NEUROCRINE BIOSCIENCES INC
Form 10-Q
October 31, 2011

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2011

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	**33-0525145**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**
12780 El Camino Real, San Diego, California	**92130**
(Address of principal executive office)	**(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 x 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 x No ¨

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

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

The number of outstanding shares of the registrant s common stock, par value $0.001 per share, was 55,256,681 as of October 26, 2011.

NEUROCRINE BIOSCIENCES, INC.

FORM 10-Q INDEX

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share information)

(unaudited)

	September 30, 2011	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 39,516	$ 54,051
Short-term investments, available for sale	72,115	72,814
Receivables under collaboration agreements	22,397	4,470
Other current assets	2,098	1,716
Total current assets	136,126	133,051
Property and equipment, net	1,687	1,532
Long-term investments	5,087	3,739
Restricted cash	6,128	6,102
Total assets	$ 149,028	$ 144,424
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 766	$ 810
Accrued liabilities	7,562	8,603
Current portion of deferred revenues	35,493	37,026
Current portion of cease-use liability	1,604	3,385
Current portion of deferred gain on sale of real estate	3,019	2,953
Total current liabilities	48,444	52,777
Deferred revenues	10,907	37,162
Deferred gain on sale of real estate	24,771	27,046
Deferred rent	1,698	1,413
Cease-use liability	5,335	6,580
Other liabilities	124	101
Total liabilities	91,279	125,079
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 55,254,016 as of September 30, 2011 and 54,882,129 as of December 31, 2010	55	55
Additional paid-in capital	783,882	781,607
Accumulated other comprehensive loss	(159)	(48)
Accumulated deficit	(726,029)	(762,269)
Total stockholders equity	57,749	19,345

Total liabilities and stockholders equity	$ 149,028	$ 144,424

See accompanying notes to the condensed consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Revenues:				
Sponsored research and development	$ 2,396	$ 5,210	$ 8,589	$ 6,519
Milestones and license fees	39,238	9,238	57,714	13,325
Total revenues	41,634	14,448	66,303	19,844
Operating expenses:				
Research and development	7,456	8,227	22,949	23,086
General and administrative	3,825	3,635	9,790	9,950
Cease-use expense	(87)	120	89	401
Total operating expenses	11,194	11,982	32,828	33,437
Income (loss) from operations	30,440	2,466	33,475	(13,593)
Other income:				
Gain on sale/disposal of assets	86	34	184	202
Deferred gain on real estate	736	715	2,209	2,145
Investment income, net	102	118	341	732
Other income, net	18		31	59
Total other income	942	867	2,765	3,138
Net income (loss)	$ 31,382	$ 3,333	$ 36,240	$ (10,455)
Net income (loss) per common share:				
Basic	$ 0.57	$ 0.06	$ 0.66	$ (0.20)
Diluted	$ 0.56	$ 0.06	$ 0.64	$ (0.20)
Shares used in the calculation of net income (loss) per common share:				
Basic	55,248	54,844	55,148	52,130
Diluted	56,378	55,648	56,309	52,130

See accompanying notes to the condensed consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2011	**2010**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income (loss)	$ 36,240	$ (10,455)
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:		
Depreciation and amortization	552	1,131
Gain on sale of assets	(184)	(202)
Realized loss on sale of investments		186
Realized gain on sale of auction rate securities		(626)
Cease-use expense	89	401
Deferred revenues	(27,788)	71,662
Deferred gain on sale of real estate	(2,209)	(2,145)
Deferred rent	332	519
Amortization of premiums on investments	1,772	451
Non-cash share-based compensation expense	2,011	2,277
Change in operating assets and liabilities:		
Accounts receivable and other assets	(18,309)	(4,713)
Accounts payable and accrued liabilities	(1,085)	818
Cease-use liability	(3,162)	(3,397)
Other liabilities	23	(1,436)
Net cash (used in) provided by operating activities	(11,718)	54,471
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of investments	(104,186)	(58,592)
Sales and maturities of investments	101,654	22,807
Deposits and restricted cash	(26)	(8)
Proceeds from sales of property and equipment	187	242
Purchases of property and equipment	(710)	(303)
Net cash used in investing activities	(3,081)	(35,854)
CASH FLOWS FROM FINANCING ACTIVITIES		
Issuance of common stock	264	21,384
Net cash provided by financing activities	264	21,384
Net (decrease) increase in cash and cash equivalents	(14,535)	40,001
Cash and cash equivalents at beginning of the period	54,051	37,329
Cash and cash equivalents at end of the period	$ 39,516	$ 77,330

See accompanying notes to the condensed consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

1. ORGANIZATION AND SIGNIFICANT ACCOUNTING POLICIES

Description of Business. Neurocrine Biosciences, Inc. (the Company or Neurocrine) 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, stress-related disorders, pain, tardive dyskinesia, uterine fibroids, diabetes, insomnia and other neurological and endocrine-related diseases and disorders. While the Company independently develops many of its product candidates, Neurocrine has entered into collaborations for six of its programs. The Company s lead clinical development program, elagolix, is a drug candidate for the treatment of endometriosis and uterine fibroids.

Basis of Presentation. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) 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 GAAP for complete financial statements. In the opinion of management, the condensed consolidated financial statements include all adjustments necessary, which are of a normal and recurring nature, for the fair presentation of the Company s financial position and of the results of operations and cash flows for the periods presented. The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries.

These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2010 included in the Company s Annual Report on Form 10-K filed with the SEC. The results of operations for the interim period shown in this report are not necessarily indicative of the results that may be expected for any other interim period or for the full year. The balance sheet at December 31, 2010 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by GAAP for complete financial statements.

Impact of Recently Issued Accounting Standards. In October 2009, the Financial Accounting Standards Board (the FASB) issued an Accounting Standard Update which replaced the concept of allocating revenue consideration amongst deliverables in a multiple-element revenue arrangement according to fair value with an allocation based on selling price. The amended guidance also establishes a hierarchy for determining the selling price of revenue deliverables sold in multiple element revenue arrangements. The selling price used for each deliverable will be based on vendor-specific objective evidence (VSOE) if available, third-party evidence if VSOE is not available, or management s estimate of an element s stand-alone selling price if neither VSOE nor third-party evidence is available. The amendments in this update also require an allocation of selling price amongst deliverables be performed based upon each deliverable s relative selling price to total revenue consideration, rather than on the residual method previously permitted. The updated guidance is effective for the first annual reporting period beginning on or after June 15, 2010, and may be applied retrospectively for all periods presented or prospectively to arrangements entered into or materially modified after the adoption date. The Company prospectively adopted the updated guidance on January 1, 2011 and will apply the amended guidance to revenue arrangements containing multiple deliverables that are entered into or significantly modified on or after January 1, 2011. The Company now allocates revenue consideration, excluding contingent consideration, based on the relative selling prices of the separate units of accounting contained within an arrangement containing multiple deliverables. Selling prices are determined using fair value, when available, or the Company s estimate of selling price when fair value is not available for a given unit of accounting. As the Company did not enter into any new collaborations or materially modify any existing collaborations during the first nine months of the year, adoption of this guidance had no impact on the Company s results of operations for the three and nine months ended September 30, 2011.

Effective January 1, 2011, the Company adopted the FASB s revised authoritative guidance for research and development milestone recognition. The revised guidance is not required and does not represent the only acceptable method of revenue recognition. Milestones, as defined per the revised guidance, are (1) events that can only be achieved in whole or in part on either the entity s performance or on the occurrence of a specific outcome resulting in the entity s performance (2) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (3) that would result in additional payments being due to the Company. The Company evaluates events under this guidance at the inception of an arrangement to determine the existence of milestones and if they are substantive. The adoption of the revised guidance has not had, and is not expected to have, a material impact on the Company s results of operations as it is consistent with its historical practice of milestone revenue recognition.

In May 2011, the FASB issued updated accounting guidance related to fair value measurements and disclosures that result in common fair value measurements and disclosures between GAAP and International Financial Reporting Standards. This guidance includes amendments that clarify the intent about the application of existing fair value measurements and disclosures, and change a principle or requirement for fair value measurements or disclosures. This guidance is effective for interim and annual periods

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beginning after December 15, 2011. The Company does not believe the adoption of this guidance will have a material impact on its consolidated financial statements.

Research and Development Expense. Research and development (R&D) expense consists primarily of salaries, payroll taxes, employee benefits, and share-based compensation charges for those individuals involved in ongoing R&D efforts; as well as scientific contractor fees, preclinical and clinical trial costs, R&D facilities costs, laboratory supply costs, and depreciation of scientific equipment. All such costs are charged to R&D expense as incurred. 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, which 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 can be made of the costs applicable to various stages of a research agreement or clinical trial. 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 significant changes to the Company s results of operations.

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

2. SIGNIFICANT COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENTS

Revenue Recognition Policy. Revenues under collaborative 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. Prior to the revised multiple element guidance adopted by the Company on January 1, 2011, 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. If and when the Company enters into a new collaboration or materially modifies an existing collaboration, the Company will be required to apply the new multiple element guidance. 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.

Abbott International Luxembourg S.à r.l. In June 2010, the Company announced an exclusive worldwide collaboration with Abbott International Luxembourg S.à r.l. (Abbott) to develop and commercialize elagolix and all next-generation gonadotropin-releasing hormone (GnRH) antagonists (collectively GnRH Compounds) for women s and men s health. Under the terms of the Company s agreement with Abbott, the Company and Abbott will work jointly to advance GnRH Compounds towards commercialization. Abbott made an upfront payment of $75 million and agreed to make additional development and regulatory milestone payments of up to $480 million and up to an additional $50 million in commercial milestone payments. The Company has assessed milestones under the revised authoritative guidance for research and development milestones and determined that the milestone payments prior to commencement of a Phase III clinical study, as defined per the agreement, meet the definition of a milestone as they are 1) events that can only be achieved in part on the Company s past performance (2) there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (3) they result in additional payments being due to the Company. Development and regulatory milestones subsequent to the commencement of a Phase III clinical study, however, currently do not meet this criteria as their achievement is based on the performance of Abbott.

