NEUROCRINE BIOSCIENCES INC
Form 10-K
February 09, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2014

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)	**(I.R.S. Employer Identification Number)**
12780 El Camino Real, San Diego, CA	**92130**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number, including area code:

(858) 617-7600

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, $0.001 par value	The NASDAQ Stock Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes þ No ¨

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No þ

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 þ 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 (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes þ No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. þ

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

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

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

The aggregate market value of the common equity held by non-affiliates of the registrant as of June 30, 2014 totaled approximately $825,571,712 based on the closing price for the registrant s Common Stock on that day as reported by the NASDAQ Stock Market. Such value excludes Common Stock held by executive officers, directors and 10% or greater stockholders as of June 30, 2014. The identification of 10% or

greater stockholders as of June 30, 2014 is based on Schedule 13G and amended Schedule 13G reports publicly filed before June 30, 2014. This calculation does not reflect a determination that such parties are affiliates for any other purposes.

As of January 26, 2015, there were 77,163,348 shares of the registrant s Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document Description	**10-K Part**
Portions of the registrant s notice of annual meeting of stockholders and proxy statement to be filed pursuant to Regulation 14A within 120 days after registrant s fiscal year end of December 31, 2014 are incorporated by reference into Part III of this report	III

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PART I

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K and the information incorporated herein by reference contain 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, estimates, could, should, would, continue, seeks, pro forma, or anticipates, or other similar words (including their use in the ne discussions of future matters such as the development 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, Management s Discussion and Analysis of Financial Condition and Results of Operations and Business, as well as other sections in this report. You should be aware that the occurrence of any of the events discussed under the heading Item 1A. Risk Factors and elsewhere in this report could substantially harm our business, results of operations and financial condition and that if any of these events occurs, the trading price of our common stock could decline and you could lose all or a part of the value of your shares of our common stock.

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

ITEM 1. ***BUSINESS***

We were originally incorporated in California in January 1992 and were reincorporated in Delaware in May 1996.

We discover and develop innovative and life-changing pharmaceuticals, in diseases with high unmet medical needs, through our novel R&D platform, focused on neurological and endocrine based diseases and disorders. Our 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 wholly owned vesicular monoamine transporter 2 (VMAT2) inhibitor for the treatment of movement disorders. We intend to maintain certain commercial rights to our VMAT2 inhibitor and evolve into a fully-integrated pharmaceutical company.

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Our Product Pipeline

The following table summarizes our most advanced product candidates currently in clinical development and those currently in research and is followed by detailed descriptions of each program:

Program	Target Indication(s)	Status	Rights
Product candidates in clinical development:			
elagolix	Endometriosis	Phase III	AbbVie
VMAT2 (NBI-98854)	Tardive Dyskinesia	Phase III	Neurocrine
elagolix	Uterine Fibroids	Phase II	AbbVie
CRF_1 Antagonist (NBI-77860)	Classic Congenital Adrenal Hyperplasia	Phase I/II	Neurocrine
VMAT2 (NBI-98854)	Tourette Syndrome	Phase I	Neurocrine
Research programs:			
VMAT2	Movement Disorders, Bipolar Disorder and Schizophrenia	Research	Neurocrine
GnRH Antagonists	Men s and Women s Health, Oncology	Research	AbbVie
Antiepileptic Drugs	Epilepsy, Essential Tremor, Pain	Research	Neurocrine
G Protein-Coupled Receptors	Other Conditions	Research	Neurocrine

Phase III indicates that we or our collaborators are conducting large-scale, multicenter comparative clinical trials on patients afflicted with a target disease in order to provide substantial evidence for efficacy and safety of the product candidate.

Phase II indicates that we or our collaborators are conducting clinical trials on groups of patients afflicted with a specific disease in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety of the product candidate.

Phase I indicates that we or our collaborators are conducting clinical trials with a smaller number of subjects to determine early safety profile, maximally tolerated dose and pharmacological properties of the product candidate in human volunteers.

Research indicates identification and evaluation of compound(s) in laboratory and preclinical models.

Product Candidates In Clinical Development

elagolix Gonadotropin-Releasing Hormone (GnRH) Antagonist

GnRH is a peptide that stimulates the secretion of the pituitary hormones that are responsible for sex steroid production and normal reproductive function. Researchers have found that chronic administration of GnRH agonists, after initial stimulation, reversibly shuts down this transmitter pathway and is clinically useful in treating hormone-dependent diseases such as endometriosis and uterine fibroids. Several companies have developed peptide GnRH agonists on this principle, such as Lupron® and Zoladex®. However, since they are peptides, they must be injected via a depot formulation rather than the preferred oral route of administration. In addition, GnRH agonists can take up to several weeks to exert their desired effect once the initial stimulation has occurred, a factor not seen with the use of GnRH antagonists. Upon administration, GnRH agonists have shown a tendency to exacerbate the condition via a hormonal flare. More importantly, the profound suppression effect observed with GnRH agonists is similar to that seen after menopause and can be associated with hot flashes and the loss of bone mineral density.

