NEUROCRINE BIOSCIENCES INC
Form 10-Q
October 29, 2015
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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)

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

(858) 617-7600

(Registrant s telephone number, including area code)

Not Applicable

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

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

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

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

Large accelerated filer x	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 x

The number of outstanding shares of the registrant s common stock, par value $0.001 per share, was 86,196,628 as of October 23, 2015.

Table of Contents

NEUROCRINE BIOSCIENCES, INC.

FORM 10-Q INDEX

Table of Contents

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share information)

(unaudited)

	September 30, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 66,378	$ 31,014
Short-term investments, available for sale	310,467	162,795
Other current assets	5,940	4,394
Total current assets	382,785	198,203
Property and equipment, net	2,874	2,507
Long-term investments, available for sale	101,986	37,492
Restricted cash	4,791	4,831
Total assets	$ 492,436	$ 243,033
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,197	$ 246
Accrued liabilities	14,514	11,508
Current portion of cease-use liability	481	467
Current portion of deferred rent	232	119
Current portion of deferred gain on sale of real estate	3,398	3,324
Total current liabilities	19,822	15,664
Deferred gain on sale of real estate	11,761	14,322
Deferred revenue	10,231	
Deferred rent	1,789	1,877
Cease-use liability	1,670	2,211
Other liabilities	220	260
Total liabilities	45,493	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 85,884,128 as of September 30, 2015 and 76,465,942 as of December 31, 2014	86	76
Additional paid-in capital	1,333,385	1,035,205
Accumulated other comprehensive loss	(609)	(277)
Accumulated deficit	(885,919)	(826,305)
Total stockholders equity	446,943	208,699
Total liabilities and stockholders equity	$ 492,436	$ 243,033

See accompanying notes to the condensed consolidated financial statements.

Table of Contents

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands, except per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenues:				
License fees	$	$	$ 19,769	$
Total revenues			19,769	
Operating expenses:				
Research and development	24,388	12,194	59,682	30,927
General and administrative	11,456	4,663	23,541	13,016
Total operating expenses	35,844	16,857	83,223	43,943
Loss from operations	(35,844)	(16,857)	(63,454)	(43,943)
Other income:				
Gain/(loss) on sale/disposal of assets		1	9	(4)
Deferred gain on real estate	828	805	2,487	2,414
Investment income, net	581	176	1,344	432
Other income, net				3
Total other income	1,409	982	3,840	2,845
Net loss	$ (34,435)	$ (15,875)	$ (59,614)	$ (41,098)
Net loss per common share:				
Basic and diluted	$ (0.40)	$ (0.21)	$ (0.71)	$ (0.56)
Shares used in the calculation of net loss per common share:				
Basic and diluted	85,856	75,948	83,927	74,050
Other comprehensive loss:				
Net loss	$ (34,435)	$ (15,875)	$ (59,614)	$ (41,098)
Net unrealized losses on available-for-sale securities	(205)	(81)	(332)	(212)
Comprehensive loss	$ (34,640)	$ (15,956)	$ (59,946)	$ (41,310)

See accompanying notes to the condensed consolidated financial statements.

4

Table of Contents

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2015	**2014**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (59,614)	$ (41,098)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	739	603
Gain on sale of assets	(2,496)	(2,410)
Deferred revenues	10,231	
Deferred rent	25	19
Amortization of premiums on investments	4,311	2,745
Non-cash share-based compensation expense	22,166	7,938
Change in operating assets and liabilities:		
Other current assets	(1,546)	(1,471)
Accounts payable and accrued liabilities	3,957	2,151
Cease-use liability	(527)	(308)
Other non-current liabilities	(40)	
Net cash used in operating activities	(22,794)	(31,831)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of investments	(376,437)	(241,156)
Sales and maturities of investments	159,628	121,373
Proceeds from sales of property and equipment	9	45
Deposits and restricted cash	40	
Purchases of property and equipment	(1,106)	(1,173)
Net cash used in investing activities	(217,866)	(120,911)
CASH FLOWS FROM FINANCING ACTIVITIES		
Issuance of common stock	276,024	136,999
Net cash provided by financing activities	276,024	136,999
Net increase (decrease) in cash and cash equivalents	35,364	(15,743)
Cash and cash equivalents at beginning of the period	31,014	44,789
Cash and cash equivalents at end of the period	$ 66,378	$ 29,046

See accompanying notes to the condensed consolidated financial statements.

