NEUROCRINE BIOSCIENCES INC
Form 10-Q
October 29, 2013
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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, 2013

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 67,343,394 as of October 23, 2013.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share information)

(unaudited)

	September 30, 2013	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$ 34,889	$ 63,754
Short-term investments, available for sale	122,022	109,259
Receivables under collaboration agreements	75	14,089
Other current assets	2,232	2,162
Total current assets	159,218	189,264
Property and equipment, net	1,739	1,900
Long-term investments	675	480
Restricted cash	4,335	4,335
Total assets	$ 165,967	$ 195,979
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,097	$ 911
Accrued liabilities	7,882	8,094
Current portion of deferred revenues	730	2,919
Current portion of cease-use liability	409	589
Current portion of deferred gain on sale of real estate	3,203	3,133
Total current liabilities	13,321	15,646
Deferred gain on sale of real estate	18,458	20,872
Deferred rent	1,955	1,840
Cease-use liability	2,789	3,097
Other liabilities	152	152
Total liabilities	36,675	41,607
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 67,343,207 as of September 30, 2013 and 66,446,888 as of December 31, 2012	67	66
Additional paid-in capital	884,355	873,981
Accumulated other comprehensive loss	(9)	(2)
Accumulated deficit	(755,121)	(719,673)

Total stockholders equity	129,292	154,372
Total liabilities and stockholders equity	$ 165,967	$ 195,979

See accompanying notes to the condensed consolidated financial statements.

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NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands, except per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Revenues:				
Sponsored research and development	$	$ 1,369	$	$ 4,938
License fees	729	7,988	2,189	26,255
Total revenues	729	9,357	2,189	31,193
Operating expenses:				
Research and development	9,490	9,860	30,330	28,066
General and administrative	3,245	3,324	10,007	10,126
Cease-use expense		135		135
Total operating expenses	12,735	13,319	40,337	38,327
Loss from operations	(12,006)	(3,962)	(38,148)	(7,134)
Other income:				
Gain on sale/disposal of assets	6		38	25
Deferred gain on real estate	781	759	2,344	2,276
Investment income, net	93	123	317	359
Other (loss) income, net	(5)	2	1	9
Total other income	875	884	2,700	2,669
Net loss	$ (11,131)	$ (3,078)	$ (35,448)	$ (4,465)
Net loss per common share:				
Basic and diluted	$ (0.17)	$ (0.05)	$ (0.53)	$ (0.07)
Shares used in the calculation of net loss per common share:				
Basic and diluted	67,199	66,342	66,868	65,355
Other comprehensive loss:				
Net loss	$ (11,131)	$ (3,078)	$ (35,448)	$ (4,465)
Net unrealized gains (losses) on available-for-sale securities	35	162	(7)	106
Comprehensive loss	$ (11,096)	$ (2,916)	$ (35,455)	$ (4,359)

See accompanying notes to the condensed consolidated financial statements.

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NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2013	**2012**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (35,448)	$ (4,465)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	515	481
Gain on sale of assets	(2,382)	(2,301)
Cease-use expense		135
Deferred revenues	(2,189)	(26,256)
Deferred rent	115	238
Amortization of premiums on investments	2,108	2,480
Non-cash share-based compensation expense	5,123	4,169
Change in operating assets and liabilities:		
Receivables under collaboration agreements and other assets	13,944	(684)
Accounts payable and accrued liabilities	(26)	(16)
Cease-use liability	(488)	(193)
Other liabilities		27
Net cash used in operating activities	(18,728)	(26,385)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of investments	(130,379)	(139,505)
Sales and maturities of investments	115,306	77,789
Proceeds from sales of property and equipment	38	25
Deposits and restricted cash		(28)
Purchases of property and equipment	(354)	(929)
Net cash used in investing activities	(15,389)	(62,648)
CASH FLOWS FROM FINANCING ACTIVITIES		
Issuance of common stock	5,252	83,414
Net cash provided by financing activities	5,252	83,414
Net decrease in cash and cash equivalents	(28,865)	(5,619)
Cash and cash equivalents at beginning of the period	63,754	50,107
Cash and cash equivalents at end of the period	$ 34,889	$ 44,488

See accompanying notes to the condensed consolidated financial statements.

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NEUROCRINE BIOSCIENCES, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

1. ORGANIZATION AND SIGNIFICANT ACCOUNTING POLICIES

Description of Business. Neurocrine Biosciences, Inc. (the Company or Neurocrine) is a clinical stage drug discovery company primarily focused on neurological and endocrine based diseases and disorders. The Company discovers and develops innovative pharmaceuticals, in diseases with high unmet medical needs or where the existing drug classes are inadequate, through a disciplined yet entrepreneurial process. Utilizing a portfolio approach to drug discovery, the Company has multiple small molecule drug candidates at various stages of pharmaceutical development. The Company develops proprietary pharmaceuticals for its pipeline, as well as collaborating with other pharmaceutical companies on its discoveries. The Company s two lead late stage clinical programs are elagolix, a GnRH antagonist for women s health that is partnered with AbbVie Inc., and a wholly owned VMAT2 inhibitor for the treatment of movement disorders.

