

NEUROCRINE BIOSCIENCES INC

Form 10-Q

April 30, 2015

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2015

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)

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Delaware
(State or other jurisdiction of
incorporation or organization)

33-0525145
(IRS Employer
Identification No.)

12780 El Camino Real,
San Diego, California
(Address of principal executive office)

92130
(Zip Code)

(858) 617-7600
(Registrant's telephone number, including area code)

Not Applicable

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

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

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

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

Large accelerated filer Accelerated filer
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

The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 85,417,797 as of April 24, 2015.

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Table of Contents**PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****NEUROCRINE BIOSCIENCES, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS****(in thousands, except share information)****(unaudited)**

	March 31, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 170,262	\$ 31,014
Short-term investments, available for sale	199,745	162,795
Receivables under collaboration agreements	30,030	
Other current assets	4,916	4,394
Total current assets	404,953	198,203
Property and equipment, net	2,543	2,507
Long-term investments, available for sale	115,452	37,492
Restricted cash	4,831	4,831
Total assets	\$ 527,779	\$ 243,033
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,270	\$ 246
Accrued liabilities	9,938	11,508
Current portion of cease-use liability	479	467
Current portion of deferred rent	152	119
Current portion of deferred gain on sale of real estate	3,348	3,324
Total current liabilities	15,187	15,664
Deferred gain on sale of real estate	13,468	14,322
Deferred revenue	10,231	
Deferred rent	1,817	1,877
Cease-use liability	2,086	2,211
Other liabilities	260	260
Total liabilities	43,049	34,334
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 85,372,303 as of March 31, 2015 and 76,465,942 as of December 31, 2014	85	76
Additional paid-in capital	1,312,321	1,035,205
Accumulated other comprehensive loss	(179)	(277)
Accumulated deficit	(827,497)	(826,305)

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Total stockholders' equity	484,730	208,699
Total liabilities and stockholders' equity	\$ 527,779	\$ 243,033

See accompanying notes to the condensed consolidated financial statements.

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	Three Months Ended March 31,	
	2015	2014
Revenues:		
License fees	\$ 19,769	\$
Total revenues	19,769	
Operating expenses:		
Research and development	16,575	8,572
General and administrative	5,482	4,153
Total operating expenses	22,057	12,725
Loss from operations	(2,288)	(12,725)
Other income:		
Gain (loss) on sale/disposal of assets	9	(10)
Deferred gain on real estate	830	804
Investment income, net	257	89
Total other income	1,096	883
Net loss	\$ (1,192)	\$ (11,842)
Net loss per common share:		
Basic and diluted	\$ (0.01)	\$ (0.17)
Shares used in the calculation of net loss per common share:		
Basic and diluted	80,349	70,260
Other comprehensive loss:		
Net loss	\$ (1,192)	\$ (11,842)
Net unrealized gains/(losses) on available-for-sale securities	98	(199)
Comprehensive loss	\$ (1,094)	\$ (12,041)

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (1,192)	\$ (11,842)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	244	178
Gain on sale of assets	(839)	(794)
Deferred revenues	10,231	
Deferred rent	(27)	6
Amortization of premiums on investments	1,011	617
Non-cash share-based compensation expense	3,600	2,447
Change in operating assets and liabilities:		
Accounts receivable under collaboration agreements and other assets	(30,552)	850
Accounts payable and accrued liabilities	(546)	(1,127)
Cease-use liability	(113)	(102)
Net cash used in operating activities	(18,183)	(9,767)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of investments	(159,221)	(108,907)
Sales and maturities of investments	43,398	43,391
Proceeds from sales of property and equipment	9	40
Purchases of property and equipment	(280)	(255)
Net cash used in investing activities	(116,094)	(65,731)
CASH FLOWS FROM FINANCING ACTIVITIES		
Issuance of common stock	273,525	136,241
Net cash provided by financing activities	273,525	136,241
Net increase in cash and cash equivalents	139,248	60,743
Cash and cash equivalents at beginning of the period	31,014	44,789
Cash and cash equivalents at end of the period	\$ 170,262	\$ 105,532

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) was incorporated in California in 1992 and reincorporated in Delaware in 1996. The Company discovers and develops innovative and life-changing pharmaceuticals, in diseases with high unmet medical needs, through its novel research and development (R&D) platform, focused on neurological and endocrine based diseases and disorders. The Company's two lead late-stage clinical programs are elagolix, a gonadotropin-releasing hormone (GnRH) antagonist for women's health that is partnered with AbbVie Inc. (AbbVie), and a vesicular monoamine transporter 2 (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 subsidiaries.