5

Table of Contents

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 2018. 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 it will implement, 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.

Since 2011, the Company has followed 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 the Company s 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 development efforts; amounts due upon the achievement of specified milestones; manufacturing and royalties on future product sales.

Table of Contents

The ASC provides guidance relating to the separation of deliverables included in an arrangement into different units of accounting and the allocation of 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 (Milestone Method). 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.

Table of Contents

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 BESP 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.

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 nine months ended September 30, 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 GnRH antagonists (collectively, GnRH Compounds) for women s and men s health. AbbVie made an upfront payment of $75 million and 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 September 30, 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.

3. INVESTMENTS

Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in comprehensive loss. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization 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.

Table of Contents

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

	September 30, 2015	December 31, 2014
Certificates of deposit	$ 11,773	$ 17,438
Commercial paper	23,939	7,498
Corporate debt securities	371,671	174,323
Securities of government sponsored entities	5,070	1,028
Total investments	$ 412,453	$ 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
September 30, 2015:					
Classified as current assets:					
Certificates of deposit	Less than 1	$ 11,040	$ 12	$	$ 11,052
Commercial paper	Less than 1	23,934	9	(4)	23,939
Corporate debt securities	Less than 1	270,468	36	(98)	270,406
Securities of government-sponsored entities	Less than 1	5,071		(1)	5,070
Total short-term available-for-sale securities		$ 310,513	$ 57	$ (103)	$ 310,467
Classified as non-current assets:					
Certificates of deposit	1 to 2	$ 720	$ 1	$	$ 721
Corporate debt securities	1 to 2	101,829	1	(565)	101,265
Total long-term available-for-sale securities		$ 102,549	$ 2	$ (565)	$ 101,986
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:					
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.

Table of Contents

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 Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses
September 30, 2015:						
Commercial paper	7,979	(4)			7,979	(4)
Corporate debt securities	230,088	(662)	5,590	(1)	235,678	(663)
Securities of government-sponsored entities	4,919	(1)			4,919	(1)
Total	$ 242,986	$ (667)	$ 5,590	$ (1)	$ 248,576	$ (668)
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 September 30, 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 nine months ended September 30, 2015.

Table of Contents

The Company s assets which were measured at fair value on a recurring basis as of September 30, 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 Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
September 30, 2015:				
Classified as current assets:				
Cash and money market funds	$ 64.0	$ 64.0	$	$
Certificates of deposit	11.1	11.1		
Commercial paper	23.9		23.9	
Securities of government-sponsored entities	5.1		5.1	
Corporate debt securities	272.8		272.8	
Subtotal	376.9	75.1	301.8	
Classified as long-term assets:				
Certificates of deposit	5.5	5.5		
Corporate debt securities	101.3		101.3	
Total	483.7	80.6	403.1	
Less cash, cash equivalents and restricted cash	(71.2)	(68.8)	(2.4)	
Total investments	$ 412.5	$ 11.8	$ 400.7	$
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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
General and administrative	$ 7.5	$ 1.3	$ 11.6	$ 3.9
Research and development	6.4	1.4	$ 10.6	$ 4.0
Total share-based compensation expense	$ 13.9	$ 2.7	$ 22.2	$ 7.9

Table of Contents

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.

As of September 30, 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 $30.5 million and $18.0 million, respectively, which is expected to be recognized ratably over a weighted average period of approximately 2.7 years and 2.9 years, respectively. Additionally, the Company has certain PRSUs outstanding. The total unrecognized estimated compensation cost related to these PRSUs is $2.7 million and is expected to be recognized ratably over the estimated period to meeting the performance criteria.

During the nine months ended September 30, 2015 and 2014, stock options to purchase approximately 1.2 million and 0.6 million shares of the Company s common stock were exercised, respectively. The cash received by the Company from stock option exercises during the nine months ended September 30, 2015 and 2014 was approximately $5.3 million and $3.8 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 nine months ended September 30, 2015 and 2014, respectively. In October 2015, the Company issued approximately 0.3 million shares of common stock pursuant to the meeting of certain performance conditions related to PRSUs.