Under the terms of the agreement, Abbott is responsible for all third-party development, marketing and commercialization costs. The Company will receive funding for certain internal collaboration expenses which includes reimbursement from Abbott for internal and external expenses related to the GnRH Compounds, which reimbursement includes up to approximately $24 million in personnel funding through the end of 2012. The Company will be entitled to a percentage of worldwide sales of GnRH Compounds for the longer of ten years or the life of the related patent rights. Under the terms of the Company s agreement with Abbott, the collaboration effort between the parties to advance GnRH Compounds towards commercialization is governed by a joint development committee with representatives from both the Company and Abbott; provided, however, that final decision making authority rests with Abbott. Abbott may terminate the collaboration at its discretion upon 180 days written notice to the Company. In such event, the Company would be entitled to specified payments for ongoing clinical development and related activities and all GnRH Compound product rights would revert to the Company. The Company s participation in the joint development committee has been determined to be a substantive deliverable under the contract, and therefore, the upfront payment has been deferred and is being recognized over the estimated term of the joint development committee, which is expected to be through the end of 2012. During the three and nine months ended September 30, 2011, the Company recorded revenues of $7.3 million and $21.8 million in amortization of up-front license fees, respectively. The Company also recorded $2.1 million and $7.5 million in sponsored research and development related to the Abbott agreement during the three and nine months ended September 30, 2011, respectively. For the three and nine months ended September 30, 2011, the Company recognized $30.0 million in milestone revenue under the Abbott collaboration, $10.0 million of which was related to advancing elagolix into Phase II clinical trials in uterine fibroids and $20.0 million of which was related to the outcome of an elagolix pre- Phase

III meeting with the U.S. Food and Drug Administration (FDA) for endometriosis. There are no other milestones under the Abbott agreement that meet the definition of a milestone under the revised authoritative guidance for research and development milestones. At September 30, 2011 the Company had $36.3 million of deferred revenue related to the Abbott agreement, which is being amortized over the remaining collaborative development period.

Boehringer Ingelheim International GmbH. In June 2010, the Company announced a worldwide collaboration with Boehringer Ingelheim International GmbH (Boehringer Ingelheim) to research, develop and commercialize small molecule GPR119 agonists for the treatment of Type II diabetes and other indications. Under the terms of the Company s agreement with Boehringer Ingelheim, the Company and Boehringer Ingelheim are working jointly to identify and advance GPR119 agonist candidates into pre-clinical development. Boehringer Ingelheim will then be responsible for the global development and commercialization of potential GPR119 agonist products. The Company received a $10 million upfront payment, and is currently receiving research funding to support discovery efforts. Boehringer Ingelheim agreed to make additional preclinical milestone payments of up to approximately $3 million and clinical development and commercial milestone payments of up to approximately $223 million. The Company has assessed milestones under the revised authoritative guidance for research and development milestones and determined that the preclinical milestone payments, as defined per the agreement, meet the definition of a milestone as they are 1) events that can only be achieved in part on the Company s performance or upon the occurrence of a specific outcome resulting in the Company s performance (2) there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (3) they result in additional payments being due to the Company. Clinical development and commercial milestone payments, however, currently do not meet this criteria as their achievement is solely based on the performance of Boehringer Ingelheim. No milestone payments were recognized during the periods presented. The Company will be entitled to a percentage of any future worldwide sales of GPR119 agonists. Under the terms of the agreement, the collaboration effort between the parties to identify and advance GPR119 agonist candidates into pre-clinical development is governed by a steering committee with representatives from both the Company and Boehringer Ingelheim; provided, however, that final decision making authority rests with Boehringer Ingelheim. Boehringer Ingelheim may terminate the agreement at its discretion upon prior written notice to the Company. In such event, the Company may be entitled to specified payments and product rights would revert to the Company. The Company s participation in the steering committee has been determined to be a substantive deliverable under the contract, and therefore, the upfront payment has been deferred and is being recognized over the estimated term of the steering committee, which is expected to be through June 2012. During the three and nine months ended September 30, 2011, the Company recorded revenues of $1.3 million and $3.8 million in amortization of up-front license fees, respectively. The Company also recorded $0.2 million and $1.0 million in sponsored research and development related to the Boehringer Ingelheim agreement during the three and nine months ended September 30, 2011, respectively. In addition, at September 30, 2011, the Company had $3.5 million of deferred license fees related to the Boehringer Ingelheim agreement, which is being amortized over the remaining collaborative research period of the agreement.

3. INVESTMENTS

Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in comprehensive income (loss). 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 investment income.

Investments consist of the following (*in thousands*):

	September 30, 2011	December 31, 2010
Certificates of deposit	$ 2,400	$ 2,397
Commercial paper	13,447	27,650
Securities of government-sponsored entities		4,498
Corporate debt securities	61,355	42,008
Total investments	$ 77,202	$ 76,553

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

	Contractual Maturity (in years)	Amortized Cost	Gross Unrealized Gains(1)	Gross Unrealized Losses(1)	Aggregate Estimated Fair Value
September 30, 2011:					
Classified as current assets:					
Certificates of deposit	Less than 1	$ 2,400	$ 1	$ (1)	$ 2,400
Commercial paper	Less than 1	13,465	2	(20)	13,447
Corporate debt securities	Less than 1	56,403	6	(141)	56,268
Total short-term available-for-sale securities		$ 72,268	$ 9	$ (162)	$ 72,115
Classified as non-current assets:					
Corporate debt securities	1 to 2	$ 5,093	$	$ (6)	$ 5,087
December 31, 2010:					
Classified as current assets:					
Certificates of deposit	Less than 1	$ 2,160	$	$ (3)	$ 2,157
Commercial paper	Less than 1	27,657	1	(8)	27,650
Securities of government-sponsored entities	Less than 1	2,000		(2)	1,998
Corporate debt securities	Less than 1	41,047	5	(43)	41,009
Total short-term available-for-sale securities		$ 72,864	$ 6	$ (56)	$ 72,814
Classified as non-current assets:					
Certificates of deposit	1 to 2	$ 240	$	$	$ 240
Securities of government-sponsored entities	1 to 2	2,500			2,500
Corporate debt securities	1 to 2	997	2		999
Total long-term available-for-sale securities		$ 3,737	$ 2	$	$ 3,739

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

The following table presents information about available-for-sale securities 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
September 30, 2011:						
Certificates of deposit	$ 1,200	$ (1)	$	$	$ 1,200	$ (1)
Commercial paper	5,962	(20)			5,962	(20)
Corporate debt securities	57,866	(147)			57,866	(147)
Total	$ 65,028	$ (168)	$	$	$ 65,028	$ (168)

December 31, 2010:

Certificates of deposit	$ 2,157	$ (3)	$	$ 2,157	$ (3)
Commercial paper	25,150	(8)		25,150	(8)
Securities of government-sponsored entities	1,998	(2)		1,998	(2)
Corporate debt securities	35,166	(43)		35,166	(43)
Total	$ 64,471	$ (56)	$	$ 64,471	$ (56)

4. AUCTION RATE SECURITIES

During the nine months ended September 30, 2010, the Company sold or redeemed auction rate securities for approximately $16.4 million. As part of these sales, the Company recognized approximately $0.5 million in gains in the Company s condensed consolidated statement of operations for the nine months ended September 30, 2010.

5. FAIR VALUE MEASUREMENTS

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, 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 include quoted prices for similar instruments in active markets and/or quoted prices for identical or similar instruments in markets that are not active near the measurement date; 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 assets which are measured at fair value on a recurring basis as of September 30, 2011 and December 31, 2010 were determined using the inputs described above (*in millions*):

		Fair Value Measurements Using		
	Carrying Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
September 30, 2011:				
Cash and money market funds	$ 40.2	$ 40.2	$	$
Certificates of deposit	2.5		2.5	
Commercial paper	13.4		13.4	
Corporate bonds	66.7		66.7	
Total	122.8	40.2	82.6	
Less cash, cash equivalents and restricted cash	(45.6)	(40.2)	(5.4)	
Total investments	$ 77.2	$	$ 77.2	$
December 31, 2010:				
Cash and money market funds	$ 56.4	$ 56.4	$	$
Certificates of deposit	2.4		2.4	
Commercial paper	27.6		27.6	
Securities of government-sponsored entities	4.5		4.5	
Corporate bonds	45.8		45.8	
Total	136.7	56.4	80.3	
Less cash, cash equivalents and restricted cash	(60.2)	(56.4)	(3.8)	
Total investments	$ 76.5	$	$ 76.5	$

6. STOCKHOLDERS EQUITY AND SHARE-BASED COMPENSATION

In May 2011, the Company adopted the Neurocrine Biosciences, Inc. 2011 Equity Incentive Plan of (the 2011 Plan) pursuant to which 5,500,000 shares of Company common stock were reserved for future issuance. The 2011 Plan is the successor to the Company s 2003 Incentive Stock Plan, 2001 Stock Option Plan, 1997 Incentive Stock Plan, 1996 Director Stock Option Plan and 1992 Incentive Stock Plan (together, the Prior Plans). Although the Company no longer grants equity awards under the Prior Plans, all outstanding stock awards granted under the Prior Plans will continue to be subject to the terms and conditions as set forth in the agreements evidencing such stock awards and the terms of the Prior

Plans, as applicable.

The 2011 Plan provides for the grant of stock options that qualify as incentive stock options under Section 422 of the Internal Revenue Code of 1986, as amended (the Code), nonstatutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards and other forms of equity compensation, as well as performance cash awards.