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Orally active, nonpeptide GnRH antagonists potentially offer several advantages over injectable GnRH peptide drugs, including rapid onset of hormone suppression without hormonal flare. Also, injection site reactions commonly observed in peptide depots are avoided and dosing can be rapidly discontinued if necessary a clinical management option not available with long-acting depot injections. Additionally, by using GnRH antagonists, it may be possible to alter the level of pituitary GnRH suppression thereby titrating circulating estrogen levels. Using this approach, an oral GnRH antagonist may provide patients relief from the painful symptoms of endometriosis while avoiding the need for the active management of bone loss.

Endometriosis. Endometriosis is associated with a multitude of symptoms, some of the most common of which include pain related both to menstruation (dysmenorrhea) and sexual intercourse (dyspareunia) as well as chronic pelvic pain throughout the menstrual cycle, infertility, and menorrhagia, among many others. The wide range of symptoms associated with endometriosis serves to complicate and delay diagnosis due to the significant overlap of symptoms with the disease profiles of other conditions. The World Endometriosis Research Foundation estimates that there are over 170 million women worldwide who suffer from endometriosis, including approximately 7.5 million women in the United States alone. We believe that the availability of an oral treatment, lacking the side effect profile of the currently available peptide GnRH agonists, may be a desirable alternative to current pharmaceutical therapies and ultimately encourage a significantly higher treatment rate.

During 2008, we completed the first Phase IIb study of elagolix (PETAL or 603 study) in which 252 patients, with a laparoscopic diagnosis of endometriosis, were treated over the initial six-month period. This multi-center, randomized, double-blind, double-dummy study consisted of three treatment groups, elagolix 150mg once daily, elagolix 75mg twice daily, and an active control, DMPA-SC. The primary purpose of this study was to assess the impact of six months of treatment of elagolix on bone mineral density as measured by a dual energy x-ray absorptiometry (DXA) scan at the conclusion of treatment and at six and 12 months post treatment. This study also assessed, as secondary endpoints, the impact of treatment on endometriosis symptoms as measured by Composite Pelvic Signs and Symptoms Scale (CPSSS), a monthly recall scale that measures dysmenorrhea, non-menstrual pelvic pain, dyspareunia, pelvic tenderness and induration (all elements of endometriosis pain). Top-line results showed that elagolix met the primary endpoint by having minimal impact on bone mineral density at the conclusion of treatment. This study also showed that elagolix had both a statistical and clinically meaningful reduction in endometriosis symptoms as measured by CPSSS with an 86% responder rate in the 150mg once daily elagolix arm of the study. Additionally, elagolix was shown to be non-inferior to DMPA-SC under the CPSSS. Patient follow up both six and 12 months post treatment showed elagolix did not result in a significant reduction in bone mineral density as measured by DXA scan, with a mean time of return to ovulation of 24 days for elagolix subjects.

Toward the conclusion of the 603 study, the U.S. Food and Drug Administration (FDA) requested that the endpoints for dysmenorrhea and non-menstrual pelvic pain be assessed on a daily basis rather than utilizing the CPSSS monthly recall scale. In addition, the FDA also provided modified wording to assess the dysmenorrhea and non-menstrual pelvic pain scores on a daily basis. Given these new independent co-primary endpoints, we conducted two additional Phase IIb trials of elagolix to evaluate these modified endpoints as proposed by the FDA, to fully explore the elagolix dose range utilizing both 150mg and 250mg doses. These two trials were designed to assess elagolix for an initial three months, with the non-elagolix treatment arms re-randomized after three months into treatment groups of either 150mg or 250mg of elagolix once daily for an additional three months.

The first additional Phase IIb trial (Lilac PETAL or 702 study) consisted of three arms, elagolix 150mg once daily, elagolix 250mg once daily and placebo. We randomized 155 subjects with a laparoscopic diagnosis of endometriosis in this trial. The three-month placebo-controlled portion of the 702 study showed that elagolix provided endometriosis sufferers with clinical improvement of symptoms, coupled with an excellent safety and tolerability profile. However, the FDA-proposed non-menstrual pelvic pain daily scale had a low baseline score and was relatively insensitive to treatment effects. There were no treatment related serious adverse events in the 702 study and the two most common adverse events were headache and nausea, which were typically mild and transient and consistent with our previous studies.