Stock Option Assumptions

The Company granted stock options to purchase approximately 1.1 million and 0.9 million shares of the Company s common stock during the nine months ended September 30, 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 nine months ended September 30, 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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Risk-free interest rate	1.8%		1.7%	2.3%
Expected volatility of common stock	65.8%		66.5%	71.2%
Dividend yield	0.0%		0.0%	0.0%
Expected option term	6.6 years		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 nine months ended September 30, 2015 and 2014, share-based

compensation expense related to stock options was $9.4 million and $6.0 million, respectively.

Restricted Stock Units

During each of the nine months ended September 30, 2015 and 2014, the Company granted approximately 0.4 million RSUs that generally vest annually over a four year period. Additionally, during the nine months ended September 30, 2015 and 2014, the Company granted 50,000 and 475,000 PRSUs, respectively. These PSRUs vest based on the achievement of pre-defined Company-specific performance criteria and expire approximately five years from the grant date. The fair value of RSUs and PRSUs are estimated based on the closing sale price of the Company s common stock on the date of the grant. For the nine months ended September 30, 2015 and 2014, share-based compensation expense related to RSUs was $4.4 million and $1.9 million, respectively. During the third quarter of 2015, the Company recognized approximately $8.3 million in expense related to PRSUs as it became probable the predefined performance conditions would be met mainly due to the Phase III results of the Kinect 3 clinical study.

Table of Contents

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.

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.

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 September 30, 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 September 30, 2015, the Company had not sold any shares under this shelf registration statement. This shelf registration statement will cease to be effective during the fourth quarter of 2015.

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) whereby it leased back for an initial term of 12 years its corporate headquarters comprised of two buildings located at 12790 El Camino Real (Front Building) and 12780 El Camino Real (Rear Building) in San Diego, California. The Company also entered into a series of lease amendments (Amendments), beginning in late 2008, through which it vacated the Front Building, but continues to occupy the Rear Building. The ultimate result of this real estate sale was a net gain of $39.1 million which was deferred in accordance with authoritative guidance. The Company recognized $2.5 million and $2.4 million of the deferred gain during the nine month periods ended September 30, 2015 and 2014, respectively, and will recognize the remaining $15.2 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.

As of September 30, 2015, the Company has two sublease agreements for approximately 30,000 square feet of the Rear Building. These subleases are expected to result in approximately $1.1 million of rental income in 2016 with this sublease rental income being recorded as an offset to rent expense. The income generated under these subleases is lower than the Company s financial obligation under the Lease for the Rear Building, as determined on a per square foot basis. Consequently, the Company is required to record a cease-use liability for the net present value of the estimated difference between the expected income to be generated under the subleases and future subleases and the Lease obligation over the remaining term of the Lease for the space that is occupied by the subtenant. The subleases provide various options to extend for additional one-year renewal periods. The current terms each of these two subleases expire in February 2017 and March 2018.

Table of Contents

The following table sets forth changes to the accrued cease-use liability during the three and nine months ended September 30, 2015 and 2014 (*in thousands*):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Beginning balance	$ 2,326	$ 2,892	$ 2,678	$ 3,096
Change in estimate			(87)	
Payments	(175)	(104)	(440)	(308)
Ending balance	$ 2,151	$ 2,788	$ 2,151	$ 2,788

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 and nine months ended September 30, 2015, the Company realized a net loss of $34.4 million and $59.6 million, respectively. Potentially dilutive securities totaled approximately 4.2 million and 4.0 million, for the three and nine months ended September 30, 2015, respectively. Options to purchase approximately 0.1 million and 0.3 million shares of common stock were outstanding during the three and nine months ended September 30, 2015, respectively, with an exercise price greater than the average market price of the underlying common shares.

For the three and nine months ended September 30, 2014, the Company realized a net loss of $15.9 million and $41.1 million, respectively. Potentially dilutive securities totaled approximately 2.8 million for each of the three and nine month periods ended September 30, 2014. Options to purchase approximately 0.9 million shares of common stock were outstanding during each of the three and nine month periods ended September 30, 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.

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 and our Quarterly Reports on Form 10-Q for the three months ended March 31, 2015 and June 30, 2015.

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.