Stock Option Assumptions

The Company granted stock options to purchase 1.6 million and 2.0 million shares of the Company s common stock during the nine months ended September 30, 2011 and 2010, respectively. The exercise price of all stock options granted during the nine months ended September 30, 2011 and 2010 was equal to the closing price of the Company s common stock on the date of grant. The estimated fair value of each stock option granted was determined on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions for the stock option grants during the three and nine months ended September 30, 2011 and 2010:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Risk-free interest rate	1.4%	1.4%	1.4%	2.2%
Expected volatility of common stock	81.8%	93.1%	82.1%	90.1%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Expected option term	6.3 years	4.5 years	6.2 years	4.6 years

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

Share-based Compensation Expense

The compensation expense related to the Company s share-based compensation arrangements has been included in the condensed consolidated statements of operations as follows (*in millions*):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
General and administrative	$ 0.7	$ 0.5	$ 1.3	$ 1.2
Research and development	0.2	0.4	0.7	$ 1.1
Total share-based compensation expense	$ 0.9	$ 0.9	$ 2.0	$ 2.3

As of September 30, 2011, total unrecognized estimated compensation cost related to non-vested stock options granted prior to that date was $7.6 million, which is expected to be recognized over a weighted average period of approximately 2.5 years. During the three months ended September 30, 2011, the Company recognized approximately $0.3 million of share-based compensation expense as a general and administrative expense in the Company s condensed consolidated statement of operations related to the separation of an executive officer.

Common Stock Activity

During the nine months ended September 30, 2011, stock options for approximately 0.1 million shares of the Company s common stock were exercised for cash of approximately $0.3 million. The Company issued approximately 0.3 million and 0.4 million shares of common stock pursuant to the vesting of restricted stock units during the nine months ended September 30, 2011 and 2010, respectively. Additionally, the Company granted 50,000 restricted stock units during the three and nine months ended September 30, 2011.

In March 2010, the Company completed a public offering of common stock in which the Company sold approximately 10.5 million shares of its common stock at an offering price of $2.20 per share. The net proceeds generated from this transaction, after underwriting discounts and commissions and offering costs, were approximately $21.4 million.

Committed Equity Financing Facility

In September 2009, the Company entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge) pursuant to which Kingsbridge committed to purchase, subject to certain conditions, up to the lesser of 7.8 million newly issued shares of the

Company s common stock or an aggregate of $75.0 million newly issued shares over the three-year term of the CEFF. The Company may access capital under the CEFF by making draw downs up to a maximum of the lesser of (i) $15 million and (ii) the greater of (x) 1.75% of its market capitalization as of the date of delivery of the draw down notice once per calendar quarter and up to 1.25% of its market capitalization as of the date of delivery of the draw down notice for any additional draw downs during such calendar quarter and (y) the lesser of (a) 2.75% of its market capitalization as of the date of delivery of the draw down notice and (b) a number of shares determined by a formula based in part on the average trading volume and trading price of the Company s common stock prior to the delivery of the draw down notice issued by the Company with respect to that draw down pricing period, subject to certain conditions, including a minimum share price threshold of $1.00. Kingsbridge may purchase shares of common stock pursuant to the CEFF at discounts ranging from 5 to 10 percent, depending on the average market price of the Company s common stock during the applicable pricing period for a draw down. The CEFF will expire on September 15, 2012 unless

otherwise terminated pursuant to the terms of the CEFF. As of September 30, 2011, the Company had not issued any shares under the CEFF.

7. REAL ESTATE

In December 2007, the Company closed the sale of its facility and associated real property for a purchase price of $109.0 million. Concurrent with the sale, the Company retired the entire $47.7 million in mortgage debt previously outstanding with respect to the facility and associated real property, and received cash of $61.0 million net of transaction costs and debt retirement. Upon the closing of the sale of the facility and associated real property, the Company entered into a lease agreement (Lease) with DMH Campus Investors, LLC (DMH) whereby it leased back, for an initial term of 12 years, its corporate headquarters comprised of two buildings located at 12790 El Camino Real (Front Building) and 12780 El Camino Real (Rear Building) in San Diego, California. The Company entered into a first lease amendment (First Lease Amendment) in December 2008 and a second lease amendment (Second Lease Amendment) in September 2009 (collectively, Amendments). The Lease has been characterized as an operating lease for financial reporting purposes.

Under the terms of the Lease and the Amendments, the Company pays base annual rent (subject to an annual fixed percentage increase), plus a 3.5% annual management fee, property taxes and other normal and necessary expenses associated with the Lease such as utilities, repairs and maintenance, etc. In lieu of a cash security deposit under the Lease, Wells Fargo Bank, N.A. issued on the Company s behalf a letter of credit in the amount of $5.7 million. The letter of credit is secured by a deposit of $6.3 million with the same bank. The Company has the right to extend the Lease for two consecutive ten-year terms and will have the first right of refusal to lease, at market rates, any facilities built on the vacant lot included in the real property sold by the Company. The terms of the Lease also require that the Company maintains $50.0 million in cash and investments at all times, or increase the security deposit by $5.0 million.

The Company initially deferred the gain on the sale of its facility and associated real property due to a repurchase right. The Company initially established a long-term liability of $108.7 million upon the close of the transaction, which represented the gross proceeds from the real estate sale. The First Lease Amendment terminated the repurchase right and the Company removed from its balance sheet the long-term liability of $108.7 million and the 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. The Company has recognized $0.7 million of the deferred gain per quarter in 2010 and 2011. During the nine months ended September 30, 2011 and 2010, the Company recognized $2.2 million and $2.1 million, respectively, of the deferred gain and will recognize the balance of the deferred gain over the remaining term of the Lease.

In December 2008, the Company entered into the First Lease Amendment which provided 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 continues to occupy the Rear Building except the portion of the Rear Building that is subleased as discussed below.

Pursuant to the terms of the First Lease Amendment, the Company is obligated to reimburse the landlord for the total cost of renovating a portion of the Front Building such that the Front Building becomes suitable for multiple tenant usage. The Company made a one-time payment of $1.0 million toward renovation costs in January 2009 and is reimbursing the landlord for the balance of the renovation costs over a four-year period through an increase in monthly rental payments (currently estimated at $108,000 per month) which began in October 2008. In September 2011, the Company and the Landlord determined the final total costs of the renovations. As a result, the Company reduced the total liability associated with the renovation costs by approximately $0.4 million. This expense reduction was recognized through the cease-use expense line item on the Company s condensed consolidated statement of operations, the same line as its original recording.

As a result of signing the First Lease Amendment and physically vacating the Front Building, the Company triggered a cease-use date for the Front Building and has estimated lease termination costs in accordance with authoritative guidance. Estimated lease termination costs for the Front Building under the First Lease Amendment included the net present value of future minimum lease payments, taxes, insurance, construction, and maintenance costs from the cease-use date to the end of the Lease, net of estimated sublease rental income. During the fourth quarter of 2008, the Company recorded an expense of $15.7 million for the net present value of these estimated lease termination costs. During 2009, the Company increased the liability by approximately $6.0 million in response to the declining economic conditions in San Diego by extending the expected period to sublease the Front Building.

In September 2009, the Company and DMH entered into the Second Lease Amendment. The Second Lease Amendment obligated the Company to vacate the Front Building and make an immediate payment of $4.0 million to DMH as an initial release fee, which was paid in October 2009. The Company continues to occupy the entire Rear Building except the portion of the Rear Building that is subleased as discussed below. Upon payment of the initial release fee, the Company was released from its obligations with respect to the Front Building, except with respect to 1) certain indemnity obligations for events prior to the payment of the initial release fee, 2) certain operating expenses for the Front Building in accordance with the terms of the Lease through July 2011, and 3) 50% of tenant improvement costs between $65 and $100 per square foot in connection with initial leases between DMH and other

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third parties for space in the Front Building. As of December 31, 2009, the Company had completely satisfied its obligation with respect to payment of tenant improvement costs. Pursuant to the Second Lease Amendment, the Company is also obligated to pay DMH an amount equivalent to the rent on the Front Building through July 2011 and then approximately $44,000 per month beginning in August 2011 through December 2019 as a rent differential payment for the Front Building, which such rent differential amounts may be prepaid by the Company in its sole discretion. Should the Company be in monetary default under the Lease beyond the normal cure periods and prior to repaying the entire rent differential balance, the rent differential payment will double. The Company made the first two $44,000 rent differential payments in August and September of 2011.

In December 2010, the Company concurrently entered into a sublease agreement (Sublease) for approximately 16,000 square feet of the Rear Building and triggered a cease-use date for the subleased space. The Sublease is expected to result in approximately $0.6 million of rental income per year over the three year term of the Sublease, with an option to extend for two one-year renewal periods. The income generated under the Sublease is lower than the Company s financial obligation under the Lease for the Rear Building with DMH as determined on a per square foot basis. Consequently, at December 31, 2010 the Company was required to record a cease-use liability for the net present value estimated difference between the expected income to be generated under the Sublease and future subleases and the Lease obligation over the remaining term of the Lease for the space that is occupied by the subtenant. This transaction resulted in approximately $2.5 million of cease-use expense, offset by a reversal of associated deferred rent of $0.2 million.

Additionally, in September 2011, the Company entered into a second sublease (the Second Sublease) for approximately 3,300 square feet of space in the Rear Building, triggering a cease-use expense of approximately $0.3 million, recorded as a separate line item on the Company s condensed consolidated statements of operations, offset by a reversal of associated deferred rent of $47,000. The Second Sublease is expected to result in approximately $0.1 million of rental income per year over the three year term of the Second Sublease. The Company has an option to extend the term of the Second Sublease for an additional twelve month renewal period.