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 subsidiary.

These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2012 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, 2012 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 February 2013, the Financial Accounting Standards Board amended the disclosure requirements regarding the reporting of amounts reclassified out of accumulated other comprehensive income. The amendment does not change the current requirement for reporting net income or other comprehensive income, but requires additional disclosures about significant amounts reclassified out of accumulated other comprehensive income including the effect of the reclassification on the related net income line items. This amendment was adopted prospectively by the Company effective January 1, 2013 and is not expected to have a significant impact on the Company s financial statements as the requirements are disclosure only in nature.

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. REVENUE RECOGNITION AND 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 were 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 agreement or materially modifies an existing collaboration agreement, 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.

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AbbVie Inc. (AbbVie). In June 2010, the Company announced an exclusive worldwide collaboration with AbbVie to develop and commercialize elagolix and all next-generation gonadotropin-releasing hormone (GnRH) antagonists (collectively, GnRH Compounds) for women s and men s health. AbbVie made an upfront payment of $75 million and has agreed to make additional development and regulatory event based payments of up to $480 million and up to an additional $50 million in commercial event based payments. The Company has assessed event based payments under the revised authoritative guidance for research and development milestones and determined that event based payments prior to commencement of a Phase III clinical study, as defined in the agreement, meet the definition of a milestone in accordance with authoritative guidance as (1) they are events that can only be achieved in part on the Company s past performance, (2) there is substantive uncertainty at the date the arrangement was entered into that the event will be achieved and (3) they result in additional payments being due to the Company. Development and regulatory event based payments subsequent to the commencement of a Phase III clinical study, however, currently do not meet these criteria as their achievement is based on the performance of AbbVie. No milestone payments were recognized during the periods presented.

Under the terms of the agreement, AbbVie is responsible for all third-party development, marketing and commercialization costs. The Company received funding for certain internal collaboration expenses, which included reimbursement from AbbVie for internal and external expenses related to the GnRH Compounds, 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 AbbVie, the collaboration effort between the parties to advance GnRH Compounds towards commercialization was governed by a joint development committee with representatives from both the Company and AbbVie. The Company s participation in the joint development committee was determined to be a substantive deliverable under the contract, and therefore, the upfront payment was deferred and recognized over the term of the joint development committee, which was completed, as scheduled, in December 2012. AbbVie 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.

During the three and nine months ended September 30, 2013 and 2012, revenues recognized under the collaboration agreement with AbbVie were as follows (*in millions*):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Amortization of up-front license fees	$	$ 7.3	$	$ 21.8
Sponsored research and development		1.4	$	$ 4.0
Revenues recognized under the AbbVie collaboration agreement	$	$ 8.7	$	$ 25.8

Boehringer Ingelheim International GmbH (Boehringer Ingelheim). In June 2010, the Company 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 Company s agreement with Boehringer Ingelheim, the Company and Boehringer Ingelheim worked jointly, during a two year collaborative research period which ended in June 2012, to identify and advance GPR119 agonist candidates into preclinical development. Following the collaborative research period, Boehringer Ingelheim is responsible for the global development and commercialization of potential GPR119 agonist products, if any. The Company received a $10 million upfront payment, and received research funding to support discovery efforts. Boehringer Ingelheim agreed to make payments of up to approximately $3 million in additional preclinical milestone payments and payments of up to approximately $223 million in clinical development and commercial event based payments. The Company has assessed milestones under the revised authoritative guidance for research and development milestones and determined that the preclinical milestone payments, as defined in the agreement, meet the definition of a milestone as (1) they are events that can only be achieved in part on the Company s performance or upon the occurrence of a specific outcome resulting from 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 these 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 preclinical development was initially governed by a steering committee with representatives from both the Company and Boehringer Ingelheim; provided, however, that final decision making authority rested with Boehringer Ingelheim. The Company s participation in the steering committee was determined to be a substantive deliverable under the contract, and therefore, the upfront payment was deferred and recognized over the two-year term of the steering committee which was completed, as scheduled, in June 2012. 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.

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During the three and nine months ended September 30, 2013 and 2012, revenues recognized under the collaboration agreement with Boehringer Ingelheim were as follows (*in millions*):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Amortization of up-front license fees	$	$	$	$ 2.2
Sponsored research and development			$	$ 1.0
Revenues recognized under the Boehringer Ingelheim collaboration agreement	$	$	$	$ 3.2

3. INVESTMENTS

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

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

	September 30, 2013	December 31, 2012
Certificates of deposit	$ 13,163	$ 12,434
Commercial paper	12,094	19,695
Corporate debt securities	89,940	77,610
Securities of government sponsored entities	7,500	
Total investments	$ 122,697	$ 109,739