These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2014 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, 2014 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 May 2014, the Financial Accounting Standards Board (FASB) amended the existing accounting standards for revenue recognition, which outlines a comprehensive revenue recognition model and supersedes most current revenue recognition guidance. The new standard requires a company to recognize revenue upon transfer of goods or services to a customer at an amount that reflects the expected consideration to be received in exchange for those goods or services. The amended guidance defines a five-step approach for recognizing revenue, which may require a company to use more judgment and make more estimates than under the current guidance. The amended guidance as currently issued will be effective for the Company starting in 2017. On April 1, 2015, the FASB voted to propose a one-year deferral to the effective date, but to permit entities to adopt one year earlier if they choose (i.e., the original effective date). The proposal will be subject to the FASB's due process requirement, which includes a period for public comments. The new standard allows for two methods of adoption: (a) full retrospective adoption, meaning the standard is applied to all periods presented, or (b) modified retrospective adoption, meaning the cumulative effect of applying the new standard is recognized as an adjustment to the opening retained earnings balance. The Company is in the process of determining the adoption method as well as the effects the adoption will have on its consolidated financial statements.

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. The Company recognizes revenue for the performance of services when each of the following four criteria is met: (i) persuasive evidence of an arrangement exists; (ii) services are rendered or products are delivered; (iii) the sales price is fixed or determinable; and (iv) collectability is reasonably assured.

Effective in 2011, the Company follows the Accounting Standards Codification (ASC) for Revenue Recognition - Multiple-Element Arrangements, if applicable, to determine the recognition of revenue under license and collaboration agreements. The terms of these agreements generally contain multiple elements, or deliverables, which may include (i) licenses to our intellectual property, (ii) materials and technology, (iii) pharmaceutical supply, (iv) participation on joint development or joint steering committees, and (v) development services. The payments the Company receives under these arrangements typically include one or more of the following: up-front license fees; funding of research and/or

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development efforts; amounts due upon the achievement of specified milestones; manufacturing and royalties on future product sales.

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The ASC provides guidance relating to the separation of deliverables included in an arrangement into different units of accounting and the allocation of arrangement consideration to the units of accounting. The evaluation of multiple-element arrangements requires management to make judgments about (i) the identification of deliverables, (ii) whether such deliverables are separable from the other aspects of the contractual relationship, (iii) the estimated selling price of each deliverable, and (iv) the expected period of performance for each deliverable.

To determine the units of accounting under a multiple-element arrangement, management evaluates certain separation criteria, including whether the deliverables have stand-alone value, based on the relevant facts and circumstances for each arrangement. The selling prices of deliverables under an arrangement may be derived using vendor specific objective evidence (VSOE), third-party evidence, or a best estimate of selling price (BESP), if VSOE or third-party evidence is not available. For most pharmaceutical licensing and collaboration agreements, BESP is utilized. The objective of BESP is to determine the price at which the Company would transact a sale if the element within the agreement was sold on a standalone basis. Establishing BESP involves management's judgment and considers multiple factors, including market conditions and company-specific factors, including those factors contemplated in negotiating the agreements, as well as internally developed models that include assumptions related to market opportunity, discounted cash flows, estimated development costs, probability of success and the time needed to commercialize a product candidate pursuant to the agreement. In validating the BESP, management considers whether changes in key assumptions used to determine the BESP will have a significant effect on the allocation of the arrangement consideration between the multiple deliverables. The allocated consideration for each unit of accounting is recognized over the related obligation period in accordance with the applicable revenue recognition criteria.

If there are deliverables in an arrangement that are not separable from other aspects of the contractual relationship, they are treated as a combined unit of accounting, with the allocated revenue for the combined unit recognized in a manner consistent with the revenue recognition applicable to the final deliverable in the combined unit. Payments received prior to satisfying the relevant revenue recognition criteria are recorded as unearned revenue in the accompanying balance sheets and recognized as revenue when the related revenue recognition criteria are met.

The Company typically receives up-front payments when licensing its intellectual property, which often occurs in conjunction with a research and development agreement. The Company recognizes revenue attributed to the license upon delivery, provided that the license has stand-alone value.

For payments payable on achievement of milestones that do not meet all of the conditions to be considered substantive, the Company recognizes the portion of the payment allocable to delivered items as revenue when the specific milestone is achieved, and the contingency is removed.

Prior to the revised multiple element guidance, described above, 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. Revenues from development milestones are accounted for in accordance with the Revenue Recognition Milestone Method Topic of the FASB ASC. Milestones are recognized when earned, as evidenced by written acknowledgment from the collaborator or other persuasive evidence that the milestone has been achieved, provided that the milestone event is substantive. A milestone event is considered to be substantive if its achievability was not reasonably assured at the inception of the agreement and the Company's efforts led to the achievement of the milestone or the milestone was due upon the occurrence of a specific outcome resulting from the Company's performance. The Company assesses whether a milestone is substantive at the inception of each agreement.

Mitsubishi Tanabe Pharma Corporation (Mitsubishi Tanabe). On March 31, 2015, the Company entered into a collaboration and license agreement with Mitsubishi Tanabe for the development and commercialization of NBI-98854 for movement disorders in Japan and other select Asian markets. Payments to the Company under this agreement include an up-front license fee of \$30 million, up to \$85 million in development and commercialization event-based payments, payments for the manufacture of pharmaceutical products, and royalties on product sales in select territories in Asia. Under the terms of the agreement, Mitsubishi Tanabe is responsible for all third-party development, marketing and commercialization costs in Japan and other select Asian markets with the exception of a single Huntington's chorea clinical trial to be performed by the Company, at an estimated cost of approximately \$12 million, should Mitsubishi Tanabe request the clinical trial. The Company will be entitled to a percentage of sales of NBI-98854 in Japan and other select Asian markets for the longer of ten years or the life of the related patent rights.