The following table sets forth changes to the accrued cease-use liability during the three and nine months ended September 30, 2011 and 2010 as follows (*in thousands*):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Beginning balance	$ 7,708	$ 9,543	$ 9,965	$ 11,530
Accreted cease-use costs	63	120	239	401
Impact of Second Sublease cease-use charge (1)	324		324	
Change in estimate	(427)		(427)	
Payments	(729)	(1,129)	(3,162)	(3,397)
Ending balance	$ 6,939	$ 8,534	$ 6,939	$ 8,534

(1) Total cease-use expense was offset by the related adjustment to deferred rent of approximately $47,000.

8. SEPARATION AND TRANSITION AGREEMENT

On August 31, 2011, the Company entered into a Separation and Transition Agreement (the Agreement) with an executive officer of the Company. Pursuant to the Agreement, the Company recorded a one-time charge totaling approximately $1.0 million, which included $0.3 million in stock-based compensation related expense. This charge was included as a general and administrative expense in the Company s condensed consolidated statement of operations.

9. EARNINGS (LOSS) PER COMMON SHARE

The Company computes net income (loss) per share using the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share is computed by dividing the net income (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 and the vesting of RSUs, were excluded from historical diluted income per share because of their anti-dilutive effect. For the three and nine months ended September 30, 2011, the Company realized net income of $31.4 million and $36.2 million, respectively. This resulted in the addition of approximately 1.1 million of potentially dilutive securities, consisting of employee equity awards, to the total diluted shares outstanding used in the calculation of net income per common share for the applicable

periods. In addition, options to purchase approximately 1.4 million shares of common stock were outstanding during the three and nine months ended September 30, 2011 but were excluded from the computation of diluted earnings per share as the options exercise price was greater than the average market price of the common shares during the period.

10. COMPREHENSIVE INCOME (LOSS)

Comprehensive income (loss) includes the Company s net income (loss) and changes in equity during the period from transactions and other events and circumstances generated from non-owner sources. The Company s components of comprehensive income (loss) consist of the net income (loss) and unrealized gains and losses on available-for-sale investments. For the three months ended September 30, 2011 and 2010, comprehensive income was $31.2 million and $3.3 million, respectively. For the nine months ended September 30, 2011 and 2010, comprehensive income (loss) was $36.1 million and $(11.0) million, respectively.

11. INCOME TAXES

In January 2007, the Company adopted the provisions of the FASB s authoritative accounting guidance, which, among other things, related to uncertain tax provisions. Under the accounting guidance, 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. There were no unrecognized tax benefits as of the date of adoption. As a result of the implementation of the guidance, the Company did not recognize an increase in the liability for unrecognized tax benefits. There were no unrecognized tax benefits included in the Company s condensed consolidated balance sheet as of September 30, 2011 that would, if recognized, affect the Company s 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 condensed consolidated balance sheets at December 31, 2010 or at September 30, 2011, and has not recognized interest and/or penalties in the condensed consolidated statement of operations for the first nine months of 2011.

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 December 31, 2010, the Company had net deferred tax assets of $76.4 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 (IRC) Sections 382 and 383, as a result of ownership changes that could occur in the future. The Company completed the IRC Section 382 analysis through December 31, 2010 and concluded that an ownership change had not occurred through December 31, 2010. Although the Company determined that an ownership change had not occurred through December 31, 2010, it is possible that an ownership change occurred subsequent to that date. The Company is in the process of updating its IRC Section 382 analysis subsequent to December 31, 2010. Until this analysis has been completed, the Company has removed the deferred tax assets for net operating losses of $238.0 million and research and development credits of $40.7 million generated through 2010 from its deferred tax asset schedule and has recorded a corresponding decrease to its valuation allowance. Due to the existence of the full valuation allowance, future changes in the Company s unrecognized tax benefits will not impact the Company s effective tax rate. Any future ownership changes could limit the Company s ability to fully utilize net operating losses and research and development credit carryforwards.

12. SUBSEQUENT EVENTS

The Company has evaluated all subsequent events that have occurred after the date of the accompanying financial statements and determined that there were no events or transactions occurring during this subsequent event reporting period which require recognition or disclosure in the Company s 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, 2010 and the three and six months ended March 31, 2011 and June 30, 2011 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, 2010 and our Quarterly Report on Form 10-Q for the three and six months ended March 31, 2011 and June 30, 2011, 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, stress-related disorders, pain, tardive dyskinesia, uterine fibroids, diabetes, 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 collaboration 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 operating cash flow losses as product candidates are advanced through the various stages of clinical development. As of September 30, 2011, we had an accumulated deficit of $726.0 million and expect to incur operating cash flow losses for the foreseeable future, which may be greater than losses in prior years. We currently have eleven programs in various stages of research and development, including six programs in clinical development. While we independently develop several of our product candidates, we have entered into collaborations for six of our programs. Our lead clinical development program, elagolix, is a drug candidate for the treatment of endometriosis and uterine fibroids that is partnered with Abbott.

Abbott International Luxembourg S.à r.l. (Abbott). In June 2010, we announced an exclusive worldwide collaboration with Abbott to develop and commercialize elagolix and all next-generation gonadotropin-releasing hormone (GnRH) antagonists (collectively, GnRH Compounds) for women s and men s health. Under the terms of our agreement with Abbott, we and Abbott are working jointly to advance GnRH Compounds towards commercialization. Abbott made an upfront payment of $75 million and agreed to make additional development and regulatory milestone payments of up to $480 million and up to an additional $50 million in commercial milestone payments. We have assessed milestones under the revised authoritative guidance for research and development milestones and determined that the milestone payments prior to commencement of a Phase III clinical study, as defined per the agreement, meet the definition of a milestone as they are 1) events that can only be achieved in part on our past performance (2) there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (3) they result in additional payments being due to us. Development and regulatory milestones subsequent to the commencement of a Phase III clinical study, however, currently do not meet this criteria as their achievement is based on the performance of Abbott.

Under the terms of the agreement, Abbott is responsible for all development, marketing and commercialization costs. We will receive funding for certain internal collaboration expenses which include reimbursement from Abbott for internal and external expenses related to the GnRH Compounds, which reimbursement includes up to approximately $24 million in personnel funding through the end of 2012. We will be entitled to a percentage of worldwide sales of GnRH Compounds for the longer of ten years or the life of the related patent rights. Under the terms of our agreement with Abbott, the collaboration effort between the parties to advance the GnRH compounds toward commercialization is governed by a joint development committee with representatives from both Neurocrine and Abbott; provided, however, that final decision making authority rests with Abbott. Abbott may terminate the collaboration at its discretion upon 180 days written notice to us. In such event, we would be entitled to specified payments for ongoing clinical development and related activities and all GnRH Compound product rights would revert to us. During the three and nine months ended September 30, 2011 and 2010, revenues recorded related to the collaboration with Abbott were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
	(In millions)			
Revenues recognized under the Abbott collaboration agreement:				
Amortization of up-front license fees	$ 7.3	$ 7.3	$ 21.8	$ 9.6
Sponsored research and development	$ 2.1	$ 4.8	$ 7.5	$ 6.1
Milestones	$ 30.0	$	$ 30.0	$

We recognized $30.0 million in milestone revenue for the three and nine months ended September 30, 2011, $10.0 million of which was related to advancing elagolix into Phase II clinical trials in uterine fibroids and $20.0 million of which was related to the outcome of an elagolix pre-Phase III meeting with the U.S. Food and Drug Administration (FDA) for endometriosis. There are no other milestones under the Abbott agreement that meet the definition of a milestone under the revised authoritative guidance for research and development milestones. In addition, at September 30, 2011, we had $36.3 million of deferred revenue related to the Abbott agreement, which is being amortized over the remaining collaborative development period.

Boehringer Ingelheim International GmbH (Boehringer Ingelheim). In June 2010, we announced a worldwide collaboration with Boehringer Ingelheim to research, develop and commercialize small molecule GPR119 agonists for the treatment of Type II diabetes and other indications. Under the terms of the agreement, we and Boehringer Ingelheim are working jointly to identify and advance GPR119 agonist candidates into pre-clinical development. Boehringer Ingelheim will then be responsible for the global development and commercialization of potential GPR119 agonist products. We received a $10 million upfront payment, and we are currently receiving research funding to support discovery efforts. Boehringer Ingelheim agreed to make additional preclinical milestone payments of up to approximately $3 million and clinical development and commercial milestone payments of up to approximately $223 million. We have assessed the milestones under the revised authoritative guidance for research and development milestones and determined that the preclinical milestone payments, as defined per the agreement, meet the definition of a milestone as they are 1) events that can only be achieved in part on our performance or upon the occurrence of a specific outcome resulting in our performance (2) there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (3) they result in additional payments being due to us. Clinical development and commercial milestone payments, however, currently do not meet this criteria as their achievement is solely based on the performance of Boehringer Ingelheim. No milestone payments were recognized during the period. We will be entitled to a percentage of any future worldwide sales of GPR119 agonists resulting from the collaboration. Under the terms of the agreement, the collaboration effort between the parties to identify and advance GPR119 agonist candidates into pre-clinical development is governed by a steering committee with representatives from both Neurocrine and Boehringer Ingelheim; provided, however, that the final decision making authority rests with Boehringer Ingelheim. Boehringer Ingelheim may terminate the agreement at its discretion upon prior written notice to us. In such event, we may be entitled to specified payments and product rights would revert to us. During the three and nine months ended September 30, 2011 and 2010, revenues recorded related to the collaboration with Boehringer Ingelheim were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
	(In millions)			
Revenues recognized under the Boehringer Ingelheim collaboration agreement:				
Amortization of up-front license fees	$ 1.3	$ 1.2	$ 3.8	$ 1.5
Sponsored research and development	$ 0.2	$ 0.4	$ 1.0	$ 0.4

At September 30, 2011, we had $3.5 million of deferred license fees related to the Boehringer Ingelheim agreement, which is being amortized over the remaining collaborative research period.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our discussion and analysis of our financial condition and results of operations is based upon financial statements that have been 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), share-based compensation, lease related activities, 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:

Revenue Recognition. 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. Prior to the revised multiple element guidance we adopted on January 1, 2011, 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. If and when we enter into a new collaboration or materially modify an existing collaboration, we will be required to apply the new multiple element guidance. 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 Expense. Our research and development expenditures include costs related to preclinical and clinical trials, scientific personnel, equipment, consultants, sponsored research, share-based compensation and allocated facility costs. We do not track fully burdened research and development costs separately for each of our drug candidates. We review our research

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and development expenses by focusing on four categories: external development, personnel, facility and depreciation, and other. External development expenses consist of costs associated with our external preclinical and clinical trials, including pharmaceutical development and manufacturing. Personnel expenses include salaries and wages, share-based compensation, payroll taxes and benefits for those individuals involved in ongoing research and development efforts. Other research and development expenses mainly represent lab supply expenses, scientific consulting expenses and other expenses.