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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, 2013:					
Classified as current assets:					
Certificates of deposit	Less than 1	$ 12,938	$	$ (16)	$ 12,922
Commercial paper	Less than 1	12,094	2	(2)	12,094
Corporate debt securities	Less than 1	89,499	24	(17)	89,506
Securities of government sponsored entities	Less than 1	7,500			7,500
Total short-term available for sale securities		$ 122,031	$ 26	$ (35)	$ 122,022
Classified as long-term assets:					
Certificates of deposit	1 to 2	240	1		241
Corporate debt securities	1 to 2	435		(1)	434
Total long-term available for sale securities		675	1	(1)	675
Total available-for-sale securities		$ 122,706	$ 27	$ (36)	$ 122,697
December 31, 2012:					
Classified as current assets:					
Certificates of deposit	Less than 1	$ 11,960	$	$ (6)	$ 11,954
Commercial paper	Less than 1	19,713		(18)	19,695
Corporate debt securities	Less than 1	77,588	33	(11)	77,610
Total short-term available-for-sale securities		$ 109,261	$ 33	$ (35)	$ 109,259
Classified as non-current assets:					
Certificates of deposit	1 to 2	480			480
Total long-term available-for-sale securities		480			480
Total available-for-sale securities		$ 109,741	$ 33	$ (35)	$ 109,739

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

The following table presents information about available-for-sale investments in an unrealized loss position but were not deemed to be other than temporarily impaired (*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, 2013:						
Certificates of deposit	$ 11,993	$ (16)	$	$	$ 11,993	$ (16)
Corporate debt securities	42,885	(18)			42,885	(18)
Commercial paper	2,495	(2)			2,495	(2)

Total	$ 57,373	$	(36)	$	$	$ 57,373	$	(36)
December 31, 2012:								
Certificates of deposit	$ 10,273	$	(6)	$	$	$ 10,273	$	(6)
Commercial paper	19,695		(18)			19,695		(18)
Corporate debt securities	37,524		(11)			37,524		(11)
Total	$ 67,492	$	(35)	$	$	$ 67,492	$	(35)

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4. 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 has been established, 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 classifies its cash equivalents and available for sale investments within Level 1 or Level 2. The Company s financial instruments, including cash and cash equivalents, accounts receivable, accounts payable, and accrued liabilities, are carried at cost, which management believes approximates fair value and would classify these financial instruments within Level 1 of the fair value hierarchy because of the short-term maturity of these instruments.

The fair value of the Company s high quality investment grade corporate debt securities is determined using proprietary valuation models and analytical tools. These valuation models and analytical tools use market pricing or prices for similar instruments that are both objective and publicly available, including matrix pricing or reported trades, benchmark yields, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids and/or offers. The Company did not reclassify any investments between levels in the fair value hierarchy during the three and nine months ended September 30, 2013.

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The Company s assets which are measured at fair value on a recurring basis as of September 30, 2013 and December 31, 2012 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, 2013:				
Classified as current assets:				
Cash and money market funds	$ 34.5	$ 34.5	$	$
Certificates of deposit	12.9	12.9		
Commercial paper	12.1		12.1	
Corporate bonds	89.9		89.9	
Securities of government sponsored entities	7.5		7.5	
Subtotal	156.9	47.4	109.5	
Classified as long-term assets:				
Certificates of deposit	4.6	4.6		
Corporate bonds	0.4		0.4	
Total	161.9	52.0	109.9	
Less cash, cash equivalents and restricted cash	(39.2)	(38.8)	(0.4)	
Total investments	$ 122.7	$ 13.2	$ 109.5	$
December 31, 2012:				
Classified as current assets:				
Cash and money market funds	$ 53.2	$ 53.2	$	$
Certificates of deposit	16.2	16.2		
Commercial paper	25.7		25.7	
Corporate bonds	82.2		82.2	
Subtotal	177.3	69.4	107.9	
Classified as long-term assets:				
Certificates of deposit	0.5	0.5		
Total	177.8	69.9	107.9	
Less cash, cash equivalents and restricted cash	(68.1)	(57.5)	(10.6)	
Total investments	$ 109.7	$ 12.4	$ 97.3	$

5. SHARE-BASED COMPENSATION

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
General and administrative	$ 0.9	$ 0.7	$ 2.6	$ 2.1
Research and development	0.8	0.7	$ 2.5	$ 2.1
Total share-based compensation expense	$ 1.7	$ 1.4	$ 5.1	$ 4.2

The fair value of equity instruments that are ultimately expected to vest, net of estimated forfeitures, are recognized and amortized on a straight-line basis over the requisite service period. The Company estimates forfeiture rates for equity awards based on past behavior for similar equity awards with further consideration given to the class of employees to whom the equity awards were granted.

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As of September 30, 2013, total unrecognized estimated compensation cost related to non-vested stock options and non-vested restricted stock units (RSUs) granted prior to that date was $10.4 million and $2.7 million, respectively, which is expected to be recognized over a weighted average period of approximately 2.2 years and 3.3 years, respectively.