Under the terms of the Company's agreement with Mitsubishi Tanabe, the collaboration effort between the parties to advance NBI-98854 towards commercialization in Japan and other select Asian markets is governed by a joint steering committee and joint development committee with representatives from both the Company and Mitsubishi Tanabe. There are no performance, cancellation, termination or refund provisions in the agreement that would have a material financial consequence to the Company. The Company does not directly control when event-based payments will be achieved or when royalty payments will begin. Mitsubishi Tanabe may terminate the agreement at its discretion upon 180 days written notice to the Company. In such event, all NBI-98854 product rights for Japan and other select Asian markets would revert to the Company.

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The Company has identified the following deliverables associated with the Mitsubishi Tanabe agreement: NBI-98854 technology license and existing know-how, development activities to be performed as part of the collaboration, and the manufacture of pharmaceutical products. The respective standalone value from each of these deliverables has been determined by applying the BSP method and the revenue was allocated based on the relative selling price method with revenue recognition timing to be determined either by delivery or the provision of services.

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As discussed above, the BESP method required the use of significant estimates. The Company used an income approach to estimate the selling price for the technology license and an expense approach for estimating development activities and the manufacture of pharmaceutical products. The development activities and the manufacture of pharmaceutical products are expected to be delivered throughout the duration of the agreement. The technology license and existing know-how was delivered on the effective date of the agreement.

For the quarter ended March 31, 2015, the Company recognized revenue under this agreement of \$19.8 million associated with the delivery of a technology license and existing know-how. In accordance with the Company's continuing performance obligations, \$10.2 million of the \$30 million up-front payment is being deferred and recognized in future periods. Under the terms of the agreement, there is no general obligation to return the up-front payment for any non-contingent deliverable.

The Company evaluated the event-based payments under the Milestone Method and concluded only one immaterial event-based payment represents a substantive milestone. Event-based payments will be recognized when earned.

The Company is eligible to receive from Mitsubishi Tanabe tiered royalty payments based on product sales in Japan and other select Asian markets. Royalties will be recognized as earned in accordance with the terms of the agreement, when product sales are reported by Mitsubishi Tanabe, the amount can be reasonably estimated, and collectability is reasonably assured.

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 (i) they are events that can only be achieved in part on the Company's past performance, (ii) there is substantive uncertainty at the date the arrangement was entered into that the event will be achieved and (iii) 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. As of March 31, 2015, \$500 million remains outstanding in future event-based payments under the agreement. However, none of the remaining event-based payments meet the definition of a milestone in accordance with authoritative accounting guidance.

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.

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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 and accretion 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 consist of the following (*in thousands*):

	March 31, 2015	December 31, 2014
Certificates of deposit	\$ 16,521	\$ 17,438
Commercial paper	11,943	7,498
Corporate debt securities	280,573	174,323
Securities of government sponsored entities	6,160	1,028
Total investments	\$ 315,197	\$ 200,287

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
March 31, 2015:					
Classified as current assets:					
Certificates of deposit	Less than 1	\$ 9,320	\$ 2	\$ (2)	\$ 9,320
Commercial paper	Less than 1	11,948	6	(11)	11,943
Corporate debt securities	Less than 1	178,406	14	(91)	178,329
Securities of government-sponsored entities	Less than 1	153			153
Total short-term available-for-sale securities		\$ 199,827	\$ 22	\$ (104)	\$ 199,745
Classified as non-current assets:					
Certificates of deposit	1 to 2	\$ 7,200	\$ 2	\$ (1)	\$ 7,201
Corporate debt securities	1 to 2	102,345	14	(115)	102,244
Securities of government-sponsored entities	1 to 2	6,004	3		6,007
Total long-term available-for-sale securities		\$ 115,549	\$ 19	\$ (116)	\$ 115,452
December 31, 2014:					
Classified as current assets:					
Certificates of deposit	Less than 1	\$ 9,072	\$	\$ (6)	\$ 9,066
Commercial paper	Less than 1	7,497	1		7,498
Corporate debt securities	Less than 1	145,321	5	(123)	145,203
Securities of government-sponsored entities	Less than 1	1,029		(1)	1,028
Total short-term available-for-sale securities		\$ 162,919	\$ 6	\$ (130)	\$ 162,795
Classified as non-current assets:					

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Certificates of deposit	1 to 2	\$ 8,400	\$	\$ (28)	\$ 8,372
Corporate debt securities	1 to 2	29,245		(125)	29,120
Total long-term available-for-sale securities		\$ 37,645	\$	\$ (153)	\$ 37,492

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

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The following table presents information about available-for-sale investments in an unrealized loss position (*in thousands*):