Asset Impairment. In accordance with authoritative guidance, 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.

Share-based Compensation. On May 25, 2011, we adopted the Neurocrine Biosciences, Inc. 2011 Equity Incentive Plan (the 2011 Plan) pursuant to which 5,500,000 shares of Company common stock were reserved for future issuance. The 2011 Plan is the successor to our 2003 Incentive Stock Plan, 2001 Stock Option Plan, 1997 Incentive Stock Plan, 1996 Director Stock Option Plan and 1992 Incentive Stock Plan (together, the Prior Plans). We grant stock options to purchase our common stock to our employees and directors under our 2011 Plan, and grant stock options to certain employees pursuant to Employment Commencement Nonstatutory Stock Option Agreements. We also grant certain employees stock bonuses and restricted stock units (RSUs) under the 2011 Plan. Additionally, we have outstanding stock options that were granted under the Prior Plans from which we no longer make grants. Share-based compensation expense was $0.9 million for each of the three months ended September 30, 2011 and 2010. For the nine months ended September 30, 2011 and 2010, share-based compensation expense was $2.0 million and $2.3 million, respectively. Stock option awards generally vest over a three year period and the related expense is ratably recognized over the same time period. 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 pursuant to authoritative guidance, and therefore individual share-based compensation awards may impact earnings disproportionately in any individual fiscal quarter.

We estimate the fair value of stock options and other equity-based compensation on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model incorporates various and highly sensitive assumptions, including, but not limited to, the expected term of the stock options, interest rates 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.

Authoritative guidance 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 stock options vest.

THREE MONTHS ENDED SEPTEMBER 30, 2011 AND 2010

Revenue

The following table summarizes our primary sources of revenue during the periods presented:

	Three Months Ended September 30,	
	2011	2010
	(In millions)	
Revenues under collaboration agreements:		
Abbott	$ 39.4	$ 12.1
Dainippon Sumitomo Pharma Co. Ltd. (DSP)	0.7	0.7
Boehringer Ingelheim	1.5	1.6
Total revenues	$ 41.6	$ 14.4

The $27.2 million increase in third quarter revenue from 2010 to 2011 was attributable to continued revenue recognition under our collaboration agreements with Abbott and Boehringer Ingelheim, for our GnRH (including elagolix) and GPR119 programs, respectively. Both of these collaboration agreements were entered into during June 2010. During the third quarter of 2011, we recognized $30.0 million in milestone revenue related to our collaboration agreement with Abbott, $10.0 million of which was related to advancing elagolix into Phase II clinical trials in uterine fibroids and $20.0 million of which was related to the outcome of an elagolix pre- Phase III meeting with the FDA for endometriosis. During the third quarter of both 2011 and 2010, we recognized

revenue of $8.6 million from the amortization of up-front license fees under these two agreements. Additionally, during the third quarter of 2011, we recognized $2.4 million in revenue from sponsored research and development reimbursement under these two agreements compared to $5.2 million during the same period in 2010.

Operating Expenses

Research and Development

Our research and development expenditures include costs related to preclinical and clinical trials, scientific personnel, equipment, consultants, sponsored research, share-based compensation and allocated facility costs. We do not track fully burdened research and development costs separately for each of our drug candidates. We review our research and development expenses by focusing on four categories: external development, personnel, facility and depreciation, and other. External development expenses consist of costs associated with our external preclinical and clinical trials, including pharmaceutical development and manufacturing. Personnel expenses include salaries and wages, share-based compensation, payroll taxes and benefits for those individuals involved in ongoing research and development efforts. Other research and development expenses mainly represent lab supply expenses, scientific consulting expenses and other expenses. We currently have eleven programs in various stages of research and development, including six programs in clinical development.

The following table presents our total research and development expenses by category during the periods presented:

	Three Months Ended September 30,	
	2011	2010
	(In millions)	
External development expense:		
Elagolix	$ 0.8	$ 1.9
VMAT2	1.0	0.6
Total external development expense	1.8	2.5
R&D personnel expense	2.9	3.2
R&D facility and depreciation expense	1.6	1.7
Other R&D expense	1.2	0.8
Total research and development expense	$ 7.5	$ 8.2

The $0.7 million decrease in research and development expense from 2010 to 2011 was primarily due to a decrease in our external development expenses as elagolix work continued to transition to Abbott. This was partially offset by an increase in our VMAT2 expenses related to continued Phase II development. Personnel expenses decreased primarily due to lower share-based compensation expense for the third quarter of 2011 as compared to the same period in 2010. Partially offsetting these decreases in personnel expense was an increase in our other R&D expense related to our scientific advisory board activity and scientific consultants utilized to advise us on multiple programs.

General and Administrative

General and administrative expenses increased to $3.8 million in the third quarter of 2011 compared with $3.6 million during the same period in 2010. The increase in expense can be primarily attributed to a $1.0 million charge related to a transition and severance agreement we entered into with an executive officer, offset by lower allocated facility costs of $0.3 million, and lower employee compensation costs of $0.6 million.

Net Income (Loss)

Our net income for the third quarter of 2011 was $31.4 million, or $0.56 per fully diluted share, compared to net income of $3.3 million, or $0.06 per fully diluted share, during the same period in 2010. The change in operating results from 2010 to 2011 was primarily a result of the revenue recognized under our collaboration agreements with Abbott and Boehringer Ingelheim.

NINE MONTHS ENDED SEPTEMBER 30, 2011 AND 2010

Revenue

The following table summarizes our primary sources of revenue during the periods presented:

	Nine Months Ended September 30,	
	2011	2010
	(In millions)	
Revenues under collaboration agreements:		
Abbott	$ 59.3	$ 15.7
Dainippon Sumitomo Pharma Co. Ltd. (DSP)	2.2	2.2
Boehringer Ingelheim	4.8	1.9
Total revenues	$ 66.3	$ 19.8

The $46.5 million increase in revenue for the nine months ended September 30, 2011 as compared to the same period in 2010 was due to continued revenue recognition under our collaboration agreements with Abbott and Boehringer Ingelheim, for our GnRH (including elagolix) and GPR119 programs, respectively. Both of these collaboration agreements were entered into during June 2010. During the nine months ended September 30, 2011, we recognized $30.0 million in milestone revenue related to our collaboration agreement with Abbott, $10.0 million of which was related to advancing elagolix into Phase II clinical trials in uterine fibroids and $20.0 million of which was related to the outcome of an elagolix pre- Phase III meeting with the FDA for endometriosis. During the nine months ended September 30, 2011, we recognized revenue of $25.6 million from the amortization of up-front license fees associated with the Abbott and Boehringer Ingelheim agreements compared to $11.1 million for the same period in 2010. Additionally, during the first nine months of 2011, we recognized $8.5 million resulting from sponsored research and development reimbursement under these two agreements compared to $6.5 million during the same period in 2010.

Operating Expenses

Research and Development

The following table presents our total research and development expenses by category during the periods presented:

	Nine Months Ended September 30,	
	2011	2010
	(In millions)	
External development expense:		
Elagolix	$ 3.4	$ 6.1
VMAT2	2.6	1.2
Total external development expense	6.0	7.3
R&D personnel expense	8.8	8.3
R&D facility and depreciation expense	4.8	5.3
Other R&D expense	3.3	2.2
Total research and development expense	$ 22.9	$ 23.1

The $0.2 million decrease in research and development expense from 2010 to 2011 was primarily due to a decrease in our external development expenses as elagolix work continued to transition to Abbott. This was partially offset by an increase in our VMAT2 expenses related to continued Phase II development. We also incurred additional personnel related expense due to increased research and development headcount. In addition, our other R&D expense increased due to scientific consultants utilized to advise us on multiple programs, coupled with increased

laboratory related costs for basic research.

General and Administrative

General and administrative expenses decreased to $9.8 million in the first nine months of 2011 compared with $10.0 million during the same period in 2010. The decrease in expense can be primarily attributed to lower allocated facility overhead costs due in part to subleasing activity. This decrease in expenses was partially offset by a charge related to a transition and severance agreement we entered into with an executive officer.

Other Income

Other income decreased to $2.8 million in the first nine months of 2011 compared with $3.1 million during the same period in 2010. The decrease in other income from 2010 to 2011 resulted primarily from a $0.5 million realized gain on the sale and redemption of auction rate securities during the first nine months of 2010.

Net Income (Loss)

Our net income for the first nine months of 2011 was $36.2 million, or $0.64 per fully diluted share, compared to a net loss of $10.5 million, or a loss of $0.20 per share, during the same period in 2010. The change in operating results from 2010 to 2011 was primarily a result of the revenue recognized under our collaboration agreements with Abbott and Boehringer Ingelheim.

LIQUIDITY AND CAPITAL RESOURCES

Net cash (used in) provided by operating activities during the first nine months of 2011 was $(11.7) million compared with $54.5 million during the same period in 2010. The $66.2 million decrease in cash flows from operating activities is primarily related to the $85 million in upfront license fees received under the Abbott and Boehringer Ingelheim collaboration agreements in 2010. This was partially offset by improved operating results of $46.7 million, of which $17.0 million of the change was related to non-cash deferred revenue, and $13.6 million of which was an increase in accounts receivable.