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The second additional Phase IIb trial (Tulip PETAL or 703 study) consisted of four arms, elagolix 150mg once daily, elagolix 250mg once daily, Prostap® SR 3.75mg (leuprorelin) and placebo. We enrolled 174 subjects with a laparoscopic diagnosis of endometriosis in this trial. The three-month placebo-controlled portion of the 703 study confirmed that elagolix and leuprorelin are associated with reductions in dysmenorrhea and non-menstrual pelvic pain daily scores when compared to placebo. However, the FDA-proposed non-menstrual pelvic pain daily scale numeric changes and dynamic range were both small. Although the adverse events reported in the 703 study as occurring more often with elagolix than with placebo were nausea and headache (≤12%), consistent with previous clinical studies of elagolix, these events were generally mild or moderate, transient and not generally associated with study discontinuation. There were no treatment related serious adverse events.

In August 2009, we held a Type C meeting with the FDA to discuss the non-menstrual pelvic pain scale as proposed by the FDA and used in the 702 and 703 studies. Based on this meeting, we modified the wording of the non-menstrual pelvic pain and dysmenorrhea daily scales and launched a new clinical trial, the Daisy PETAL Study (901 study). This parallel, double-blind, placebo-controlled clinical trial was designed to provide an assessment of the modified scales over an eight-week treatment period of 150mg elagolix, followed by sixteen weeks of open-label treatment. This trial commenced in September 2009 and randomized approximately 130 subjects. In May 2010, we announced the results of this trial which showed the symptoms of dysmenorrhea and non-menstrual pelvic pain, as measured by the modified daily scales, both improved significantly in the elagolix treated arms (p-value<0.001 and p-value<0.01, respectively). Daily dysmenorrhea pain scores were a 2.1 at baseline (0-3 scale) with a 1.13 reduction in the elagolix arm compared to a 0.37 reduction in the placebo arm at eight weeks. Daily non-menstrual pelvic pain scores were a 1.4 at baseline (0-3 scale) with a 0.47 reduction in the elagolix arm compared to a 0.19 reduction in the placebo arm at eight weeks. There were no treatment related serious adverse events in the 901 study and the two most common adverse events were headache and nausea, which were typically mild and transient and consistent with our previous studies.

We have a worldwide collaboration with AbbVie to develop and commercialize elagolix and all next-generation non-peptide GnRH antagonists for women s and men s health indications. AbbVie has primary responsibility for all regulatory interactions with the FDA related to elagolix and the next-generation GnRH antagonists covered by the collaboration.

The endometriosis Phase III program is assessing two separate doses of elagolix (150mg once daily and 200mg twice daily) over a 24-week treatment period. The initial randomized, parallel, double-blind, placebo-controlled pivotal trial (Violet PETAL) enrolled 872 women in approximately 160 clinical sites throughout the United States, Canada and Puerto Rico. The co-primary endpoints were a comparison of the daily non-menstrual pelvic pain and daily dysmenorrhea scores during the third month of treatment to the respective daily baseline scores utilizing a responder analysis. Maintenance of response at month six was also assessed utilizing the same daily scales.

On January 8, 2015, AbbVie released the top-line results of the initial six months of placebo controlled dosing of the Violet PETAL study. After six months of continuous treatment, both doses of elagolix (150 mg once daily and 200 mg twice daily) met the study s co-primary endpoints (p<0.001) of reducing scores of non-menstrual pelvic pain and dysmenorrhea associated with endometriosis, at month three, as well as at month six.

The observed safety profile of elagolix in the Violet PETAL study was consistent with observations from prior studies. Among the most common adverse events were hot flash, headache, nausea and fatigue. While most adverse events were similar across treatment groups, some, such as hot flash and bone mineral density loss were dose-dependent. Overall discontinuation rates were similar across treatment groups and discontinuations specifically due to adverse events were 5.9%, 6.4%, and 9.7% for placebo, 150 mg once daily and 200 mg twice daily, respectively.

Additional efficacy and safety endpoints for the patients enrolled in the Violet PETAL study will be measured through one year of continuous dosing as well as for a period of time after the final dose. The one-year dosing portion of this study is expected to conclude in May 2015.

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The second Phase III study of elagolix was initiated by AbbVie during 2013. This study (Solstice study) is similar in design to the Violet PETAL study with the same co-primary endpoints of daily non-menstrual pelvic pain and daily dysmenorrhea, comparing the third month of treatment to the respective daily baseline scores utilizing a responder analysis. This trial is anticipated to enroll 788 women with moderate to severe endometriosis-associated pain at more than 200 sites globally**.** Top-line efficacy results from the Solstice study are expected in late 2015.

