 did not have a material impact on its consolidated results of operations and financial condition.

In May 2008, the FASB issued SFAS No. 162, The Hierarchy of Generally Accepted Accounting Principles (SFAS 162). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statement of nongovernmental entities that are presented in conformity with generally accepted accounting principles (the GAAP hierarchy). SFAS 162 will become effective 60 days following the Securities and Exchange Commission's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles. The Company does not expect the adoption of SFAS 162 to have a material effect on its consolidated results of operations and financial condition.

4. SHARE-BASED COMPENSATION

The Company's net loss for the three months ended September 30, 2008 and 2007 includes \$1.7 million and \$2.6 million, respectively, of compensation expense related to the Company's share-based compensation awards. The Company's net loss for the nine months ended September 30, 2008 and 2007 includes \$6.2 million and \$7.8 million, respectively, of compensation expense related to the Company's share-based compensation awards. As of September 30, 2008, total unrecognized estimated compensation cost related to non-vested stock options and non-vested restricted stock units (RSUs) granted prior to that date was \$4.7 million and \$7.5 million, respectively, which is expected to be recognized over a weighted average period of approximately 1.9 and 2.1 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):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2008	2007	2008	2007
General and administrative	\$ 0.6	\$ 1.3	\$3.2	\$4.2
Research and development	1.1	1.3	3.0	3.6

Cash received from stock option exercises for the nine months ended September 30, 2008 and 2007 was \$33,000 and \$0.6 million, respectively. The Company issued approximately 316,000 shares of common stock pursuant to stock option exercises, the vesting of RSUs, and distributions of stock awards from the Company's deferred compensation plan during the nine months ended September 30, 2008.

Stock Option Assumptions

The exercise price of all options granted during the nine month periods ended September 30, 2008 and 2007 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 with the following weighted-average assumptions for option grants during the three and nine months ended September 30, 2008 and 2007:

Three Months Ended	Nine Months Ended
September 30,	September 30,

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	2008	2007	2008	2007
Risk-free interest rate	3.33%	4.45%	2.67%	4.81%
Expected volatility of common stock	68.08%	63.43%	68.58%	65.32%
Dividend yield	0.0%	0.0%	0.0%	0.0%
	4.75	4.75	4.75	4.75
Expected option term	years	years	years	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.

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5. 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.

6. FAIR VALUE MEASUREMENTS

As described in Note 3, the Company adopted 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

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

The Company's long-term investments at September 30, 2008 include (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). Additionally, all of the Company's auction rate securities maintain the highest credit rating of AAA. 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.

At present, in the event the Company needs to access the funds that are in an illiquid state, it 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, then the Company could be required to hold them to maturity. The Company does not have a need to access these funds for operational purposes in the foreseeable future. The Company will continue to monitor and evaluate these investments on an ongoing basis for impairment. Although the auction rate security investments continue to pay interest according to their stated terms, based on valuation models the Company has recorded an unrealized loss of approximately \$0.6 million in accumulated other comprehensive loss as a reduction in shareholders' equity, reflecting adjustments to auction rate security holdings that the Company has concluded have a temporary decline in value due to a lack of liquidity in the global credit markets. In addition, the Company has recognized a realized loss of approximately \$0.7 million in other income(expense) on auction rate securities for which the Company has concluded that an other-than-temporary impairment exists. The carrying value in long-term investments for these auction rate securities at September 30, 2008 is approximately \$21.3 million.

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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 valuation model as of September 30, 2008. The key driver of this valuation model is the expected term to redemption. The UBS auction rate securities were valued with a term to redemption of 1.75 years consistent with the terms contained in the offer disclosed in Note 17 to these financial statements. The Citi auction rate securities were valued with a term to redemption of 5 years. Changes to this assumption for a 2 year term and an 8 year term to redemption for the Citi auction rate securities yielded an impact on the valuation of these securities of \$0.4 million and \$(0.3) million, respectively. Other items this analysis considers are the collateralization underlying the security investments, the creditworthiness of the counterparty, the timing of expected future cash flows, and the expected term to liquidity. The significant assumptions of this valuation model were discount margins ranging from 212 to 392 basis points and an estimated term to redemption as described above. These securities were also compared, when possible, to other observable market data with similar characteristics to the securities held by the Company.

Factors that may impact the valuation of the Company's auction rate securities portfolio 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.