Net cash used in investing activities during the first nine months of 2011 was $3.1 million compared to $35.9 million for the same period in 2010. The fluctuation in net cash used in investing activities 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. Additionally, during the nine months ended September 30, 2011 and 2010, we purchased $0.7 million and $0.3 million, respectively, of new equipment.

Net cash provided by financing activities during the first nine months of 2011 was $0.3 million compared to $21.4 million during the same period in 2010. The $21.1 million decrease in cash provided by financing activities was primarily due to net proceeds of $21.4 million from our public offering of common stock in March 2010, offset by $0.3 million in option exercises in 2011.

At September 30, 2011, our cash, cash equivalents, and investments totaled $116.7 million compared with $130.6 million at December 31, 2010.

Equity Financing. In March 2010, we completed a public offering of common stock in which we sold approximately 10.5 million shares of our common stock at an offering price of $2.20 per share. The net proceeds generated from this transaction, after underwriting discounts and commissions and offering costs, were approximately $21.4 million.

Committed Equity Financing Facility. In September 2009, we entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge) pursuant to which Kingsbridge committed to purchase, subject to certain conditions, up to the lesser of 7.8 million newly issued shares of our common stock or an aggregate of $75.0 million newly issued shares over the three-year term of the CEFF. We may access capital under the CEFF by making draw downs up to a maximum of the lesser of (i) $15 million and (ii) the greater of (x) 1.75% of its market capitalization as of the date of delivery of the draw down notice once per calendar quarter and up to 1.25% of its market capitalization as of the date of delivery of the draw down notice for any additional draw downs during such calendar quarter and (y) the lesser of (a) 2.75% of its market capitalization as of the date of delivery of the draw down notice and (b) a number of shares determined by a formula based in part on the average trading volume and trading price of our common stock prior to the delivery of the draw down notice issued by us with respect to that draw down pricing period, subject to certain conditions, including a minimum share price threshold of $1.00. Kingsbridge may purchase shares of common stock pursuant to the CEFF at discounts ranging from 5 to 10 percent, depending on the average market price of our common stock during the applicable pricing period for a draw down. As of September 30, 2011, we had not issued any shares under the CEFF.

Shelf Registration Statement. In December 2010, the Securities and Exchange Commission (SEC) declared effective a shelf registration statement filed by us earlier that month. The shelf registration statement allows us to issue shares of our common stock from time to time for an aggregate initial offering price of up to $125 million. The specific terms of offerings, if any, under the shelf registration statement would be established at the time of such offerings.

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 may seek to access the public or private equity markets whenever conditions are favorable. For example, we have an effective shelf registration statement on file with the SEC which allows us to issue shares of our common stock from time to time for an aggregate initial offering price up to an additional $125 million. We may also seek additional funding through strategic alliances and other financing mechanisms such as our CEFF with Kingsbridge. We cannot assure you that adequate funding will be available on terms acceptable to us, if at all. Any additional equity financings will be dilutive to our stockholders and any additional debt may involve operating covenants that may restrict our business. If adequate funds are not available through these means, 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 cash flow losses from operations. We cannot assure you that we will successfully develop our products under development or that our products, if successfully developed, will generate revenues sufficient 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 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 average maturity of our investments does not exceed 36 months. If a 10% change in interest rates had occurred on September 30, 2011, 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 risk exposure.

NEW ACCOUNTING PRONOUNCEMENTS

In October 2009, the Financial Accounting Standards Board (the FASB) issued an Accounting Standard Update which replaces the concept of allocating revenue consideration amongst deliverables in a multiple-element revenue arrangement according to fair value with an allocation based on selling price. The amended guidance also establishes a hierarchy for determining the selling price of revenue deliverables sold in multiple element revenue arrangements. The selling price used for each deliverable will be based on vendor-specific objective evidence (VSOE) if available, third-party evidence if VSOE is not available, or management s estimate of an element s stand-alone selling price if neither VSOE nor third-party evidence is available. The amendments in this update also require an allocation of selling price amongst deliverables be performed based upon each deliverable s relative selling price to total revenue consideration, rather than on the residual method previously permitted. The updated guidance is effective for the first annual reporting period beginning on or after June 15, 2010, and may be applied retrospectively for all periods presented or prospectively to arrangements entered into or materially modified after the adoption date. We prospectively adopted the updated guidance on January 1, 2011 and will apply the amended guidance to revenue arrangements containing multiple deliverables that are entered into or significantly modified on or after January 1, 2011. We now allocate revenue consideration, excluding contingent consideration, based on the relative selling prices of the separate units of accounting contained within an arrangement containing multiple deliverables. Selling prices are determined using fair value, when available, or our estimate of selling price when fair value is not available for a given unit of accounting. As we did not enter into any new collaborations or materially modify any existing collaborations, adoption of this guidance had no impact on our results of operations for the three and nine months ended September 30, 2011.

Effective January 1, 2011, we adopted the FASB s revised authoritative guidance for research and development milestone recognition. The revised guidance is not required and does not represent the only acceptable method of revenue recognition. Milestones, as defined per the revised guidance, are (1) events that can only be achieved in whole or in part on either the entity s performance or on the occurrence of a specific outcome resulting in the entity s performance (2) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (3) that would result in additional payments being due to us. We evaluate events under this guidance at the inception of an arrangement to determine the existence of milestones and if they are substantive. The adoption of the revised guidance has not had and is not expected to have a material impact on our results of operations as it is consistent with its historical practice of milestone revenue recognition.

In May 2011, the FASB issued updated accounting guidance related to fair value measurements and disclosures that result in common fair value measurements and disclosures between GAAP and International Financial Reporting Standards. This guidance includes amendments that clarify the intent about the application of existing fair value measurements and disclosures, and change a principle or requirement for fair value measurements or disclosures. This guidance is effective for interim and annual periods beginning after December 15, 2011. We do not believe the adoption of this guidance will have a material impact on our consolidated financial statements.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains 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, inte estimates, could, should, would, continue, seeks, proforma, or anticipates, or other similar words (including their use in the negative 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 reports required by the Exchange Act of 1934, as amended, 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, 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.

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, 2010, 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

**** 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 U.S. Food and Drug Administration (FDA) or similar foreign regulatory authority may not approve an Investigational New Drug (IND) or foreign equivalent filings required to initiate human clinical studies for our drug candidates or may require additional time consuming pre-clinical studies prior to such approval;
- the product candidate may not prove to be effective or as effective as other competing product candidates;
- we may discover that a product candidate may cause harmful side effects;
- the results may not replicate the results of earlier, smaller trials;
- the FDA or similar foreign regulatory authorities may require use of new or experimental endpoints that may prove insensitive to treatment effects;
- 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.

These risks and uncertainties impact all of our clinical programs. Specifically, with respect to our GnRH program, any of the clinical, regulatory or operational events described above could delay timelines for the completion of our Phase III endometriosis program or our Phase II uterine fibroids program, completion of these programs and/or ultimate filings for regulatory approvals. Similarly, our VMAT2 inhibitor program and urocortin 2 programs may be delayed if any of the events above lead to delayed enrollment in, or completion of, the Phase II clinical trials of our lead candidates in those programs. Specifically, our VMAT2 inhibitor program will be delayed if the results of the Phase II study with our lead candidate (NBI-98854) do not support advancing the lead candidate to later stage clinical trials or if toxicology studies required by the FDA are not acceptable to the FDA. With respect to our lead Corticotropin Releasing Factor (CRF1) receptor antagonist 561679, while academic collaborative clinical trials are ongoing to evaluate its effects in post-traumatic stress disorder, anxiety and alcoholism, the top-line efficacy and safety results from a Phase II clinical trial utilizing 561679 in patients experiencing a major depressive episode revealed no benefit of 561679 compared with placebo. Uncertainty regarding future development of indiplon is described below under the risk factor entitled *There is uncertainty regarding future development of our product candidate, indiplon, which may never receive regulatory approval or be commercialized.*

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.

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. We have active collaboration agreements with Abbott International Luxembourg S.à r.l., Boehringer Ingelheim International GmbH, 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, and our recently executed collaboration agreements with Abbott and Boehringer Ingelheim provide for, among other things, significant future payments should certain development, regulatory and commercial milestones be achieved. 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 our current corporate collaborators and to enter into new collaborations in the future, the development and commercialization of our programs would be substantially delayed, and our ability to receive future funding would be substantially impaired 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.

Because the development of our product candidates is subject to a substantial degree of technological uncertainty, we may not succeed in developing any of our product candidates.

All of our product candidates are in research, clinical development or subject to review by the FDA. Only a small number of research and development programs ultimately result in commercially successful drugs. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons. These reasons include the possibilities that the potential products may:

be found ineffective or cause harmful side effects during preclinical studies or clinical trials;

fail to receive necessary regulatory approvals on a timely basis or at all;

be precluded from commercialization by proprietary rights of third parties;

be difficult to manufacture on a large scale; or

be uneconomical to commercialize or fail to achieve market acceptance.

If any of our products encounters any of these potential problems, we may never successfully market that product.

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 applications and enforcing or defending patent claims, if any, 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 to the full extent currently 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;
- the costs involved in filing and pursuing patent applications, enforcing patent claims, or engaging in interference proceedings or other patent litigation;
- 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 (SEC) which allows us to issue shares of our common stock from time to time for an aggregate initial offering price of up to $125 million, and we have a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge) covering the potential sale of shares of our common stock for up to $75 million in gross proceeds. In addition, we have previously financed capital purchases and may continue to pursue opportunities to obtain additional debt financing in the future. In the past few years, the credit markets and the financial services industry have experienced 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, including funds raised under the CEFF, will be dilutive to our stockholders and any additional debt financings may involve operating covenants that restrict our business.