Uterine Fibroids. Uterine fibroids are benign hormonally responsive tumors that form in the wall of the uterus. They are the most common solid tumor in women with a prevalence rate of at least 25% (American College of Obstetricians and Gynecologists). While many women do not have symptoms, depending on the size, location and number, uterine fibroids can cause pelvic pain, reproductive problems, and severe bleeding that can lead to anemia. Due to the severity of symptoms, treatment sometimes requires surgery, including the removal of the uterus. In fact, uterine fibroids is a leading indication for hysterectomy in the United States, with approximately 250,000 hysterectomies performed each year related to uterine fibroids (Whiteman *et al AJOG* 2008, *198,* e1). We believe that a safe and effective oral therapy would be a preferred treatment regimen rather than surgical intervention.

During 2011, AbbVie initiated a randomized, double-blind, placebo-controlled, Phase IIa study of approximately 300 women to assess the safety and efficacy of elagolix in the treatment of uterine fibroids. The primary endpoint in this study was an assessment of blood loss after three months of treatment with elagolix. The dose ranging study evaluated various doses of elagolix compared to placebo. Additional efficacy endpoints were also evaluated including change in uterine volume, fibroid volume, and change in menstrual patterns. Based on the results of this study, AbbVie launched a Phase IIb uterine fibroids study for elagolix in 2013.

The Phase IIb clinical trial has enrolled approximately 520 women with heavy uterine bleeding due to uterine fibroids and will assess uterine blood loss after six months of treatment across various dosing regimens of elagolix, utilizing a quantitative assessment tool for blood loss, alkaline hematin. Secondary efficacy endpoints include change in uterine volume, fibroid volume, and menstrual patterns. Safety assessments of bone mineral density, comparing baseline to month six, will be performed via DXA scan. Patients will also be followed off drug for up to six months. This study is expected to be completed in the second half of 2015.

Vesicular Monoamine Transporter 2 Inhibitor (VMAT2) (NBI-98854)

VMAT2 is a protein concentrated in the human brain that is essential for the transmission of nerve impulses between neurons. VMAT2 is primarily responsible for packaging and transporting monoamines (dopamine, norepinephrine, serotonin, and histamine) among nerve cells. Specifically, dopamine enables neurotransmission among nerve cells that are involved in voluntary and involuntary motor control. Disease states such as tardive dyskinesia, Huntington s chorea, schizophrenia, Tourette syndrome and tardive dystonia are characterized in part by a hyperdopaminergic state in the brain, and modulation of neuronal dopamine levels may provide symptomatic benefits for patients with these conditions.

Tardive dyskinesia (TD) is defined by hyperkinetic involuntary movements which arise after months or years of treatment with dopamine receptor blocking agents, e.g. antipsychotics for schizophrenia, bipolar disorder, and depression, and Reglan® (metoclopramide) for nausea and vomiting and gastric emptying in patients with gastroparesis. Features of the disorder may include grimacing, tongue protrusion, lip smacking, puckering and pursing of the lips, and rapid eye blinking. Rapid movements of the extremities may also occur. The impact on daily function and the quality of life for individuals suffering from TD can be substantial. While the prevalence rates of TD can vary greatly in accordance with the population being studied, it is estimated that approximately 500,000 individuals are affected by TD in the United States alone (Kantar Health).

To address the unmet medical needs of patients suffering from TD, we are developing NBI-98854. NBI-98854 is a potent, highly selective, VMAT2 inhibitor that is effective in regulating pre-synaptic release of dopamine. This selectivity should reduce the likelihood of off target side effects. Additionally, we have

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designed this novel compound to provide low, sustained, plasma and brain concentrations of the active drug to minimize the potential side effects associated with excessive dopamine depletion, while at the same time having minimal impact on the other monoamines, e.g. norepinephrine and serotonin. With these features, NBI-98854 should be well tolerated in patients. NBI-98854 has been evaluated in several Phase I studies and four Phase II studies to assess its safety, tolerability and efficacy and to establish a treatment regimen to be used in future clinical trials. We believe that the potential efficacy and safety profile of NBI-98854 will address many of the shortcomings of current off-label treatments. Finally, NBI-98854 may be useful in the treatment of other disorders, such as Huntington s chorea, schizophrenia, Tourette syndrome and tardive dystonia.

During 2009, a Phase I single ascending dose clinical trial of NBI-98854 was completed in healthy male volunteers in Canada under an approved Clinical Trial Application with Health Canada. This trial showed NBI-98854 to be generally safe and well tolerated. There were no serious adverse events, clinically significant drug-related laboratory abnormalities or clinically significant electrocardiogram (ECG) findings. The characteristics of NBI-98854 met the pre-specified pharmacokinetic requirements for the trial: dose proportionality, low maximum concentration with adequate area-under-curve for drug exposure, low variability and a half-life which supports once per day dosing.