	Less Than 12 Months		12 Months or Greater		Total	
	Estimated		Estimated		Estimated	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
March 31, 2015:						
Certificates of deposit	\$ 6,437	\$ (3)	\$ 240	\$	\$ 6,677	\$ (3)
Commercial paper	4,974	(11)			4,974	(11)
Corporate debt securities	204,039	(192)	6,371	(14)	210,410	(206)
Total	\$ 215,450	\$ (206)	\$ 6,611	\$ (14)	\$ 222,061	\$ (220)
December 31, 2014:						
Certificates of deposit	\$ 16,957	\$ (34)	\$	\$	\$ 16,957	\$ (34)
Corporate debt securities	149,477	(248)			149,477	(248)
Securities of government-sponsored entities	1,028	(1)			1,028	(1)
Total	\$ 167,462	\$ (283)	\$	\$	\$ 167,462	\$ (283)

The primary objective of the Company's investment portfolio is to enhance overall returns in an efficient manner while maintaining safety of principal, prudent levels of liquidity and acceptable levels of risk. The Company's investment policy limits interest-bearing security investments to certain types of instruments issued by institutions with primarily investment grade credit ratings and places restrictions on maturities and concentration by asset class and issuer.

The Company reviews the available-for-sale investments for other-than-temporary declines in fair value below cost basis each quarter and whenever events or changes in circumstances indicate that the cost basis of an asset may not be recoverable. This evaluation is based on a number of factors, including the length of time and the extent to which the fair value has been below the cost basis and adverse conditions related specifically to the security, including any changes to the credit rating of the security, and the intent to sell, or whether the Company will more likely than not be required to sell the security before recovery of its amortized cost basis. The assessment of whether a security is other-than-temporarily impaired could change in the future due to new developments or changes in assumptions related to any particular security. As of March 31, 2015 and December 31, 2014, the Company believes the cost bases for available-for-sale investments were recoverable in all material respects.

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 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 months ended March 31, 2015.

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The Company's assets which were measured at fair value on a recurring basis as of March 31, 2015 and December 31, 2014 were determined using the inputs described above and are as follows (*in millions*):

	Carrying Value	Fair Value Measurements Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
March 31, 2015:				
Classified as current assets:				
Cash and money market funds	\$ 136.4	\$ 136.4	\$	\$
Certificates of deposit	9.3	9.3		
Commercial paper	17.4		17.4	
Securities of government-sponsored entities	0.2		0.2	
Corporate debt securities	206.7		206.7	
Subtotal	370.0	145.7	224.3	
Classified as long-term assets:				
Certificates of deposit	12.1	12.1		
Corporate debt securities	102.2		102.2	
Securities of government-sponsored entities	6.0		6.0	
Total	490.3	157.8	332.5	
Less cash, cash equivalents and restricted cash	(175.1)	(141.2)	(33.9)	
Total investments	\$ 315.2	\$ 16.6	\$ 298.6	\$
December 31, 2014:				
Classified as current assets:				
Cash and money market funds	\$ 28.7	\$ 28.7	\$	\$
Certificates of deposit	9.1	9.1		
Commercial paper	7.5		7.5	
Securities of government-sponsored entities	1.5		1.5	
Corporate debt securities	147.0		147.0	
Subtotal	193.8	37.8	156.0	
Classified as long-term assets:				
Certificates of deposit	13.2	13.2		
Corporate debt securities	29.1		29.1	
Total	236.1	51.0	185.1	
Less cash, cash equivalents and restricted cash	(35.8)	(33.5)	(2.3)	
Total investments	\$ 200.3	\$ 17.5	\$ 182.8	\$

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	
	March 31,	
	2015	2014
General and administrative	\$ 1.7	\$ 1.2
Research and development	1.9	1.2
Total share-based compensation expense	\$ 3.6	\$ 2.4

The fair value of equity instruments that vest based on continued employee service, net of estimated forfeitures, is recognized and amortized on a straight-line basis over the requisite service period. For restricted stock units (RSUs) with performance-based vesting requirements (PRSUs), no expense is recorded until the performance condition is probable of being achieved. 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 March 31, 2015, total unrecognized estimated compensation cost related to non-vested stock options and non-vested RSUs, that vest over a given service period, granted prior to that date was \$26.3 million and \$19.4 million, respectively, which is expected to be recognized over a weighted average period of approximately 3.2 years and 3.4 years, respectively. Additionally, the Company has approximately 0.5 million PRSUs outstanding. The total unrecognized estimated compensation cost related to these PRSUs is \$11.0 million and is expected to be recognized at the point when the performance conditions have been achieved, which is when these events will become probable.

During the three months ended March 31, 2015 and 2014, stock options to purchase approximately 0.7 million and 0.4 million shares of the Company's common stock were exercised, respectively. The cash received by the Company from stock option exercises during the three months ended March 31, 2015 and 2014 was approximately \$2.8 million and \$3.0 million, respectively. The Company also issued approximately 0.2 million and 0.1 million shares of common stock pursuant to the vesting of RSUs during the three months ended March 31, 2015 and 2014, respectively.