During the nine months ended September 30, 2013 and 2012, stock options to purchase approximately 0.9 million and 0.1 million shares of the Company s common stock were exercised, respectively. The cash received by the Company from stock option exercises during the nine months ended September 30, 2013 and 2012 was approximately $5.3 million and $0.4 million, respectively. The Company also issued approximately 50,000 shares of common stock pursuant to the vesting of RSUs during the nine months ended September 30, 2012.

Stock Option Assumptions

The Company granted stock options to purchase approximately 0.8 million and 1.4 million shares of the Company s common stock during the nine months ended September 30, 2013 and 2012, respectively. The Company did not grant any stock options during the three months ended September 30, 2013. These stock options generally vest monthly over a four-year period. The exercise price of all stock options granted during the nine months ended September 30, 2013 and 2012 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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Risk-free interest rate		0.9%	1.4%	1.3%
Expected volatility of common stock		72.1%	75.8%	79.4%
Dividend yield		0.0%	0.0%	0.0%
Expected option term		6 years	7.3 years	6.8 years

The Black-Scholes option-pricing model incorporates various and highly sensitive assumptions including expected volatility, expected term and interest rates. The expected volatility is based on the historical volatility of the Company s common stock over the most recent period commensurate with the estimated expected term of the Company s stock options. The expected option term is estimated based on historical experience as well as the status of the employee. For example, directors and officers have a longer expected option term than all other employees. Additionally, recent grants of stock options have a contractual life of ten years, versus seven years for older option grants, and the vesting period for recent option grants has been extended to four years, which together have also resulted in an increase in the expected option term over time. The risk-free rate for periods within the contractual life of the option is based upon observed interest rates appropriate for the expected term of the Company s employee stock options. The Company has never declared or paid dividends and has no plans to do so in the foreseeable future. For the nine months ended September 30, 2013 and 2012, share-based compensation expense related to stock options was $4.5 million and $4.2 million, respectively.

Restricted Stock Units

The Company granted RSUs covering approximately 0.4 million shares of its common stock to its employees during the nine months ended September 30, 2013. These RSUs vest on an annual basis over a four year period. The fair value of RSUs is estimated based on the closing sale price of the Company s common stock on the date of issuance. For the nine months ended September 30, 2013, share-based compensation expense related to RSUs was $0.6 million.

6. STOCKHOLDERS EQUITY

Equity Financing

In January 2012, the Company completed a public offering of common stock in which the Company sold 10.9 million shares of its common stock at an offering price of $8.10 per share. The shares were sold pursuant an effective shelf registration statement with the SEC. The net proceeds generated from this transaction, after underwriting discounts and commissions and offering costs, were approximately $83.0 million.

Shelf Registration Statements

In December 2012, the SEC declared effective a shelf registration statement filed by the Company in November 2012. The shelf registration statement allows the Company to issue shares of its common stock from time to time for an aggregate initial offering price of up to $150 million.

In December 2010, the SEC declared effective a shelf registration statement filed by the Company earlier in that month. The shelf registration statement allows the Company to issue shares of its common stock from time to time for an aggregate initial offering price of up to $125 million. As of September 30, 2013, the Company had approximately $37 million still available under this shelf registration statement. This shelf registration statement will expire in December 2013.

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The specific terms of future offerings, if any, under a shelf registration statement would be established at the time of such offerings.

7. REAL ESTATE

In December 2007, the Company closed the sale of its facility and associated real property for a purchase price of $109 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 also entered into a series of lease amendments (Amendments), beginning in late 2008, through which it vacated the Front Building, but continues to occupy the Rear Building. The ultimate result of this real estate sale was a net gain of $39.1 million which was deferred in accordance with authoritative guidance. The Company recognized $2.3 million of the deferred gain during each of the nine month periods ended September 30, 2013 and 2012, and will recognize the remaining $21.7 million of the deferred gain over the initial Lease term which will expire at the end of 2019.

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. 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 $4.2 million, which is secured by a deposit of equal amount with the same bank. The Company also has the right to extend the Lease for two consecutive ten-year terms.

In December 2010, the Company entered into a sublease agreement (Sublease) for approximately 16,000 square feet of the Rear Building. The Sublease is expected to result in approximately $0.6 million of rental income per year over the three year term of the Sublease and is recorded as an offset to rent expense. The Sublease provides 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 $2.5 million of gross cease-use expense, and a reversal of $173,000 in associated deferred rent, each being recorded in December 2010. In August 2012, the Company extended the terms of the Sublease and increased the leased square footage to approximately 17,000 square feet. This transaction resulted in approximately $150,000 of gross cease-use expense, and a reversal of $15,000 in associated deferred rent, each being recorded in September 2012.

In September 2011, the Company entered into a second sublease agreement (Second Sublease) for approximately 3,300 square feet of space in the Rear Building. The Second Sublease is expected to result in approximately $0.1 million in rental income per year over the three year term and is recorded as an offset to rent expense. The Second Sublease provides an option to extend for a one-year renewal period. Similar to the Sublease, the Second Sublease resulted in $0.3 million of gross cease-use expense, and a reversal of $47,000 in associated deferred rent, each being recorded in September 2011.