During 2010, we completed a multiple, repeat dose Phase I study of NBI-98854 in healthy male volunteers. This trial also showed NBI-98854 to be generally safe and well tolerated, and again displayed the desired pharmacokinetic requirements. There were no serious adverse events, clinically significant drug-related laboratory abnormalities or clinically significant ECG findings.

Based on the successful completion of this second Phase I study, we initiated a Phase IIa open label dose exploration study of NBI-98854 in six patients with TD in late 2010. This study was designed to assess, over a twelve-day dosing period, the efficacy, safety and tolerability of NBI-98854 in schizophrenia patients who have moderate to severe TD. The impact on the dyskinesia was assessed utilizing the Abnormal Involuntary Movement Scale (AIMS). The study inclusion criteria included a baseline total score of at least nine on the first seven physical components of AIMS, with at least two body regions receiving scores of moderate (3) or severe (4). For the study the mean baseline score was 14.3 (AIMS total items 1-7, possible total score of 28). The dosing regimen consisted of three, four-day periods of NBI-98854, at increasing doses of 12.5mg, 25mg, and 50mg administered once daily. After discontinuation of NBI-98854, a seven-day washout period was followed by a final assessment. After the twelve days of dosing, the mean AIMS score decreased to 8.4, a reduction of 41.3%. Reduction in abnormal involuntary movements was shown across multiple assessment points. After the seven-day washout period, most patients AIMS scores returned to their baseline levels. The adverse events reported during administration of NBI-98854 were transient and mild or moderate including one subject with dizziness and one with restlessness. One subject became anxious and agitated seven days after study medication due to the patient s return to baseline-intensity TD.

Upon successful completion of this open-label Phase IIa study, we filed an Investigational New Drug (IND) Application with the FDA to permit the initiation of larger Phase II studies in patients with TD in the United States.

In September 2011, we began a second Phase II study in TD patients. This 32 patient placebo-controlled, double-blind, randomized, cross-over study, used a within-subject comparison for safety and efficacy evaluation. Patients were randomized to either 12.5mg or 50mg doses of NBI-98854 for a two-week dosing period, and each patient also had a two-week placebo dosing period. The primary efficacy endpoint of the study was a comparison of placebo versus active AIMS scores at the end of the two dosing periods.

After database lock and unblinding of study data, an inconsistent pattern of AIMS scores emerged at one of the eight sites that was not evident during the blinded data review. Based on these findings, the AIMS data from this single site was removed and a post-hoc analysis was completed which demonstrated a clinically meaningful and statistically significant improvement in TD symptoms for the subjects receiving the 50mg once daily dose.

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These subjects had a significant reduction in TD symptoms at the end of two weeks of active treatment versus the end of two weeks of placebo (difference in LS mean of 4.2 for the 50mg period versus the placebo period, p-value=0.002). As expected, the 12.5mg dosing group was not statistically better during the active treatment period than during the placebo period (difference in LS mean of 0.4 for the 12.5mg period versus placebo period, p-value=0.68).

When including the data from the site in question, this study did not meet the pre-specified primary endpoint of reducing the AIMS scores during active treatment periods. The efficacy results from the entire study population showed a non-significant reduction in TD at the end of two weeks of active treatment versus the end of two weeks of placebo (difference in LS mean of 1.1 for the 50mg period versus the placebo period (n=15), p-value=0.42) (difference in LS mean of 0.7 for the 12.5mg period versus placebo period (n=17), p-value=0.59).

We also performed a second post-hoc analysis, engaging a single, independent, blinded AIMS assessor to review the videotaped AIMS assessments at all of the eight sites that participated in the trial. This AIMS assessor scored, in a blinded fashion, the videotaped baseline, day fifteen and day twenty-nine AIMS assessments. This independent secondary post-hoc analysis demonstrated a clinically meaningful and statistically significant improvement in TD symptoms for the subjects receiving the 50mg once daily dose. These subjects had a significant reduction in TD symptoms at the end of two weeks of active treatment versus the end of two weeks of placebo (difference in LS mean of 3.0 for the 50mg period versus the placebo period, p-value=0.008). As expected, the 12.5mg dosing group was not statistically better during the active treatment period than during the placebo period (difference in LS mean of 0.7 for the 12.5mg period versus placebo period, p-value=0.54).

NBI-98854 was generally safe and well tolerated during the fourteen days of treatment. The frequency of treatment-emergent adverse events was 17% during the placebo period and 24% and 32% in the 12.5mg and 50mg treatment periods, respectively. There were no serious adverse events during the treatment period. The most common adverse event was headache and one subject in the 50mg group discontinued due to akathisia.