Assets measured at fair value as of September 30, 2008 are classified below based on the three fair value hierarchy tiers described above (in thousands):

Description	9/30/2008	Fair Value Measurements at September 30, 2008 Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and Money market funds	\$ 61.7	\$ 61.7		
Commercial paper	24.8	24.8		
Corporate debt securities	1.9	1.9		
U.S. Government securities	14.9	14.9		
Auction rate securities (1)	21.3			\$ 21.3
Total	\$ 124.6	\$ 103.3	\$	\$ 21.3

Activity for assets measured at fair value during the nine month period ended September 30, 2008 using significant unobservable inputs (Level 3) is presented in the table below (in thousands):

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3)
Beginning balance as of December 31, 2007	\$
Transfers into Level 3	22.6 (0.6)

Total unrealized losses included in other comprehensive income		
Total realized losses included in other income(expense)		(0.7)

Ending balance	\$	21.3
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Amount of total gains or losses for the period included in earnings attributable to the change in unrealized gains or losses relating to assets still held at the reporting date	\$	(0.7)
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- (1) The Company estimated the fair value of these auction rate securities 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.

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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 interest 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.

8. IMPAIRMENT OF LONG-LIVED ASSETS

In accordance with SFAS No. 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.

9. RESTRUCTURING CHARGES

In December 2007, 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 125 employees. 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 first quarter of 2008. During 2008, the Company recorded an additional net charge of \$2.0 million (primarily all general and administrative expense) for severance related to certain executives and other personnel departing the Company. The Company expects this restructuring to reduce annual expenses by approximately \$19.0 million.

As of September 30, 2008, the Company had a remaining balance of approximately \$2.1 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 nine months of 2008 are as follows (in thousands):

Accrual balance as of December 31, 2007	\$ 6,924
Payments	(6,768)
Additional accruals	2,357
Adjustments	(405)
Accrual balance as of September 30, 2008	\$ 2,108

10. RETENTION PROGRAM

On February 27, 2008, the Board of Directors of the Company approved an employee retention program (Retention Program) to provide the Company with a mechanism to retain its non-officer and executive officer employees who were not subject to the Company's December 2007 restructuring program. As part of the Retention Program, the Board approved a one-time cash retention payment totaling \$3.2 million, 60% of which was paid in the first quarter of 2008 and the remaining 40% of which is payable at the end of 2008, assuming such individual remains in good standing as an employee at such time. In addition, the Board approved the issuance of RSUs covering an aggregate of 1,203,000 shares and stock options covering an aggregate of 501,000 shares to its executive officers and certain employees, all of which were issued in the first quarter of 2008.

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11. LOSS PER COMMON SHARE

The Company computes net loss per share in accordance with SFAS No. 128, Earnings Per Share. Under the provisions of SFAS No. 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 0.2 million and 1.5 million for the three months ended September 30, 2008 and 2007, respectively, and 42,000 and 1.6 million for the nine months ended September 30, 2008 and 2007, respectively.

12. COMPREHENSIVE LOSS

Comprehensive loss is calculated in accordance with SFAS No. 130, Comprehensive Income. SFAS No. 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 September 30, 2008 and 2007, comprehensive loss was \$17.9 million and \$27.6 million, respectively. For the nine months ended September 30, 2008 and 2007, comprehensive loss was \$61.3 million and \$79.2 million, respectively.

13. 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.

14. 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.

15. 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 adoption of FIN 48 did not impact the Company's financial condition, results of operations or cash flows.

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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, 2007 and at September 30, 2008, and has not recognized interest and/or penalties in the statement of operations for the first nine months of 2008.

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.

At January 1, 2008, the Company had net deferred tax assets of \$65.8 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 \$194.4 million and research and development credits of \$37.1 million generated through 2007 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.

16. LITIGATION

On June 19, 2007, Construction Laborers Pension Trust of Greater St. Louis filed a purported class action lawsuit in the United States District Court for the Southern District of California under the caption Construction Laborers Pension Trust of Greater St. Louis v. Neurocrine Biosciences, Inc., et al., 07-cv-1111-IEG-RBB. On June 26, 2007, a second purported class action lawsuit with similar allegations was also filed. On October 16, 2007, both lawsuits were consolidated into one purported class action under the caption In re Neurocrine Biosciences, Inc. Securities Litigation, 07-cv-1111-IEG-RBB. The court also selected lead plaintiffs and ordered them to file a consolidated complaint. On November 30, 2007, lead plaintiffs filed the Consolidated Amended Complaint (CAC), which alleged, among other things, that the Company and certain of its officers and directors violated federal securities laws by making allegedly false and misleading statements regarding the progress toward FDA approval and the potential for market success of indiplon in the 15 mg dosage unit. On January 11, 2008, the Company and the individual defendants filed a motion to dismiss the CAC. Following a hearing on April 22, 2008, the court granted the motion to dismiss but gave the lead plaintiffs leave to file an amended complaint. On June 11, 2008, the lead plaintiffs filed the Second Consolidated Amended Complaint (SAC). On July 8, 2008, the Company and the individual defendants filed a motion to dismiss the SAC. The court granted the motion to dismiss on September 23, 2008 but gave lead plaintiffs further leave to file a Third Consolidated Amended Complaint (TAC). On October 23, 2008, rather than filing a TAC, the lead plaintiffs filed a Notice of Election to Stand on the SAC, requesting that the court enter a final judgment dismissing the matter so that the lead plaintiffs could appeal to the Ninth Circuit Court of Appeals. The Company does not currently know if the lead plaintiffs intend to appeal within the 60 day time period, but if they do, the Company will vigorously oppose such appeal.