In November 2012, the Company entered into a third sublease agreement (Third Sublease) for approximately 14,000 square feet of space in the Rear Building. The Third Sublease is expected to result in approximately $0.5 million in rental income per year over the three and a half year term and is recorded as an offset to rent expense. The Third Sublease provides the subtenant with an option to extend the term for two one-year renewal periods. Similar to the previous subleases, the Third Sublease resulted in $1.2 million of gross cease-use expense, and a reversal of $250,000 in associated deferred rent, each being recorded in December 2012.

At September 30, 2013 and 2012, the Company had recorded in its condensed consolidated balance sheet an aggregate cease-use liability related to the Sublease (as amended), the Second Sublease and the Third Sublease of $3.2 million and $2.5 million, respectively.

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The following table sets forth changes to the accrued cease-use liability during the three and nine months ended September 30, 2013 and 2012 (*in thousands*):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Beginning balance	$ 3,295	$ 2,463	$ 3,686	$ 2,592
Impact of sublease cease-use charges (1)		150		150
Payments	(97)	(64)	(488)	(193)
Ending balance	$ 3,198	$ 2,549	$ 3,198	$ 2,549

(1) Total cease-use expense in 2012 was offset by the related adjustment to deferred rent of approximately $15,000

8. LOSS PER COMMON SHARE

The Company computes basic net loss per share using the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss for the period by the weighted average number of common and common equivalent shares outstanding during the period. Additionally, potentially dilutive securities, composed of incremental common shares issuable upon the exercise of stock options and the vesting of RSUs, are excluded from the diluted loss per share calculation because of their anti-dilutive effect.

For the three and nine months ended September 30, 2013, the Company realized a net loss of $11.1 million and $35.4 million, respectively. Potentially dilutive securities totaled approximately 2.5 million and 2.2 million for the three and nine months ended September 30, 2013, respectively. Options to purchase approximately 0.1 million and 0.3 million shares of common stock were outstanding during the three and nine months ended September 30, 2013, respectively, with an exercise price greater than the average market price of the underlying common shares.

For the three and nine months ended September 30, 2012, the Company realized a net loss of $3.1 million and $4.5 million, respectively. Potentially dilutive securities excluded from the historical diluted loss per share totaled 1.3 million for each of the three and nine months ended September 30, 2012, respectively. Options to purchase 2.3 million shares of common stock were outstanding during each of the three and nine months ended September 30, 2012, with an exercise price greater than the average market price of the underlying common shares.

9. RESEARCH AND DEVELOPMENT

Research and development (R&D) expenses 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 of the costs applicable to various stages of a research agreement or clinical trial can be made. Accrued clinical costs are subject to revisions as trials progress. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

10. 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.

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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, 2012 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, 2012 and our Quarterly Reports on Form 10-Q for the three months ended March 31, 2013 and the six months ended June 30, 2013.

OVERVIEW

We are a clinical stage drug discovery company primarily focused on neurological and endocrine based diseases and disorders. We discover and develop innovative pharmaceuticals, in diseases with high unmet medical needs or where the existing drug classes are inadequate, through a disciplined yet entrepreneurial process. Utilizing a portfolio approach to drug discovery, we have multiple small molecule drug candidates at various stages of pharmaceutical development. We develop proprietary pharmaceuticals for our pipeline, as well as collaborate with other pharmaceutical companies on our discoveries. Our two lead late stage clinical programs are elagolix, a GnRH antagonist for women s health that is partnered with AbbVie Inc., and a wholly owned VMAT2 inhibitor for the treatment of movement disorders. We intend to maintain certain commercial rights to our VMAT2 inhibitor and evolve into a fully-integrated pharmaceutical company.

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. While we independently develop many of our product candidates, we have entered into collaborations for several of our programs, 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, 2013, we had an accumulated deficit of $755.1 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. Our lead clinical development program, elagolix, is a drug candidate for the treatment of endometriosis and uterine fibroids that is partnered with AbbVie Inc.

AbbVie Inc. (AbbVie). In June 2010, we announced an exclusive worldwide collaboration with AbbVie to develop and commercialize elagolix and all next-generation GnRH antagonists (collectively, GnRH Compounds) for women s and men s health. AbbVie made an upfront payment of $75 million and has agreed to make additional development and regulatory event based payments of up to $480 million and up to an additional $50 million in commercial event based payments. We have assessed event based payments under the revised authoritative guidance for research and development milestones and determined that event based payments prior to commencement of a Phase III clinical study, as defined in the agreement, meet the definition of a milestone in accordance with authoritative guidance as (1) they are events that can only be achieved in part on our past performance, (2) there is substantive uncertainty at the date the arrangement was entered into that the event will be achieved and (3) they result in additional payments being due to us. Development and regulatory event based payments subsequent to the commencement of a Phase III clinical study, however, currently do not meet these criteria as their achievement is based on the performance of AbbVie. No milestone payments were recognized during the periods presented.