Table of Contents

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. We intend to maintain certain commercial rights to our VMAT2 inhibitor and other programs to evolve into a fully-integrated pharmaceutical company.

During the quarter ended June 30, 2015, we suspended two planned clinical studies of our CRF Antagonist, NBI-77860, due to previously unobserved pre-clinical findings.

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 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 September 30, 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.

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 nine months 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

Table of Contents

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) and share-based compensation. 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.

Since 2011, we have followed 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. 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.

Table of Contents

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 September 30, 2015 and 2014 was $13.9 million and $2.7 million, respectively. For the nine months ended September 30, 2015 and 2014, we recognized share-based compensation expense of $22.2 million and $7.9 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 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. During the third quarter of 2015, we recognized approximately $8.3 million in expense related to PRSUs due to the Phase III results of the Kinect 3 clinical study.

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

THREE MONTHS ENDED SEPTEMBER 30, 2015 AND 2014

Operating Expenses

Research and Development

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

	Three Months Ended September 30,	
	2015	2014
	(In millions)	
External development expense:		
VMAT2	$ 9.1	$ 2.6
Corticotropin-Releasing Factor (CRF)	0.4	0.9
Other	0.1	1.1
Total external development expense	9.6	4.6
R&D personnel expense	11.3	4.7
R&D facility and depreciation expense	1.6	1.5
Other R&D expense	1.9	1.4
Total R&D expense	$ 24.4	$ 12.2

R&D expense increased by $12.2 million; from $12.2 million in the third quarter of 2014 to $24.4 million in the third quarter of 2015. Approximately $5.0 million of this increase in R&D expense is due to higher external development expenses in 2015. Our VMAT2 Phase III clinical program, which was initiated during the second half of 2014, is responsible for the majority of this increase

Table of Contents

in external development expenses. Approximately $6.6 million of the increase in R&D expense was due to higher R&D personnel related expense. Share-based compensation expense increased by approximately $5.0 million from 2014 to 2015, approximately $4.0 million of which was related to PRSUs recognized in the third quarter of 2015. An increase in R&D headcount and other personnel related costs accounted for the balance of the increase in personnel expense. Other R&D expense also increased by $0.5 million from 2014 to 2015 primarily due to external consulting expenses as we expanded our efforts on the New Drug Application (NDA) for NBI-98854 in tardive dyskinesia.

General and Administrative

General and administrative expense increased by $6.8 million; from $4.7 million in the third quarter of 2014 to $11.5 million in the third quarter of 2015. The majority of this increase in overall expense was due to higher personnel related expenses. Share-based compensation expense increased by approximately $6.2 million from 2014 to 2015, approximately $4.3 million of which was related to PRSUs recognized in the third quarter of 2015. An increase in headcount and other personnel related costs accounted for approximately $0.6 million of additional increase in personnel expense.

Net Loss

Our net loss for the third quarter of 2015 was $34.4 million, or a net loss of $0.40 per share, compared to a net loss of $15.9 million, or a net loss of $0.21 per share, during the same period in 2014. The increase in our net loss from 2014 to 2015 was a result of the above mentioned higher expenses.

NINE MONTHS ENDED SEPTEMBER 30, 2015 AND 2014

License Fee Revenues

As discussed above, during the third quarter of 2015, we entered into a 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 included an up-front license fee of $30 million. During the first nine months of 2015, we 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:

	Nine Months Ended September 30,	
	2015	2014
	(In millions)	
External development expense:		
VMAT2	$ 20.8	$ 4.5
CRF	2.9	1.8
Other	0.7	1.8

Total external development expense	24.4	8.1
R&D personnel expense	24.9	14.1
R&D facility and depreciation expense	4.4	4.3
Other R&D expense	6.0	4.4
Total R&D expense	$ 59.7	$ 30.9

The $28.8 million increase in nine-month R&D expenses from 2014 to 2015 was primarily due to a $16.3 million increase in external development expenses related to our VMAT2 Phase III clinical program, which was initiated during the second half of 2014. Approximately $10.8 million of the increase in R&D expense was due to higher R&D personnel related expense. Share-based compensation expense increased by approximately $6.6 million from 2014 to 2015; approximately $4.0 million of which was related to PRSUs recognized in the third quarter of 2015. An increase in R&D headcount and other personnel related costs accounted for the balance of the increase in personnel expense. Other R&D expense also increased by $1.6 million from 2014 to 2015 primarily due to external consulting expenses as we expanded our efforts on the NDA for NBI-98854 in tardive dyskinesia.