The larger Phase IIb TD program began in 2012. The initial Phase IIb study (Kinect 1 Study) was a randomized, parallel, double-blind, placebo-controlled, clinical trial utilizing the capsule formulation of NBI-98854 in moderate to severe TD patients with underlying schizophrenia or schizoaffective disorder. This 109 subject study assessed two doses of once daily NBI-98854 over a six-week placebo-controlled dosing period. Approximately half of the randomized subjects received placebo and half received one of two doses of NBI-98854. The two NBI-98854 dosing groups consisted of a 50mg group for six weeks and a group that began at 100mg for the initial two weeks and then converted to 50mg for the final four weeks of placebo-controlled dosing period. Subsequent to the placebo-controlled dosing, all subjects were eligible to enter a six-week open label safety extension, whereby 50mg of NBI-98854 was administered once daily with additional AIMS assessments. The primary endpoint of the study was a comparison of placebo versus active scores utilizing the AIMS at the end of week six as assessed by the on-site AIMS assessors.

The 50mg dose of NBI-98854 did not reach statistical significance for the primary endpoint at week six. As discussed below, in a post-hoc analysis, utilizing a blinded central video AIMS assessment, both the 100mg dose (at Week 2) and the 50 mg dose (at Week 6) showed a statistically significant and clinically meaningful reduction in TD symptoms.

NBI-98854 was generally safe and well tolerated during the twelve weeks of the Kinect 1 Study. During the six-week placebo-controlled treatment period the frequency of treatment-emergent adverse events was 37% for placebo and 26% for NBI-98854. There were no drug-related serious adverse events. The most common treatment emergent adverse event was mild and transient somnolence during the placebo-controlled portion of the study.

Participants in the Kinect 1 Study were assessed utilizing the Barnes Akathisia Ratings Scale (BARS) for akathisia and the Simpson-Angus Scale (SAS) for parkinsonism. Both of these scales documented minimal symptoms at baseline and were measured as stable to improved during the twelve weeks of treatment. Subjects

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were also assessed using various safety scales including the Positive and Negative Syndrome Scale (PANSS) for Schizophrenia, the Calgary Depression Scale for Schizophrenia and the Columbia-Suicide Severity Rating Scale (C-SSRS); all of these scores were measured as stable to improved from baseline. Clinical hematology, chemistry and ECG monitoring indicated no emergent safety signals. There were no apparent drug-drug interactions identified in subjects who were utilizing a range of psychotropic and other concomitant medications.

In November 2013, we convened a Scientific Advisory Board (SAB) to review the results of the Kinect 1 Study. The SAB was formed to specifically focus on the dose levels and the AIMS assessment tool. Based on the results of the Kinect 1 Study and the advice from the SAB, the protocol for the second Phase IIb study (Kinect 2 Study) was amended to change the primary endpoint from on-site AIMS assessments to a blinded central video assessment conducted by two movement disorder specialists who would review the AIMS videos in a scrambled fashion and concur on a final AIMS score for each video.

The Kinect 2 Study, was a randomized, parallel, double-blind, placebo-controlled, clinical trial utilizing the capsule formulation of NBI-98854 in moderate to severe TD patients with underlying mood disorders, schizophrenia and schizoaffective disorders, and gastrointestinal disorders. This study randomized 102 patients into a six-week placebo-controlled dosing period where half of the subjects received placebo and half received NBI-98854. The study began with all subjects on once daily 25mg of NBI-98854, or placebo. The treating physician was then permitted to escalate the dose at two-week intervals, at the end of week two and at the end of week four, to a maximum dose of once daily 75mg. The dose escalation was determined by the treating physician based on week two and week four on-site AIMS assessments coupled with safety and tolerability assessments at these same time points. By week six, approximately 70% of the ITT subjects, randomized to NBI-98854, were titrated to the 75 mg dose, approximately 20% were titrated to the 50mg dose and the remaining subjects received 25 mg of NBI-98854. The primary endpoint of the study was a comparison of placebo versus active scores utilizing the AIMS at the end of week six as assessed by scrambled blinded central video assessment conducted by two movement disorder specialists. The mean baseline AIMS score for the placebo group was 7.9 compared to 8.0 for the NBI-98854 group.