In addition, on June 25, 2007, a shareholder derivative complaint was filed in the Supreme Court of the State of California for the County of San Diego by Ralph Lipeles under the caption, Lipeles v. Lyons. The complaint was brought purportedly on the Company's behalf against certain current and former officers and directors and alleges, among other things, that the named officers and directors breached their fiduciary duties by directing us to make allegedly false statements about the progress toward FDA approval and the potential for market success of indiplon in the 15 mg dosage unit. All proceedings in this matter have been stayed pending final judgment in the federal securities class action.

The Company intends to take all appropriate action in responding to these matters. Due to the uncertainty of the ultimate outcome of these matters, the impact, if any, on the Company's future financial results is not subject to reasonable estimate as of September 30, 2008.

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17. SUBSEQUENT EVENTS

Auction Rate Securities

On October 7, 2008, UBS extended an offer of Auction Rate Securities Rights (ARS Rights) to holders of illiquid Auction Rate Securities (ARS) that were maintained by UBS as of February 13, 2008. The ARS Rights provide the holder with the ability to sell the ARS along with the ARS Rights to UBS, at the par value of the ARS, during an applicable exercise period. The ARS Rights grant UBS the sole discretion and right to sell or otherwise dispose of ARS without any 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 is scheduled to close on November 14, 2008.

The Company has \$14.6 million (par value) of ARS that are maintained by UBS. The Company has elected to participate in the ARS Rights program for all of its outstanding ARS maintained by UBS. Under the terms of the ARS Rights offer, the applicable exercise period for the Company 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 ARS, should a loan be needed. It is the Company's intention to sell the ARS and ARS Rights to UBS on June 30, 2010.

Property Consolidation

During the fourth quarter of 2008, the Company will complete the process of relocating all of its operations into the Rear Building. Upon completion of this relocation and certain other events, a cease-use date will occur as defined under the provisions of SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities. On that date, the Company will record a present value liability and a corresponding charge based on the remaining lease rentals offset by any potential sublease rentals and other costs that the Company anticipates it will incur to lease the Front Building. The Company is currently analyzing the impact that this cease-use date event will have on its financial statements.

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, 2007 and the three and six months ended March 31 and June 30, 2008 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2007 and our Quarterly Reports on Form 10-Q for the three and six months ended March 31 and June 30, 2008, 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, irritable bowel syndrome, anxiety, depression, pain, diabetes, insomnia and other neurological and endocrine-related diseases and disorders. 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 collaborations with pharmaceutical companies for two of our programs. Our lead clinical development program, elagolix, is a drug candidate for the treatment of endometriosis.

In December 2007, 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 125 employees. In connection with this restructuring, we recorded a one-time charge of approximately \$6.9 million in the fourth quarter of 2007, of which \$4.9 million was included in research and development expense and \$2.0 million was included in general and administrative expense. 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 first quarter of 2008. During the first nine months of 2008, we incurred an additional \$2.0 million charge (net) for severance related to certain executives and other personnel departing the Company. We expect this restructuring to reduce annual expenses by approximately \$19.0 million.

On February 27, 2008, we approved an employee retention program (Retention Program) to provide us with a mechanism to retain our non-officer and executive officer employees who were not subject to our December 2007 restructuring program. As part of the Retention Program, we approved a one-time cash retention payment totaling \$3.2 million, 60% of which was paid in the first quarter of 2008 and the remaining 40% of which is payable at the end of 2008, assuming such individual remains in good standing as an employee at such time. In addition, we approved the issuance of restricted stock units (RSUs) covering an aggregate of 1,203,000 shares and stock options covering an aggregate of 501,000 shares to our executive officers and certain employees, all of which were issued in the first quarter of 2008.

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During the fourth quarter, we will complete the process of relocating all of our operations into the Rear Building. Upon completion of this relocation and certain other events, a cease-use date will occur as defined under the provisions of SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities. On that date, we will record a present value liability and a corresponding charge based on the remaining lease rentals offset by any potential sublease rentals and other costs that we will incur to lease the Front Building. We are currently analyzing the impact that this a cease-use date event will have on our financial statements.

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 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 re