Stock Option Assumptions

The Company granted stock options to purchase approximately 0.7 million and 0.8 million shares of the Company's common stock during the three months ended March 31, 2015 and 2014, respectively. These stock options generally vest monthly over a four-year period. The exercise price of all stock options granted during the three months ended March 31, 2015 and 2014 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 March 31,	
	2015	2014
Risk-free interest rate	1.6%	2.3%
Expected volatility of common stock	66.6%	71.3%
Dividend yield	0.0%	0.0%
Expected option term	6.7 years	7.1 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. 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 three months ended March 31, 2015 and 2014, share-based compensation expense related to stock options was \$2.4 million and \$1.9 million, respectively.

Restricted Stock Units

During the three months ended March 31, 2015, the Company granted approximately 0.4 million RSUs that vest annually over a four year period. Additionally, during the three months ended March 31, 2015 and 2014, the Company granted 50,000 and 475,000 PRSUs, respectively. These PRSUs vest based on the achievement of pre-defined Company-specific performance criteria and expire approximately five years from the grant date. As the performance based criteria for vesting for the PRSUs is not currently probable, no associated expense has been recorded for these PRSUs during the three months ended March 31, 2015. The fair value of RSUs is estimated based on the closing sale price of the Company's common stock on the date of the RSU grant. For the three months ended March 31, 2015 and 2014, share-based compensation expense related to RSUs was \$1.2 million and \$0.5 million, respectively.

6. STOCKHOLDERS EQUITY**Equity Financing**

In February 2015, the Company completed a public offering of common stock in which the Company sold 8.0 million shares of its common stock at an offering price of \$36.00 per share. The net proceeds generated from this transaction, after underwriting discounts and commissions and offering costs, were approximately \$270.7 million.

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In February 2014, the Company completed a public offering of common stock in which the Company sold 8.0 million shares of its common stock at an offering price of \$17.75 per share. The net proceeds generated from this transaction, after underwriting discounts and commissions and offering costs, were approximately \$133.2 million.

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Shelf Registration Statements

In February 2014, the Company filed an automatic shelf registration statement which immediately became effective by rule of the SEC. For so long as the Company continues to satisfy the requirements to be deemed a well-known seasoned issuer, this shelf registration statement allows the Company to issue an unlimited number of shares of its common stock from time to time. As of March 31, 2015, the Company had sold 16.0 million shares under this shelf registration statement.

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. As of March 31, 2015, the Company had not sold any shares under this shelf registration statement.

The specific terms of future offerings, if any, under any of the shelf registration statements 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 \$0.8 million of the deferred gain during each of the three month periods ended March 31, 2015 and 2014, respectively, and will recognize the remaining \$16.8 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 \$4.6 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 initial 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, and was extended for the 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.

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The following table sets forth changes to the accrued cease-use liability during the three months ended March 31, 2015 and 2014 (*in thousands*):

	Three Months Ended	
	March 31,	
	2015	2014
Beginning balance	\$ 2,678	\$ 3,096
Payments	(113)	(102)
Ending balance	\$ 2,565	\$ 2,994

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. In computing the diluted net loss, potentially dilutive securities, composed of incremental common shares issuable upon the exercise of stock options and warrants and the vesting of RSUs and PRSUs, are excluded from the diluted loss per share calculation because of their anti-dilutive effect.

For the three months ended March 31, 2015, the Company realized a net loss of \$1.2 million. Potentially dilutive securities totaled approximately 3.9 million for the three months ended March 31, 2015. Options to purchase approximately 0.1 million shares of common stock were outstanding during the three months ended March 31, 2015 with an exercise price greater than the average market price of the underlying common shares.

For the three months ended March 31, 2014, the Company realized a net loss of \$11.8 million. Potentially dilutive securities totaled approximately 3.0 million for the three months ended March 31, 2014. Options to purchase approximately 0.9 million shares of common stock were outstanding during the three months ended March 31, 2014 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.

Table of Contents**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, 2014 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, 2014.

OVERVIEW

We discover and develop innovative and life-changing pharmaceuticals, in diseases with high unmet medical needs, through our novel research and development (R&D) platform, focused on neurological and endocrine based diseases and disorders. 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.

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 R&D 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 December 31, 2014, we had an accumulated deficit of \$826.3 million and expect to incur operating cash flow losses for the foreseeable future, which may be greater than losses in prior years.

Our two lead late-stage clinical programs are elagolix, a gonadotropin-releasing hormone (GnRH) antagonist in Phase III development for the treatment of endometriosis and Phase II clinical studies for the treatment of uterine fibroids that is partnered with AbbVie Inc. (AbbVie), and a vesicular monoamine transporter 2 (VMAT2) inhibitor for the treatment of movement disorders, currently in Phase III development. Additionally, in 2014 we advanced a third drug candidate into clinical development, our corticotropin releasing factor (CRF) receptor antagonist for the treatment of classic congenital adrenal hyperplasia (CAH). We intend to maintain certain commercial rights to our VMAT2 inhibitor and CRF antagonist programs to evolve into a fully-integrated pharmaceutical company.

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. The goal of the agreement is to develop and commercialize GnRH Compounds. 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 R&D 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. As of March 31, 2015, \$500 million remains outstanding in future event-based payments under the agreement. However, none of the remaining event-based payments meet the definition of a milestone in accordance with authoritative accounting guidance.