Table of Contents

General and Administrative

General and administrative expense increased to $23.5 million in the first nine months of 2015 compared with $13.0 million during the same period in 2014. The majority of this $10.5 million increase in overall expense was due to higher personnel related expenses. Share-based compensation expense increased by approximately $7.7 million from 2014 to 2015; approximately $4.3 million of which was related to PRSUs recognized in the third quarter of 2015. An increase in headcount and other personnel related costs accounted for approximately $1.9 million of additional increase in personnel expense. Increases in market research, licensing and other professional fees accounted for approximately $0.8 million of the increase in general and administrative expenses from 2014 to 2015.

Net Loss

Our net loss for the first nine months of 2015 was $59.6 million, or a net loss of $0.71 per share, compared to a net loss of $41.1 million, or a net loss of $0.56 per share, during the same period in 2014. Although 2015 revenue increased by $19.8 million due to the up-front license fee from Mitsubishi Tanabe, this revenue increase was offset by an increase in 2015 operating expenses of $39.3 million, as discussed above. Additionally, we realized an increase in other income of approximately $1.0 million, period to period, primarily associated with increased interest income due to higher investment principal balances.

LIQUIDITY AND CAPITAL RESOURCES

Net cash used in operating activities during the first nine months of 2015 was $22.8 million compared to $31.8 million during the same period in 2014. The $9.0 million change in cash flows from operating activities is primarily due to a $30 million up-front payment from Mitsubishi Tanabe received in the second quarter of 2015. This up-front payment was offset by an increase in operating expenses of approximately $39.3 million, approximately $14.3 million of which consisted of non-cash share-based compensation expense.

Net cash used in investing activities during the first nine months of 2015 was $217.9 million compared to $120.9 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.

Net cash provided by financing activities during the first nine months of 2015 was $276.0 million compared to $137.0 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 $5.3 million and $3.8 million in cash proceeds during the first nine months of 2015 and 2014, respectively.

At September 30, 2015, our cash, cash equivalents, and investments totaled $478.8 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 September 30, 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 September 30, 2015, we had not sold any shares under this shelf registration statement. By rule of the SEC, this shelf registration statement will cease to be effective during the fourth quarter of 2015.

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.

Table of Contents

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 September 30, 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 September 30, 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.

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 2018. 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 we will implement 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, intends, estimates, could, should, would, continue, seeks, proforma, or antici words (including their use in the negative), or by discussions of future matters such as the development or regulatory approval of new products, technology enhancements, possible changes in legislation and other statements that are not historical. These statements include but are not limited to statements under the captions Risk Factors, and Management s Discussion and Analysis of Financial Condition and Results of Operations as well as other sections in this report. You should be aware that the occurrence of any of the events discussed under the heading in Part II titled Item 1A. Risk Factors and elsewhere in this report could substantially harm our business, results of operations and financial condition and that if any of these events occurs, the trading price of our common stock could decline and you could lose all or a part of the value of your shares of our common stock.

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

Table of Contents

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports required by the Securities 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 Officer, 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. 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 September 30, 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;

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;

we or the FDA or similar foreign regulatory authorities may suspend the trials;

Table of Contents

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 initiation of the Phase III 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 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.

Table of Contents

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;

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 for these securities 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 $15.00 per share to approximately $57.00 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;

Table of Contents

announcements of technological innovations or new therapeutic products by us or others;

general economic and market conditions, including economic and market conditions affecting the biotechnology industry;

developments in patent or other proprietary rights;

developments related to the FDA;

future sales of our common stock by us or our stockholders;

comments by securities analysts;

fluctuations in our operating results;

government regulation;

health care reimbursement;

failure of any of our product candidates, if approved, to achieve commercial success; and

public concern as to the safety of our drugs.