At week six, AIMS scores, as assessed by blinded central video raters, were reduced by 2.6 points in the NBI-98854 intention-to-treat (ITT) group (n=45) compared to a reduction of 0.2 points in the placebo arm (n=44) ($p<0.001$). Additionally, the responder rate (>= 50% improvement from baseline) was 49% in the NBI-98854 ITT group compared to 18% in placebo ($p=0.002$). In the per-protocol (PP) group (n=78) AIMS scores were reduced by 3.3 points for those subjects taking NBI-98854 ($p<0.001$), with a corresponding responder rate of 59% ($p<0.001$). The improvement in week six AIMS was also corroborated by on-site treating physicians utilizing the Clinical Global Impression Tardive Dyskinesia (CGI-TD) scale scores. Treating clinicians determined that approximately 67% of the subjects taking NBI-98854 were much improved or very much improved at week six compared to only 16% of the placebo subjects ($p<0.001$) in this pre-specified key secondary efficacy endpoint.

In the Kinect 2 Study NBI-98854 was generally safe and well tolerated. During the six-week treatment period the frequency of treatment-emergent adverse events was 33% for placebo and 43% for NBI-98854. There were no drug related serious adverse events. The most common treatment emergent adverse events were fatigue in five subjects (9.8%) randomized to NBI-98854 versus two subjects (4.1%) in the placebo group, and headache reported by four subjects (7.8%) on NBI-98854 versus two subjects (4.1%) on placebo. Discontinuation rates were similar in both the NBI-98854 and placebo treatment groups with five per study arm (none of which were study drug related).

Participants in the Kinect 2 Study were assessed utilizing the BARS for akathisia and the SAS for parkinsonism. Both of these scales documented minimal symptoms at baseline and there was no worsening during the six weeks of treatment. Clinical hematology, chemistry and ECG monitoring indicated no emergent safety signals. There were no drug-drug interactions identified in subjects who were utilizing a range of psychotropic and other concomitant medications.

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Subsequent to completion of the Kinect 2 Study, in a post-hoc analysis, the Kinect 1 Study videos were evaluated by performing the same comparison of placebo versus active scores employed in the Kinect 2 Study. We engaged two movement disorder specialists, both of whom were not involved with the Kinect 1 Study, to assess the Kinect 1 Study baseline and week six videos utilizing AIMS in a randomized blinded central video assessment. These raters scored the mean baseline AIMS of 8.0 for the Kinect 1 Study. After six weeks of treatment, these raters scored the placebo group in the Kinect 1 Study with a mean reduction from baseline of 0.1 points while the NBI-98854 group was scored with a mean reduction from baseline of 1.3 points. Utilizing this analysis, NBI-98854 in the Kinect 1 Study showed a statistically significant change from baseline.

The data from the Kinect 1 and Kinect 2 studies, along with the other Phase I and Phase II clinical studies, preclinical work, and drug manufacturing data formed the basis for an end of Phase II meeting that was held with the FDA in June of 2014. During this meeting, the FDA reviewed the current data package and overall clinical development plan for NBI-98854 including the proposed Phase III development to support the registration of NBI-98854 in the United States as a treatment for tardive dyskinesia. Based on the results of this meeting and the related minutes, we are conducting a single placebo-controlled Phase III study of NBI-98854, the Kinect 3 Study.

The Kinect 3 Study was launched in the fourth quarter of 2014. The design of the Kinect 3 Study is a randomized, parallel-group, double-blind, placebo-controlled clinical trial utilizing the capsule formulation of NBI-98854 in moderate to severe TD subjects with an underlying diagnosis of mood disorder, schizophrenia or schizoaffective disorder. The primary endpoint in the Kinect 3 Study will be the mean change from baseline in the AIMS as assessed by blinded central raters. The Kinect 3 Study will include approximately 240 subjects randomized to either placebo, once daily 40mg of NBI-98854 or once daily 80mg of NBI-98854 for 6 weeks of placebo-controlled dosing followed by an extension of active dosing through Week 48. Top-line efficacy data from the Kinect 3 Study is expected in the second half of 2015.

In addition to the Kinect 3 Study, we are also conducting a separate one-year open-label safety study of NBI-98854 (the Kinect 4 Study) which we believe will be used to support the filing of a New Drug Application in TD that is expected in 2016.

In October 2014, the FDA granted us breakthrough therapy designation for NBI-98854, in TD. Breakthrough therapy designation is granted for a drug that is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on clinically significant endpoints over available therapies. This designation also allows intensive discussions with the FDA which are intended to expedite the development and review process of eligible drugs. The breakthrough therapy designation was granted, in part, based on the results of the Phase IIb Kinect studies of NBI-98854 in approximately 220 patients with TD.

Tourette syndrome. Tourette syndrome is a neurological disorder that consists of rapid, non-rhythmic stereotyped motor and vocal tics. Motor tics are typically characterized by facial grimacing, head jerks, extremity movements and other dystonic movements. Vocal tics typically include grunting, throat clearing, and repeating words and phrases. The average age of onset for Tourette syndrome is at approximately six years, with symptoms reaching their peak severity at approximately age ten. Tourette syndrome is more commonly diagnosed in males than females and may also be associated with attention deficit hyperactivity disorder and obsessive compulsive disorder. We believe there are approximately 400,000 people with Tourette syndrome in the United States.