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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Mitsubishi Tanabe Pharma Corporation (Mitsubishi Tanabe). On March 31, 2015, we entered into a collaboration and license agreement with Mitsubishi Tanabe for the development and commercialization of NBI-98854 for movement disorders in Japan and other select Asian markets. Payments from Mitsubishi Tanabe under this agreement include an up-front license fee of \$30 million, up to \$85 million in development and commercialization event-based payments, payments for the manufacture of pharmaceutical products, and royalties on product sales in select territories in Asia. Under the terms of the agreement, Mitsubishi Tanabe is responsible for all third-party development, marketing and commercialization costs in Japan and other select Asian markets with the exception of a single Huntington's chorea clinical trial to be performed by us, at a cost of approximately \$12 million, should Mitsubishi Tanabe request the clinical trial. We will be entitled to a percentage of sales of NBI-98854 in Japan and other select Asian markets for the longer of ten years or the life of the related patent rights. Under the terms of the agreement with Mitsubishi Tanabe, the collaboration effort between the parties to advance NBI-98854 towards commercialization is governed by a joint steering committee and joint development committee with representatives from both Neurocrine and Mitsubishi Tanabe. Mitsubishi Tanabe may terminate the agreement at its discretion upon 180 days' written notice to us. In such event, all NBI-98854 product rights in Japan and other select Asian markets would revert to us. During the first quarter of 2015, we have recorded revenues of \$19.8 million related to the up-front license fee. In accordance with our continuing performance obligations, \$10.2 million of the \$30 million upfront payment is being deferred and recognized in future periods.

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 (R&D 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. We recognize revenue for the performance of services when each of the following four criteria is met: (i) persuasive evidence of an arrangement exists; (ii) services are rendered or products are delivered; (iii) the sales price is fixed or determinable; and (iv) collectability is reasonably assured.

Effective in 2011, we follow the Accounting Standards Codification (ASC) for Revenue Recognition - Multiple-Element Arrangements and the ASC for Collaborative Arrangements, if applicable, to determine the recognition of revenue under our license and collaboration agreements. The terms of these agreements generally contain multiple elements, or deliverables, which may include (i) licenses to our intellectual property, (ii) materials and technology, (iii) pharmaceutical supply, (iv) participation on joint development or joint steering committees, and (v) development services. The payments we receive under these arrangements typically include one or more of the following: up-front license fees; funding of research and/or development efforts; amounts due upon the achievement of specified milestones; manufacturing and royalties on future product sales.

The ASC provides guidance relating to the separation of deliverables included in an arrangement into different units of accounting and the allocation of arrangement consideration to the units of accounting. The evaluation of multiple-element arrangements requires management to make judgments about (i) the identification of deliverables, (ii) whether such deliverables are separable from the other aspects of the contractual relationship, (iii) the estimated selling price of each deliverable, and (iv) the expected period of performance for each deliverable.

To determine the units of accounting under a multiple-element arrangement, we evaluate certain separation criteria, including whether the deliverables have stand-alone value, based on the relevant facts and circumstances for each arrangement. The selling prices of deliverables under an arrangement may be derived using vendor specific objective evidence (VSOE), third-party evidence, or a best estimate of selling price (BESP), if VSOE or third-party evidence is not available. For most pharmaceutical licensing and collaboration agreements, BESP is utilized. The objective of BESP is to determine the price at which the Company would transact a sale if the element within the agreement was sold on a standalone basis. Establishing BESP involves management's judgment and considers multiple factors, including market conditions and company-specific factors, including those factors contemplated in negotiating the agreements, as well as internally developed models that include assumptions related to market opportunity, discounted cash flows, estimated development costs, probability of success and the time needed to commercialize a product candidate pursuant to the agreement. In validating the BESP, we consider whether changes in key assumptions used to determine the BESP will have a significant effect on the allocation of the arrangement consideration between the multiple deliverables. The allocated consideration for each unit of accounting is recognized over the related obligation period in accordance with the applicable revenue recognition criteria.

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If there are deliverables in an arrangement that are not separable from other aspects of the contractual relationship, they are treated as a combined unit of accounting, with the allocated revenue for the combined unit recognized in a manner consistent with the revenue recognition applicable to the final deliverable in the combined unit. Payments received prior to satisfying the relevant revenue recognition criteria are recorded as unearned revenue in the accompanying balance sheets and recognized as revenue when the related revenue recognition criteria are met.

We typically receive up-front payments when licensing our intellectual property, which often occurs in conjunction with a research and development agreement. We recognize revenue attributed to the license upon delivery, provided that the license has stand-alone value.

For payments payable on achievement of milestones that do not meet all of the conditions to be considered substantive, we recognize the portion of the payment allocable to delivered items as revenue when the specific milestone is achieved, and the contingency is removed.

Prior to the revised multiple element guidance, described above, adopted by us 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. Revenues from development milestones are accounted for in accordance with the Revenue Recognition Milestone Method Topic of the FASB ASC. Milestones are recognized when earned, as evidenced by written acknowledgment from the collaborator or other persuasive evidence that the milestone has been achieved, provided that the milestone event is substantive. A milestone event is considered to be substantive if its achievability was not reasonably assured at the inception of the agreement and our efforts led to the achievement of the milestone or the milestone was due upon the occurrence of a specific outcome resulting from our performance. We assess whether a milestone is substantive at the inception of each agreement.