Under the terms of the agreement, AbbVie is responsible for all third-party development, marketing and commercialization costs. We received funding for certain internal collaboration expenses, which included reimbursement from AbbVie for internal and external expenses related to the GnRH Compounds, 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 AbbVie, the collaboration effort between the parties to advance GnRH Compounds towards commercialization was governed by a joint development committee with representatives from both us and AbbVie. The collaborative development portion of the agreement concluded, as scheduled, on December 31, 2012. Our participation in the joint development committee was determined to be a substantive deliverable under the contract, and therefore, the upfront payment was deferred and recognized over the term of the joint development committee, which was completed in December 2012. AbbVie 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. Since the inception of the agreement, we have recorded revenues of $75.0 million related to the amortization of up-front license fees, $30.0 million in milestone revenue, and $37.0 million in sponsored development revenue.

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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 our agreement with Boehringer Ingelheim, we and Boehringer Ingelheim worked jointly, during a two year collaborative research period which ended in June 2012, to identify and advance GPR119 agonist candidates into preclinical development. Following the collaborative research period, Boehringer Ingelheim is responsible for the global development and commercialization of potential GPR119 agonist products, if any. We received a $10 million upfront payment, and received research funding to support discovery efforts. Boehringer Ingelheim agreed to make payments of up to approximately $3 million in additional preclinical milestone payments and payments of up to approximately $223 million in clinical development and commercial event based payments. We have assessed milestones under the revised authoritative guidance for research and development milestones and determined that the preclinical milestone payments, as defined in the agreement, meet the definition of a milestone as (1) they are events that can only be achieved in part on our performance or upon the occurrence of a specific outcome resulting from our performance, (2) there is substantive uncertainty at the date the arrangement was 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 these criteria as their achievement is solely based on the performance of Boehringer Ingelheim. No milestone payments were recognized during the periods presented. We 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 preclinical development was initially governed by a steering committee with representatives from both us and Boehringer Ingelheim; provided, however, that final decision making authority rested with Boehringer Ingelheim. The collaborative research portion of the agreement concluded, as scheduled, on June 15, 2012. Our participation in the steering committee was determined to be a substantive deliverable under the contract, and therefore, the upfront payment was deferred and recognized over the two-year term of the steering committee which was completed in June 2012. 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. Since the inception of the agreement, we have recorded revenues of $10.0 million related to amortization of up-front license fees and $3.0 million in sponsored research.

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 (GAAP). 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, and 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 us on January 1, 2011, upfront, nonrefundable payments for license fees and advance payments for sponsored research revenues received in excess of amounts earned were 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 we enter into a new collaboration agreement or materially modify an existing collaboration agreement, we will be required to apply the revised multiple element guidance. 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 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 laboratory supply expenses, scientific consulting expenses and other expenses.

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Share-based Compensation. We grant stock options to purchase our common stock to our employees and directors under our 2011 Equity Incentive Plan (the 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 previous option plans from which we no longer make grants. Share-based compensation expense recognized in accordance with authoritative guidance for each of the three month periods ended September 30, 2013 and 2012 was $1.7 million and $1.4 million, respectively. For the nine months ended September 30, 2013 and 2012, we recognized share-based compensation expense of $5.1 million and $4.2 million, respectively.

For purposes of calculating share-based compensation, we estimate the fair value of stock option awards using a Black-Scholes option-pricing model. The determination of the fair value of share-based compensation awards utilizing the Black-Scholes model is affected by our stock price and a number of assumptions, including but not limited to expected stock price volatility over the term of the awards and the expected term of stock options. Our stock options have characteristics significantly different from those of traded options, and changes in the assumptions can materially affect the fair value estimates. The fair value of RSUs is estimated based on the closing sale price of the Company s common stock on the date of issuance.

Stock option awards and RSUs generally vest over a three to four year period and the corresponding expense is ratably recognized over those same time periods.

If factors change and we employ different assumptions, share-based compensation expense may differ significantly from what we have recorded in the past. If there is a difference between the assumptions used in determining share-based compensation expense and the actual factors which become known over time, specifically with respect to anticipated forfeitures, we may change the input factors used in determining share-based compensation expense for future grants. These changes, if any, may materially impact our results of operations in the period such changes are made. If actual forfeitures vary from our estimates, we will recognize the difference in compensation expense in the period the actual forfeitures occur or at the time of vesting.

THREE MONTHS ENDED SEPTEMBER 30, 2013 AND 2012

Revenue

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

	Three Months Ended September 30,	
	2013	2012
	(In millions)	
Revenues under collaboration agreements:		
AbbVie	$	$ 8.7
Dainippon Sumitomo Pharma Co. Ltd.	0.7	0.7
Total revenues	$ 0.7	$ 9.4

The $8.7 million decrease in third quarter revenue from 2012 to 2013 was primarily due to the completion of the collaborative development portion of the AbbVie collaboration agreement for elagolix, which concluded as scheduled on December 31, 2012.