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

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

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

We are dependent on licenses from third parties for some of our key technologies. These licenses typically subject us to various commercialization, reporting and other obligations. If we fail to comply with these obligations, we could

lose important rights. For example, we license some of the core technologies used in our research and development activities and collaborations from third parties, including the GnRH receptor which we license from The Mount Sinai School of Medicine of the City University of New York for use in the elagolix program. If we were to default on our obligations under any of our licenses, we could lose some or all of our rights to develop, market and sell products covered by these licenses. Likewise, if we were to lose our rights under a license to use proprietary research tools, it could adversely affect our existing collaborations or adversely affect our ability to form new collaborations. We also face the risk that our licensors could, for a number of reasons, lose patent protection or lose their rights to the technologies we have licensed, thereby impairing or extinguishing our rights under our licenses with them.

We have limited marketing experience, and no sales force or distribution capabilities, and if our products are approved, we may not be able to commercialize them successfully.

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

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

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

Table of Contents

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

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

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

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

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

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

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

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

We may require additional funding to continue our research and product development programs, to conduct preclinical studies and clinical trials, for operating expenses and to pursue regulatory approvals for product candidates, for the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims, if any, product in-licensing and any possible acquisitions, and we may require additional funding to establish manufacturing and marketing capabilities in the future. We believe that our existing capital resources, together with investment income, and future payments due under our strategic alliances, will be sufficient to satisfy our current and projected funding requirements for at least the next 12 months. However, these resources might be insufficient to conduct research and development programs to the full extent currently planned. If we cannot obtain adequate funds, we may

be required to curtail significantly one or more of our research and development programs or obtain funds through additional arrangements with corporate collaborators or others that may require us to relinquish rights to some of our technologies or product candidates.

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

- continued scientific progress in our research and development programs;
- the magnitude and complexity of our research and development programs;
- progress with preclinical testing and clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in filing and pursuing patent applications, enforcing patent claims, or engaging in interference proceedings or other patent litigation;
- competing technological and market developments;
- the establishment of additional strategic alliances;
- the cost of commercialization activities and arrangements, including manufacturing of our product candidates; and
- the cost of product in-licensing and any possible acquisitions.

We intend to seek additional funding through strategic alliances, and may seek additional funding through public or private sales of our securities, including equity securities. For example, we have an effective shelf registration statement on file with the Securities and Exchange Commission (SEC) which, for so long as we continue to satisfy the requirements to be deemed a well-known seasoned issuer, allows us to issue an unlimited number of shares of our common stock from time to time. We also have an effective shelf

Table of Contents

registration statement on file with the SEC which allows us to issue shares of our common stock from time to time for an aggregate initial offering price of up to $150 million. In the event that we fail to satisfy the requirements to be deemed a well-known seasoned issuer, we would be limited to using this shelf registration statement which may be used for the issuance of shares of our common stock for an aggregate initial offering price of up to only $150 million. In addition, we have previously financed capital purchases and may continue to pursue opportunities to obtain additional debt financing in the future. Additional equity or debt financing might not be available on reasonable terms, if at all. Any additional equity financings will be dilutive to our stockholders and any additional debt financings may involve operating covenants that restrict our business.

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

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

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

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

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

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

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

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

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

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

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

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

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, new SEC regulations and NASDAQ rules, are creating uncertainty for companies such as ours. These laws, regulations and standards are subject to varying interpretations in some cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are committed to maintaining high standards of

Table of Contents

corporate governance and public disclosure. As a result, our efforts to comply with evolving laws, regulations and standards have resulted in, and are likely to continue to result in, increased general and administrative expenses and management time related to compliance activities. If we fail to comply with these laws, regulations and standards, our reputation may be harmed and we might be subject to sanctions or investigation by regulatory authorities, such as the SEC. Any such action could adversely affect our financial results and the market price of our common stock.

Risks Related to Our Industry

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

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

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

Health care reform measures and other recent legislative initiatives could adversely affect our business.

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payers to contain or reduce the costs of health care. In the United States, comprehensive health care reform legislation was enacted by the Federal government and we expect that there will continue to be a number of federal and state proposals to implement government control over the pricing of prescription pharmaceuticals. In addition, increasing emphasis on reducing the cost of health care in the United States will continue to put pressure on the rate of adoption and pricing of prescription pharmaceuticals. Moreover, in some foreign jurisdictions, pricing of prescription pharmaceuticals is already subject to government control. Additionally, other recent federal legislation imposes new obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. Among the requirements of this new legislation, manufacturers are required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding distribution of the drug product. Further, under this new legislation, manufacturers will have drug product investigation, quarantine, disposition, notification and purchaser license verification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are

otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

We are currently unable to predict what additional legislation or regulation, if any, relating to the health care industry may be enacted in the future or what effect recently enacted Federal legislation or any such additional legislation or regulation would have on our business. The pendency or approval of such proposals or reforms could result in a decrease in our stock price or limit our ability to raise capital or to enter into collaboration agreements for the further development and commercialization of our programs and products.