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

Since our inception, we have incurred significant net losses, including net losses of $8.0 million and $51.0 million for the years ended December 31, 2010 and 2009, respectively. As a result of ongoing operating losses, we had an accumulated deficit of $726.0 million as of September 30, 2011. While we expect to be profitable for the year ending December 31, 2011, we do not expect to be operating cash flow positive in 2011 nor do we expect to remain profitable for the foreseeable future after 2011.

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 product candidates;

in-license or acquire new product development opportunities;

implement additional internal systems and infrastructure; and

hire additional clinical, scientific and marketing personnel.

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

The CEFF that we entered into with Kingsbridge may not be available to us if we elect to make a draw down, may require us to make additional blackout or other payments to Kingsbridge, could cause our stock price to decline and may result in dilution to our stockholders.

The CEFF entitles us to sell and obligates Kingsbridge to purchase, from time to time over a period of three years, newly issued shares of our common stock up to the lesser of an aggregate of approximately 7.8 million shares or $75 million, subject to certain conditions and restrictions. Kingsbridge will not be obligated to purchase shares under the CEFF unless certain conditions are met, which include a minimum price for our common stock; the accuracy of representations and warranties made to Kingsbridge; compliance with laws; effectiveness of the registration statement filed by us with the SEC with respect to the CEFF; and the continued listing of our stock on the Nasdaq Global Select Market or other specified markets. In addition, Kingsbridge is permitted to terminate the CEFF if it obtains actual knowledge that a material and adverse event has occurred affecting our business, operations, properties or financial condition. If we are unable to access funds through the CEFF, or if the CEFF is terminated by Kingsbridge, we may be unable to access capital on favorable terms or at all.

We are entitled, in certain circumstances, to deliver a blackout notice to Kingsbridge to suspend the registration statement filed by us with the SEC with respect to the CEFF and prohibit Kingsbridge from selling shares. If we deliver a blackout notice in the 15 calendar days following the settlement of a draw down, or if the registration statement is not effective in circumstances not permitted by the registration rights agreement, then we must make a payment to Kingsbridge, calculated on the basis of the number of shares held by Kingsbridge acquired by way of the most recent drawdown prior to the blackout notice and actually held by Kingsbridge multiplied by the change in the market price of our common stock during the period in which the use of the registration statement is suspended. If the trading price of our common stock declines during a suspension of the registration statement, the blackout or other payment could be significant.

Should we sell shares to Kingsbridge under the CEFF, or issue shares in lieu of a blackout payment, it will have a dilutive effect on the holdings of our current stockholders, and may result in downward pressure on the price of our common stock. If we draw down under the CEFF, we will issue shares to Kingsbridge at a discount of up to 10 percent from the volume weighted average price of our common stock. If we draw down amounts under the CEFF when our share price is decreasing, we will need to issue more shares to raise the same amount than if our stock price was higher. Issuances in the face of a declining share price will have an even greater dilutive effect than if our share price were stable or increasing, and may further decrease our share price.

There is uncertainty regarding future development of our product candidate, indiplon, which may never receive regulatory approval or be commercialized.

In December 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. We have not received the final minutes of this meeting. We continue to evaluate various alternatives for the indiplon program.

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 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.

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The price of our common stock is volatile.

The market prices for securities of biotechnology and pharmaceutical companies historically have been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Over the course of the last 12 months, the price of our common stock has ranged from approximately $5.00 per share to approximately $9.00 per share. The market price of our common stock may fluctuate in response to many factors, including:

- the results of our clinical trials;
- developments concerning new and existing collaboration agreements;
- announcements of technological innovations or new therapeutic products by us or others;
- general economic and market conditions;
- developments in patent or other proprietary rights;
- developments related to the FDA;
- future sales of our common stock by us or our stockholders (or Kingsbridge, if we elect to draw down under our CEFF with Kingsbridge);
- comments by securities analysts;
- fluctuations in our operating results;
- government regulation;
- health care reimbursement;
- failure of any of our product candidates, if approved, to achieve commercial success; and
- public concern as to the safety of our drugs.

Because our operating results may vary significantly in future periods, our stock price may decline.

Our quarterly revenues, expenses and operating results have fluctuated in the past and are likely to fluctuate significantly in the future. Our revenues are unpredictable and may fluctuate, among other reasons, due to our achievement of product development objectives and milestones, clinical trial enrollment and expenses, research and development expenses and the timing and nature of contract manufacturing and contract research payments. A high portion of our costs are predetermined on an annual basis, due in part to our significant research and development costs. Thus, small declines in revenue could disproportionately affect operating results in a quarter. Because of these factors, our operating

results in one or more future quarters may fail to meet the expectations of securities analysts or investors, which could cause our stock price to decline.

We license some of our core technologies and drug candidates from third parties. If we default on any of our obligations under those licenses, we could lose our rights to those technologies and drug candidates.

We are dependent on licenses from third parties for some of our key technologies. These licenses typically subject us to various commercialization, reporting and other obligations. If we fail to comply with these obligations, we could lose important rights. For example, we have licensed indiplon from DOV Pharmaceuticals, Inc. In addition, we license some of the core technologies used in our research and development activities and collaborations from third parties, including the CRF receptor we license from The Salk Institute and use in our CRF_1 program, urocortin 2 which we license from Research Development Foundation, and the GnRH receptor we license from Mount Sinai School of Medicine and use in our elagolix program. If we were to default on our obligations under any of our licenses, we could lose some or all of our rights to develop, market and sell products covered by these licenses. Likewise, if we were to lose our rights under a license to use proprietary research tools, it could adversely affect our existing collaborations or adversely affect our ability to form new collaborations. We also face the risk that our licensors could, for a number of reasons, lose patent protection or lose their rights to the technologies we have licensed, thereby impairing or extinguishing our rights under our licenses with them.

We have limited marketing experience, sales force or distribution capabilities, and if our products are approved, we may not be able to commercialize them successfully.

Although we do not currently have any marketable products, our ability to produce revenues ultimately depends on our ability to sell our products if and when they are approved by the FDA. We currently have limited experience in marketing and selling pharmaceutical products. If we fail to establish successful marketing and sales capabilities or fail to enter into successful marketing arrangements with third parties, our product revenues will suffer.

The independent clinical investigators and contract research organizations that we rely upon to conduct our clinical trials may not be diligent, careful or timely, and may make mistakes, in the conduct of our trials.

We depend on independent clinical investigators and contract research organizations (CROs) to conduct our clinical trials under their agreements with us. The investigators are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If independent investigators fail to devote sufficient time and resources to our drug development programs, or if their performance is substandard, it may delay or prevent the approval of our FDA applications and our introduction of new drugs. The CROs we contract with for execution of our clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Failure of the CROs to meet their obligations could adversely affect clinical development of our products. Moreover, these independent investigators and CROs may also have relationships with other commercial entities, some of which may compete with us. If independent investigators and CROs assist our competitors at our expense, it could harm our competitive position.

We have no manufacturing capabilities. If third-party manufacturers of our product candidates fail to devote sufficient time and resources to our concerns, or if their performance is substandard, our clinical trials and product introductions may be delayed and our costs may rise.

We have in the past utilized, and intend to continue to utilize, third-party manufacturers to produce the drug compounds we use in our clinical trials and for the potential commercialization of our future products. We have no experience in manufacturing products for commercial purposes and do not currently have any manufacturing facilities. Consequently, we depend on, and will continue to depend on, several contract manufacturers for all production of products for development and commercial purposes. If we are unable to obtain or retain third-party manufacturers, we will not be able to develop or commercialize our products. The manufacture of our products for clinical trials and commercial purposes is subject to specific FDA regulations. Our third-party manufacturers might not comply with FDA regulations relating to manufacturing our products for clinical trials and commercial purposes or other regulatory requirements now or in the future. Our reliance on contract manufacturers also exposes us to the following risks:

- contract manufacturers may encounter difficulties in achieving volume production, quality control and quality assurance, and also may experience shortages in qualified personnel. As a result, our contract manufacturers might not be able to meet our clinical schedules or adequately manufacture our products in commercial quantities when required;

- switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly on acceptable terms, or at all;

- our contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store or distribute our products; and

- drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the U.S. Drug Enforcement Administration, and other agencies to ensure strict compliance with good manufacturing practices and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers compliance with these regulations and standards.

Our current dependence upon third parties for the manufacture of our products may harm our profit margin, if any, on the sale of our future products and our ability to develop and deliver products on a timely and competitive basis.

If we are unable to retain and recruit qualified scientists or if any of our key senior executives discontinues his or her employment with us, it may delay our development efforts.

We are highly dependent on the principal members of our management and scientific staff. The loss of any of these people could impede the achievement of our development objectives. Furthermore, recruiting and retaining qualified scientific personnel to perform research and development work in the future is critical to our success. We may be unable to attract and retain personnel on acceptable terms given the competition among biotechnology, pharmaceutical and health care companies, universities and non-profit research institutions for experienced scientists. In addition, we rely on a significant number of consultants to assist us in formulating our research and development strategy. Our consultants may have commitments to, or advisory or consulting agreements with, other entities that may limit their availability to us.

We may be subject to claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is commonplace in the biotechnology industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Governmental and third-party payors may impose sales and pharmaceutical pricing controls on our products that could limit our product revenues and delay sustained profitability.

The continuing efforts of government and third-party payors to contain or reduce the costs of health care through various means may reduce our potential revenues. These payors efforts could decrease the price that we receive for any products we may develop and sell in the future. In addition, third-party insurance coverage may not be available to patients for any products we develop. If government and third-party payors do not provide adequate coverage and reimbursement levels for our products, or if price controls are enacted, our product revenues will suffer.

If physicians and patients do not accept our products, we may not recover our investment.

The commercial success of our products, if they are approved for marketing, will depend upon the acceptance of our products as safe and effective by the medical community and patients.