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Operating Expenses

Research and Development

The following table presents our total research and development (R&D) expenses by category during the periods presented:

	Three Months Ended September 30,	
	2013	2012
	(In millions)	
External development expense:		
Elagolix	$	$ 0.6
VMAT2	3.6	2.2
Other	0.3	0.8
Total external development expense	3.9	3.6
R&D personnel expense	3.4	3.7
R&D facility and depreciation expense	1.4	1.5
Other R&D expense	0.8	1.1
Total R&D expense	$ 9.5	$ 9.9

The $0.4 million decrease in third quarter R&D expenses from 2012 to 2013 was primarily due to lower compensation related costs and lower laboratory supply costs offset by higher external development expenses related to our VMAT2 program as it continues in Phase IIb development.

General and Administrative

General and administrative expenses were relatively unchanged with $3.2 million expended during the third quarter of 2013 compared with $3.3 million expended during the same period in 2012.

Net Loss

Our net loss for the third quarter of 2013 was $11.1 million, or a net loss of $0.17 per share, compared to a net loss of $3.1 million, or a net loss of $0.05 per share, during the same period in 2012. The increase in our net loss from 2012 to 2013 was primarily a result of lower revenue recognized under our collaboration agreement with AbbVie, as the collaborative portion for this agreement concluded as scheduled in December 2012.

NINE MONTHS ENDED SEPTEMBER 30, 2013 AND 2012

Revenue

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

	Nine Months Ended September 30,	
	2013	2012
	(In millions)	
Revenues under collaboration agreements:		
AbbVie	$	$ 25.8

Dainippon Sumitomo Pharma Co. Ltd.	2.2	2.2
Boehringer Ingelheim		3.2
Total revenues	$ 2.2	$ 31.2

Revenues for the first nine months of 2013 were $2.2 million, compared to $31.2 million for the same period in 2012. The decrease in revenue was primarily due to the completion of the collaborative development portion of the AbbVie collaboration agreement, which concluded as scheduled on December 31, 2012, and the completion of the collaborative research portion of the agreement with Boehringer Ingelheim, which was completed as planned in June 2012.

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Operating Expenses

Research and Development

The following table presents our total R&D expenses by category during the periods presented:

	Nine Months Ended September 30,	
	2013	2012
	(In millions)	
External development expense:		
Elagolix	$	$ 1.8
VMAT2	10.2	5.3
Other	1.1	1.4
Total external development expense	11.3	8.5
R&D personnel expense	11.6	11.0
R&D facility and depreciation expense	4.1	4.4
Other R&D expense	3.3	4.2
Total R&D expense	$ 30.3	$ 28.1

The $2.2 million increase in nine-month R&D expenses from 2012 to 2013 was primarily due to higher external development expenses related to our VMAT2 program as it continues in Phase IIb development and a $0.4 million increase in share-based compensation expense. These increases were offset by a $0.8 million decrease in scientific consultants utilized to advise on multiple programs, and lower elagolix related costs as the full responsibility for that program has transitioned to AbbVie.

General and Administrative

General and administrative expenses were relatively unchanged with $10.0 million expended during the first nine months of 2013 compared with $10.1 million expended during the same period in 2012.

Net Loss

Our net loss for the first nine months of 2013 was $35.4 million, or a net loss of $0.53 per share, compared to net loss of $4.5 million, or net loss of $0.07 per share, during the same period in 2012. The increase in our net loss from 2012 to 2013 was primarily a result of lower revenue recognized under our collaboration agreements with AbbVie and Boehringer Ingelheim, coupled with increased R&D expenses driven by our VMAT2 Phase IIb clinical program.

LIQUIDITY AND CAPITAL RESOURCES

Net cash used in operating activities during the first nine months of 2013 was $18.7 million compared to $26.4 million during the same period in 2012. The $7.7 million change is primarily related to $14.1 million in accounts receivable at December 31, 2012 which was received during the first quarter of 2013, offset by higher R&D expenses primarily due to expanded efforts on our VMAT2 program.

Net cash used in investing activities during the first nine months of 2013 was $15.4 million compared to $62.6 million during the same period in 2012. The fluctuation in net cash used in investing activities resulted primarily from the timing differences in investment purchases, sales and maturities of investments, and the fluctuation of our portfolio mix between cash equivalents and short-term investment holdings.

Net cash provided by financing activities during the first nine months of 2013 was $5.3 million compared to $83.4 million during the same period in 2012. The decrease in cash provided by financing activities was primarily due to net proceeds of approximately $83.0 million from our public offering of common stock in January 2012. Stock option exercises yielded approximately $5.3 million and $0.4 million for the first nine months of 2013 and 2012, respectively.

At September 30, 2013, our cash, cash equivalents, and investments totaled $157.6 million compared with $173.5 million at December 31, 2012.

Equity Financing. In January 2012, we completed a public offering of common stock in which we sold 10.9 million shares of our common stock at an offering price of $8.10 per share. The shares were sold pursuant to an effective shelf registration statement with the Securities and Exchange Commission (SEC). The net proceeds generated from this transaction, after underwriting discounts and commissions and offering costs, were approximately $83.0 million.

Shelf Registration Statements. In December 2012, the SEC declared effective a shelf registration statement that we filed in November 2012. 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 $150 million. As of September 30, 2013, we had not sold any shares under this shelf registration statement.