Research and Development Expense. Our R&D 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 R&D costs separately for each of our drug candidates. We review our R&D 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 R&D efforts. Other R&D expenses mainly represent laboratory supply expenses, scientific consulting expenses and other expenses.

Share-based Compensation. We grant stock options to purchase our common stock to our employees and directors under our 2011 Equity Incentive Plan, as amended (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 the three months ended March 31, 2015 and 2014 was \$3.6 million and \$2.4 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 our 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. For RSUs with performance-based vesting requirements (PRSUs), no expense is recorded until the performance condition is probable of being achieved.

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.

Table of Contents**THREE MONTHS ENDED MARCH 31, 2015 AND 2014****License Fee Revenues**

As discussed above, during the first quarter of 2015, we entered into collaboration and license agreement with Mitsubishi Tanabe for the development and commercialization of our VMAT2 inhibitor NBI-98854 for movement disorders in Japan and other select Asian markets. Payments from Mitsubishi Tanabe under this agreement include an up-front license fee of \$30 million. During the first quarter of 2015, we have recorded revenues of \$19.8 million related to the up-front license fee.

Operating Expenses**Research and Development**

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

	Three Months Ended March 31,	
	2015	2014
	(In millions)	
External development expense:		
VMAT2	\$ 5.2	\$ 0.6
CRF	1.5	0.3
Other	0.3	0.2
Total external development expense	7.0	1.1
R&D personnel expense	6.6	4.7
R&D facility and depreciation expense	1.5	1.3
Other R&D expense	1.5	1.5
Total R&D expense	\$ 16.6	\$ 8.6

R&D expense increased by \$8.0 million; from \$8.6 million in the first quarter of 2014 to \$16.6 million in the first quarter of 2015. The majority of this increase in R&D expense is due to a \$5.9 million increase in external development expenses from 2014 to 2015. Our VMAT2 Phase III clinical program, which was initiated during the second half of 2014, is responsible for \$4.6 million of the increase in external development expenses. Additionally, in late 2014 we announced a new program, our CRF antagonist for congenital adrenal hyperplasia which increased external development expenses by approximately \$1.2 million. Approximately \$1.9 million of the increase in R&D expense was due to higher R&D personnel related expense, primarily due to an increase in headcount coupled with a \$0.7 million increase in share-based compensation.

General and Administrative

General and administrative expense increased to \$5.5 million in the first quarter of 2015 compared with \$4.2 million during the same period in 2014. The \$1.3 million increase in general and administrative expense is primarily due to higher personnel related costs (increased by \$1.0 million), with share-based compensation costs accounting for half of this increase. Additionally, external costs related to market research and other professional services were \$0.1 million higher for the first quarter of 2015 when compared to the same period in 2014.

Net Loss

Our net loss for the first quarter of 2015 was \$1.2 million, or a net loss of \$0.01 per share, compared to a net loss of \$11.8 million, or a net loss of \$0.17 per share, during the same period in 2014. The decrease in our net loss from 2014 to 2015 was primarily a result of \$19.8 million in revenue recognized from the up-front license fee from Mitsubishi Tanabe. This license fee revenue was offset by an increase in operating expenses of \$9.3 million.

LIQUIDITY AND CAPITAL RESOURCES

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Net cash used in operating activities during the first three months of 2015 was \$18.2 million compared to \$9.8 million during the same period in 2014. The \$8.4 million increase is primarily due to an increase in operating expenses of \$9.3 million.

Net cash used in investing activities during the first three months of 2015 was \$116.1 million compared to \$65.7 million during the same period in 2014. 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 and long-term investment holdings.

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Net cash provided by financing activities during the first three months of 2015 was \$273.5 million compared to \$136.2 million during the same period in 2014. The increase in cash provided by financing activities was primarily due to net proceeds of approximately \$270.7 million from our public offering of common stock in February 2015, compared to net proceeds of approximately \$133.2 million from our public offering of common stock in February 2014. Stock option exercises yielded approximately \$2.8 million and \$3.0 million in cash proceeds during the first three months of 2015 and 2014, respectively.

At March 31, 2015, our cash, cash equivalents, and investments totaled \$485.5 million compared with \$231.3 million at December 31, 2014.

Equity Financing. In February 2015, we completed a public offering of common stock in which we sold 8.0 million shares of our common stock at an offering price of \$36.00 per share. The net proceeds generated from this transaction, after underwriting discounts and commissions and offering costs, were approximately \$270.7 million.

In February 2014, we completed a public offering of common stock in which we sold 8.0 million shares of our common stock at an offering price of \$17.75 per share. The net proceeds generated from this transaction, after underwriting discounts and commissions and offering costs, were approximately \$133.2 million.