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

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

Table of Contents

Competition may also arise from, among other things:

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

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

We are performing research on or developing products for the treatment of several disorders including endometriosis, tardive dyskinesia, uterine fibroids, Tourette syndrome, classic congenital adrenal hyperplasia, stress-related disorders, pain, and other neurological and endocrine-related diseases and disorders, and there are a number of competitors to products in our research pipeline. If one or more of our competitors products or programs are successful, the market for our products may be reduced or eliminated.

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

- capital resources;
- research and development resources, including personnel and technology;
- regulatory experience;
- preclinical study and clinical testing experience;
- manufacturing and marketing experience; and
- production facilities.

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

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

- obtain patent protection for our products;

preserve our trade secrets;

prevent third parties from infringing upon our proprietary rights; and

operate without infringing upon the proprietary rights of others, both in the United States and internationally. Because of the substantial length of time and expense associated with bringing new products through the development and regulatory approval processes in order to reach the marketplace, the pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Accordingly, we intend to seek patent protection for our proprietary technology and compounds. However, we face the risk that we may not obtain any of these patents and that the breadth of claims we obtain, if any, may not provide adequate protection of our proprietary technology or compounds.

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

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

Table of Contents

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

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

Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees and independent contractors, such as principal investigators, consultants, commercial partners and vendors, could include failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. Employee and independent contractor misconduct could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation.

Any relationships with healthcare professionals, principal investigators, consultants, customers (actual and potential) and third-party payors in connection with our current and future business activities are and will continue to be subject, directly or indirectly, to federal and state healthcare laws. If we are unable to comply, or have not fully complied, with such laws, we could face penalties, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations.

Our business operations and activities may be directly, or indirectly, subject to various federal and state healthcare laws, including without limitation, fraud and abuse laws, false claims laws, data privacy and security laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers. These laws may restrict or prohibit a wide range of business activities, including, but not limited to, research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as proposed and future sales, marketing and education programs.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws. If our operations or activities are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to, without limitation, civil, criminal and

administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

In addition, any sales of our product candidates once commercialized outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

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

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

Table of Contents

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

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

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store confidential and sensitive information on our networks and in our data centers. This information includes, among other things, our intellectual property and proprietary information, the confidential information of our collaborators and licensees, and the personally identifiable information of our employees. It is important to our operations and business strategy that this information remains secure and is perceived to be secure. Despite security measures, however, our information technology and network infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance, or other disruptions. Any such attack or breach could compromise our networks and data centers and the information stored there could be accessed, publicly disclosed, lost, or stolen. Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, delays and impediments to our discovery and development efforts, and damage to our reputation.

ITEM 5: Other Information

Not applicable.

Table of Contents

ITEM 6. EXHIBITS

Exhibit Number	Description
3.1	Certificate of Incorporation(1)
3.2	Certificate of Amendment to Certificate of Incorporation(1)
3.3	Bylaws, as amended(2)
4.1	Form of Common Stock Certificate(3)
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
32*	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

(1) Incorporated by reference to the Company s Annual Report on Form 10-K filed on February 8, 2013

(2) Incorporated by reference to (a) Exhibit 3.1 to the Company s Current Report on Form 8-K dated October 8, 2015, (b) Exhibit 3.1 to the Company s Current Report on Form 8-K dated September 4, 2015 and (c) the Company s Registration Statement on Form S-1 (Registration No. 333-03172)

(3) Incorporated by reference to the Company s Registration Statement on Form S-1 (Registration No. 333-03172)

* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of Neurocrine Biosciences, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Except as specifically noted above, the Company s Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K have a Commission File Number of 000-22705.

Table of Contents

SIGNATURES

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

NEUROCRINE BIOSCIENCES, INC.

(Registrant)

Dated: October 29, 2015

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