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In December 2010, the 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. As of September 30, 2013, we had approximately $37 million still available under this shelf registration statement. This shelf registration statement will expire in December 2013.

The specific terms of future offerings, if any, under a 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 may 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 effective shelf registration statements on file with the SEC which allow us to issue shares of our common stock from time to time for an aggregate initial offering price up to $187 million. We may also seek additional funding through strategic alliances or other financing mechanisms. 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 12 months. If a 10% change in interest rates had occurred on September 30, 2013, 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 February 2013, the Financial Accounting Standards Board amended the disclosure requirements regarding the reporting of amounts reclassified out of accumulated other comprehensive income. The amendment does not change the current requirement for reporting net income or other comprehensive income, but requires additional disclosures about significant amounts reclassified out of accumulated other comprehensive income including the effect of the reclassification on the related net income line items. We adopted this amendment prospectively effective January 1, 2013 and the adoption is not expected to have a significant impact on our financial statements as the requirements are disclosure only in nature.

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

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similar words (including their use in the negative), or by discussions of future matters such as the development or regulatory approval of new products, technology enhancements, possible changes in legislation and other statements that are not historical. These statements include but are not limited to statements under the captions Risk Factors, and Management s Discussion and Analysis of Financial Condition and Results of Operations as well as other sections in this report. You should be aware that the occurrence of any of the events discussed under the heading in Part II titled Item 1A. Risk Factors and elsewhere in this report could substantially harm our business, results of operations and financial condition and that if any of these events occurs, the trading price of our common stock could decline and you could lose all or a part of the value of your shares of our common stock.

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our 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.

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PART II: OTHER INFORMATION

ITEM 1A. RISK FACTORS

The following risk factors do not reflect any material changes to the risk factors set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012, 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 on Form 10-Q 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 preclinical 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 or results of toxicology studies required by the FDA may not be acceptable to the FDA;
- 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 gonadotropin-releasing hormone (GnRH) program with AbbVie Inc. (AbbVie) any of the clinical, regulatory or operational events described above could delay timelines for the completion of the Phase III endometriosis program or the Phase II uterine fibroids program, require suspension of these programs and/or obviate filings for regulatory approvals. Similarly, our VMAT2 inhibitor program will be impacted if any of the events above lead to delayed enrollment in, or completion of, the Phase II clinical trials of our lead candidate or the results of the ongoing Phase II clinical trials do not support advancing to later stage development.

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 collaboration agreements with AbbVie, Boehringer Ingelheim International GmbH (Boehringer Ingelheim) and Dainippon Sumitomo Pharma Co. Ltd. and previously have had collaborations with Pfizer, GlaxoSmithKline, 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 collaboration agreements with AbbVie 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;

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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.

**** We do not and will not have access to all information regarding the product candidates we licensed to AbbVie.***

We do not and will not have access to all information regarding the products being developed and potentially commercialized by AbbVie, including potentially material information about clinical trial design and execution, safety reports from clinical trials, spontaneous safety reports if a product candidate is later approved and marketed, regulatory affairs, process development, manufacturing, marketing and other areas known by AbbVie. In addition, we have confidentiality obligations under our agreement with AbbVie. Thus, our ability to keep our shareholders informed about the status of product candidates under our collaboration with AbbVie will be limited by the degree to which AbbVie keeps us informed and allows us to disclose such information to the public. If AbbVie fails to keep us informed about the clinical development and regulatory approval of our collaboration and product candidates licensed to it, we may make operational and investment decisions that we would not have made had we been fully informed, which may materially and adversely affect our business and operations.

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

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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 effective shelf registration statements 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 $187 million. 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 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 and negative cash flow from operations. As a result of historical operating losses, we had an accumulated deficit of $755.1 million as of September 30, 2013. While we were profitable for the years ended December 31, 2012 and 2011, we did not generate positive cash flows from operations in either year. We do not expect to remain profitable, nor do we expect to become

cash flow positive, for the foreseeable future.

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

- seek regulatory approvals for our product candidates;
- develop, formulate, manufacture and commercialize our 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.

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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 $7.00 per share to approximately $17.00 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;
- 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, for example the GnRH receptor we license from The Mount Sinai School of Medicine of the City University of New York for use in the 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, and no 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.

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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.

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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, the Dodd-Frank Wall Street Reform and Consumer Protection Act, 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.

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). 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 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, 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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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, tardive dyskinesia, uterine fibroids, 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.

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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.

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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.

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ITEM 6. EXHIBITS

Exhibit Number	Description
3.1	Certificate of Incorporation (1)
3.2	Certificate of Amendment to Certificate of Incorporation (1)
3.3	Bylaws, as amended (1)
4.1	Form of Common Stock Certificate (2)
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 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 Annual Report on Form 10-K filed on February 8, 2013 (File No. 000-22705)
(2) Incorporated by reference to the Company s Registration Statement on Form S-1 (Registration No. 333-03172)
* 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.

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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 29, 2013

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