Shelf Registration Statements. In February 2014, we filed an automatic shelf registration statement which immediately became effective by rule of the SEC. For so long as we continue to satisfy the requirements to be deemed a well-known seasoned issuer, this shelf registration statement allows us to issue an unlimited number of shares of our common stock from time to time. As of March 31, 2015, we had sold 16.0 million shares under this shelf registration statement.

In December 2012, the SEC declared effective a shelf registration statement filed by us 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 March 31, 2015, we had not sold any shares under this shelf registration statement.

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 R&D programs as planned. The amount and timing of expenditures will vary depending upon a number of factors, including progress of our R&D 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 an effective shelf registration statement on file with the SEC which allows us to issue an unlimited number of shares of our common stock from time to time. 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.

OFF-BALANCE SHEET ARRANGEMENTS

As of March 31, 2015, we did not have any off-balance sheet arrangements.

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 March 31, 2015, 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.

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NEW ACCOUNTING PRONOUNCEMENTS

In May 2014, the Financial Accounting Standards Board (FASB) issued an Accounting Standards Update (ASU), Revenue from Contracts with Customers, which outlines a comprehensive revenue recognition model and supersedes most current revenue recognition guidance. The new standard requires a company to recognize revenue upon transfer of goods or services to a customer at an amount that reflects the expected consideration to be received in exchange for those goods or services. The ASU defines a five-step approach for recognizing revenue, which may require a company to use more judgment and make more estimates than under the current guidance. The ASU as currently issued will be effective for us starting in 2017. On April 1, 2015, the FASB voted to propose a one-year deferral to the effective date, but to permit entities to adopt one year earlier if they choose (i.e., the original effective date). The proposal will be subject to the FASB's due process requirement, which includes a period for public comments. The new standard allows for two methods of adoption: (a) full retrospective adoption, meaning the standard is applied to all periods presented, or (b) modified retrospective adoption, meaning the cumulative effect of applying the new standard is recognized as an adjustment to the opening retained earnings balance. We are in the process of determining the adoption method as well as the effects the adoption will have on our consolidated financial statements.

FORWARD-LOOKING STATEMENTS

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

Forward-looking statements can be identified by the use of forward-looking words such as believes, expects, hopes, may, will, plan, intend, estimates, could, should, would, continue, seeks, proforma, or anticipates, or other similar words (including their use in the negative) in 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.

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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.

Changes in Internal Control over Financial Reporting

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officers, of any change to our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. In connection with the collaboration and license agreement entered into with Mitsubishi Tanabe in March 2015, we have developed additional internal controls over our process for accounting for revenue generating contracts. Except for these additional controls, our evaluation did not identify significant changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934) that occurred during the quarter ended March 31, 2015, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

ITEM 1A. RISK FACTORS

The following Risk Factors do not reflect any material changes to the Risk Factors set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, 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) Application or foreign equivalent filings required to initiate human clinical studies for our drug candidates or the FDA may require additional preclinical or clinical studies as a condition of the initiation of Phase I clinical studies, progression from Phase I to Phase II, or Phase II to Phase III, or for New Drug Application (NDA) approval;

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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 required toxicology studies 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;

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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 timelines for the enrollment in, or completion of, the Phase III tardive dyskinesia or the Phase I Tourette syndrome clinical trials of NBI-98854.

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 our current collaborators, and may need to enter into future collaborations to develop and commercialize certain of our product candidates.***

Our strategy for fully developing and commercializing elagolix is dependent upon maintaining our current collaboration agreement with AbbVie. This collaboration agreement provides for significant future payments should certain development, regulatory and commercial milestones be achieved, and royalties on future sales of elagolix. Under this agreement, AbbVie is responsible for, among other things, conducting clinical trials and obtaining required regulatory approvals for elagolix; as well as manufacturing and commercialization of elagolix in the event it receives regulatory approval.

Because of our reliance on AbbVie, the development and commercialization of elagolix could be substantially delayed, and our ability to receive future funding could be substantially impaired, if AbbVie:

failed to gain the requisite regulatory approval of elagolix;

did not successfully launch and commercialize elagolix;

did not conduct its collaborative activities in a timely manner;

did not devote sufficient time and resources to our partnered program;

terminated its agreement with us;

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

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

merged with a third party that wants to terminate our agreement.

In March 2015, we entered into a collaboration and license agreement with Mitsubishi Tanabe to develop and commercialize NBI-98854 in Japan and other select Asian markets. We will rely on Mitsubishi Tanabe to achieve certain development, regulatory and commercial milestones which, if achieved, could generate significant future revenue for us. Our collaboration with Mitsubishi Tanabe is subject to risks and uncertainties similar to those described above. In addition, we may need to enter into other collaborations to assist in the development and commercialization of other product candidates we are developing now or may develop in the future, and any such future collaborations would be subject to similar risks and uncertainties.

These issues and possible disagreements with AbbVie, Mitsubishi Tanabe or any future corporate collaborators could lead to delays in the collaborative research, development or commercialization 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 currently in research or clinical development. 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;

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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.

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 \$826.3 million as of December 31, 2014. We do not expect to be profitable, or generate positive cash flows from operations, for the year ending December 31, 2015.

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

**The 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 \$12.00 per share to approximately \$45.00 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;