The market acceptance of our products could be affected by a number of factors, including:

- the timing of receipt of marketing approvals;
- the safety and efficacy of the products;
- the success of existing products addressing our target markets or the emergence of equivalent or superior products; and
- the cost-effectiveness of the products.

In addition, market acceptance depends on the effectiveness of our marketing strategy, and, to date, we have very limited sales and marketing experience or capabilities. If the medical community and patients do not ultimately accept our products as being safe, effective, superior and/or cost-effective, we may not recover our investment.

Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and NASDAQ rules, are creating uncertainty for companies such as ours. These laws, regulations and standards are subject to varying interpretations in some cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, our efforts to comply with evolving laws, regulations and standards have resulted in, and are likely to continue to result in, increased general and administrative expenses and management time related to compliance activities. In particular, our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 and the related regulations regarding our required assessment of our internal controls over financial reporting requires, and we expect to continue to require, the commitment of significant financial and managerial resources. If we fail to comply with these laws, regulations and standards, our reputation may be harmed and we might be subject to sanctions or investigation by regulatory authorities, such as the SEC. Any such action could adversely affect our financial results and the market price of our common stock.

Risks Related to Our Industry

We may not receive regulatory approvals for our product candidates or approvals may be delayed.

Regulation by government authorities in the United States and foreign countries is a significant factor in the development, manufacture and marketing of our proposed products and in our ongoing research and product development activities. Any failure to receive the regulatory approvals necessary to commercialize our product candidates would harm our business. The process of obtaining these approvals and the subsequent compliance with federal and state statutes and regulations require spending substantial time and financial resources. If we fail or our collaborators or licensees fail to obtain or maintain, or encounter delays in obtaining or maintaining, regulatory approvals, it could adversely affect the marketing of any products we develop, our ability to receive product or royalty revenues, our recovery of prepaid royalties, and our liquidity and capital resources. All of our products are in research and development, and we have not yet received regulatory approval to

commercialize any product from the FDA or any other regulatory body. In addition, we have limited experience in filing and pursuing applications necessary to gain regulatory approvals, which may impede our ability to obtain such approvals.

In particular, human therapeutic products are subject to rigorous preclinical testing and clinical trials and other approval procedures of the FDA and similar regulatory authorities in foreign countries. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertising, promotion, sale and distribution of biopharmaceutical products. Securing FDA approval requires the submission of extensive preclinical and clinical data and supporting information to the FDA for each indication to establish the product candidate s safety and efficacy. The approval process may take many years to complete and may involve ongoing requirements for post-marketing studies. Any FDA or other

regulatory approval of our product candidates, once obtained, may be withdrawn. If our potential products are marketed abroad, they will also be subject to extensive regulation by foreign governments.

Health care reform measures could adversely affect our business.

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payers to contain or reduce the costs of health care. In the United States, comprehensive health care reform legislation was enacted by the Federal government and we expect that there will continue to be a number of federal and state proposals to implement government control over the pricing of prescription pharmaceuticals. In addition, increasing emphasis on reducing the cost of health care in the United States will continue to put pressure on the rate of adoption and pricing of prescription pharmaceuticals. Moreover, in some foreign jurisdictions, pricing of prescription pharmaceuticals is already subject to government control. We are currently unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect the recently enacted Federal healthcare reform legislation or any such additional legislation or regulation would have on our business. The pendency or approval of such proposals or reforms could result in a decrease in our stock price or limit our ability to raise capital or to enter into collaboration agreements for the further development and commercialization of our programs and products.

We face intense competition, and if we are unable to compete effectively, the demand for our products, if any, may be reduced.

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition in the development and marketing of our product candidates from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies.

Competition may also arise from, among other things:

- other drug development technologies;
- methods of preventing or reducing the incidence of disease, including vaccines; and
- new small molecule or other classes of therapeutic agents.

Developments by others may render our product candidates or technologies obsolete or noncompetitive.

We are performing research on or developing products for the treatment of several disorders including endometriosis, stress-related disorders, pain, diabetes, insomnia, and other neurological and endocrine-related diseases and disorders, and there are a number of competitors to products in our research pipeline. If one or more of our competitors products or programs are successful, the market for our products may be reduced or eliminated.

Compared to us, many of our competitors and potential competitors have substantially greater:

- capital resources;
- research and development resources, including personnel and technology;
- regulatory experience;
- preclinical study and clinical testing experience;

manufacturing and marketing experience; and

production facilities.

If we are unable to protect our intellectual property, our competitors could develop and market products based on our discoveries, which may reduce demand for our products.

Our success will depend on our ability to, among other things:

obtain patent protection for our products;

preserve our trade secrets;

prevent third parties from infringing upon our proprietary rights; and

operate without infringing upon the proprietary rights of others, both in the United States and internationally.

Because of the substantial length of time and expense associated with bringing new products through the development and regulatory approval processes in order to reach the marketplace, the pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Accordingly, we intend to seek patent protection for our proprietary technology and compounds. However, we face the risk that we may not obtain any of these patents and that the breadth of claims we obtain, if any, may not provide adequate protection of our proprietary technology or compounds.

We also rely upon unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, through confidentiality agreements with our commercial collaborators, employees and consultants. We also have invention or patent assignment agreements with our employees and some, but not all, of our commercial collaborators and consultants. However, if our employees, commercial collaborators or consultants breach these agreements, we may not have adequate remedies for any such breach, and our trade secrets may otherwise become known or independently discovered by our competitors.

In addition, although we own a number of patents, the issuance of a patent is not conclusive as to its validity or enforceability, and third parties may challenge the validity or enforceability of our patents. We cannot assure you how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court or in other proceedings. It is possible that a competitor may successfully challenge our patents or that challenges will result in limitations of their coverage. Moreover, competitors may infringe our patents or successfully avoid them through design innovation. To prevent infringement or unauthorized use, we may need to file infringement claims, which are expensive and time-consuming. In addition, in an infringement proceeding a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. Interference proceedings declared by the United States Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patent applications or those of our licensors. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and be a distraction to management. We cannot assure you that we will be able to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

The technologies we use in our research as well as the drug targets we select may infringe the patents or violate the proprietary rights of third parties.

We cannot assure you that third parties will not assert patent or other intellectual property infringement claims against us or our collaborators with respect to technologies used in potential products. If a patent infringement suit were brought against us or our collaborators, we or our collaborators could be forced to stop or delay developing, manufacturing or selling potential products that are claimed to infringe a third party s intellectual property unless that party grants us or our collaborators rights to use its intellectual property. In such cases, we could be required to obtain licenses to patents or proprietary rights of others in order to continue to commercialize our products. However, we may not be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all. Even if our collaborators or we were able to obtain rights to the third party s intellectual property, these rights may be non-exclusive, thereby giving our competitors access to the same intellectual property. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations as a result of patent infringement claims, which could severely harm our business.

We face potential product liability exposure far in excess of our limited insurance coverage.

The use of any of our potential products in clinical trials, and the sale of any approved products, may expose us to liability claims. These claims might be made directly by consumers, health care providers, pharmaceutical companies or others selling our products. We have obtained limited product liability insurance coverage for our clinical trials in the amount of $10 million per occurrence and $10 million in the aggregate. However, our insurance may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, juries have awarded large judgments in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us would decrease our cash reserves and could cause our stock price to fall.

Our activities involve hazardous materials, and we may be liable for any resulting contamination or injuries.

Our research activities involve the controlled use of hazardous materials. We cannot eliminate the risk of accidental contamination or injury from these materials. If an accident occurs, a court may hold us liable for any resulting damages, which may harm our results of operations and cause us to use a substantial portion of our cash reserves, which would force us to seek additional financing.

ITEM 6. EXHIBITS

3.1	Restated Certificate of Incorporation. (1)
3.2	Certificate of Amendment to Certificate of Incorporation. (2)
3.3	Bylaws. (1)
3.4	Certificate of Amendment of Bylaws. (3)
3.5	Certificate of Amendment of Bylaws. (4)
3.6	Certificate of Amendment of Bylaws. (5)
4.1	Form of Common Stock Certificate. (1)
10.1*	Transition and Separation Agreement dated August 31, 2011 between the Company and Margaret E. Valeur-Jensen, Ph.D., J.D.
10.2**	First Amendment to Collaboration and License Agreement dated August 31, 2011 between the Company and Abbott International Luxembourg S.à r.l.
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934.
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934.
32***	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS****	XBRL Instance Document.
101.SCH****	XBRL Taxonomy Extension Schema Document.
101.CAL****	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF****	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB****	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE****	XBRL Taxonomy Extension Presentation Linkbase Document.

(1) Incorporated by reference to the Company s Registration Statement on Form S-1 (Registration No. 333-03172)
(2) Incorporated by reference to the Company s Quarterly Report on Form 10-Q filed on August 9, 2006
(3) Incorporated by reference to the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 1997 filed on April 10, 1998
(4) Incorporated by reference to the Company s Quarterly Report on Form 10-Q filed on August 9, 2004
(5) Incorporated by reference to the Company s Current Report on Form 8-K filed on February 9, 2010
* Indicates management contract or compensatory plan or arrangement.
** Confidential treatment has been requested with respect to certain portions of the exhibit.
*** These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of Neurocrine Biosciences, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.
**** Pursuant to applicable securities laws and regulations, we are deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and are not subject to liability under any anti-fraud provisions of the federal securities laws as long as we have made a good faith attempt to comply with the submission requirements and promptly amend the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. Users of this data are advised that, pursuant to Rule 406T, these interactive data files are deemed not filed and otherwise are not subject to liability.

The Company s Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, listed above, have a Commission File number of 000-22705.

SIGNATURES

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Dated: October 31, 2011

/s/ Timothy P. Coughlin
Timothy P. Coughlin
Vice President and Chief Financial Officer
(Duly authorized officer and Principal Financial Officer)