We have completed juvenile rodent preclinical studies of NBI-98854 and based on the results of these preclinical studies, we have initiated the T-Force Study in children and adolescents with Tourette syndrome. The T-Force Study is an open-label, multiple ascending dose, pharmacokinetic and pharmacodynamic study to evaluate the safety, tolerability and exposure-response of NBI-98854 in children and adolescents with Tourette syndrome. A total of 36 patients will be evaluated over 14 days of once daily dosing followed by 7 days off-drug at approximately 10 study centers in the United States. The study is divided into two dosing groups consisting of children (ages 6-11) and adolescents (ages 12-18), and each age group is further divided into three dosing cohorts

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of six patients each. After completing the initial two weeks of dosing with the first adolescent cohort, an independent review of both safety and pharmacokinetic results will occur prior to escalating the dose level for the second cohort of adolescents. In parallel, while initiating the second cohort of adolescents, the first cohort of children (ages 6-11) will also be administered NBI-98854 for a two-week period. Subsequent dose escalations for children and adolescents will be based, in part, on the pharmacokinetic and safety data from the previous cohort in each age group. Additionally, the patient s Tourette symptoms will be evaluated weekly via the Yale Global Tic Severity Scale, the Premonitory Urge for Tics Scale as well as an overall Clinical Global Impression in Tourette syndrome Scale. We expect data from this study in the second half of 2015.

Corticotropin-Releasing Factor (CRF) Receptor$_1$ Antagonist (NBI-77860)

CRF is a hypothalamic hormone released directly into the hypophyseal portal vasculature which acts on specific CRF_1 receptors on corticotropes in the anterior pituitary to stimulate the release of adrenocorticotropin (ACTH). The primary role of ACTH is the stimulation of the synthesis and release of adrenal steroids including cortisol. Cortisol from the adrenals, have a negative feedback role at the level of the hypothalamus that decreases CRF release as well as at the level of the pituitary to inhibit the release of ACTH. This tight control loop is known as the hypothalamic-pituitary-adrenal (HPA) axis. Blockade of CRF receptors at the pituitary has been shown to decrease the release of ACTH and subsequently attenuate the production and release of adrenal steroids.

Classic congenital adrenal hyperplasia (classic CAH) is a group of autosomal recessive genetic disorders that affects approximately 20,000-30,000 people in the United States and results in an enzyme deficiency altering the production of adrenal steroids. Because of this deficiency, the adrenal glands have little to no cortisol biosynthesis resulting in a potentially life-threatening condition. If left untreated, classic CAH can result in salt wasting, dehydration and eventually death. Even with cortisol replacement, persistent elevation of ACTH from the pituitary gland results in excessive androgen levels leading to virilization of females including precocious puberty, menstrual irregularity, short stature, hirsutism, acne and fertility problems.

Corticosteroids are the current standard of care for classic CAH and are used chronically to both correct the endogenous cortisol deficiency and reduce the excessive ACTH levels and androgen excess. However, the dose and duration of steroid use required to suppress ACTH is well above the normal physiological level of cortisol; resulting in metabolic syndrome, bone loss, growth impairment, and Cushing s syndrome as common and serious side effects.

NBI-77860 is a potent, selective, orally-active, non-peptide CRF receptor antagonist as demonstrated in a range of in vitro and in vivo assays. Blockade of CRF receptors at the pituitary has been shown to decrease the release of ACTH, which in turn decreases the production of adrenal steroids including androgens, and potentially the symptoms associated with classic CAH. Lower ACTH levels would also reduce the amount of exogenous corticosteroid necessary for classic CAH patients to thrive avoiding the side-effects currently associated with excessive steroid therapy.

In 2014, we conducted an initial pilot clinical trial of NBI-77860 in adult females with refractory classic CAH. The trial was a blinded, single-site, pharmacokinetic/pharmacodynamic study assessing two single, ascending doses of NBI-77860 against placebo. The eight study participants visited the investigative site for three separate overnight visits consisting of bedtime dosing with placebo or one of two active doses of NBI-77860. Each of the visits was separated by a three-week washout period. Key pharmacodynamic biomarker measurements included adrenocorticotropic hormone (ACTH), 17-hydroxyprogesterone (17-OHP), androgen, and cortisol levels collected in the morning after dosing. Data from this initial single dose exploratory study demonstrated a robust decrease in both ACTH and 17-OHP.

Based on the results of this initial pilot study, we initiated a second clinical study of NBI-77860 in classic CAH. The 1401 study is a Phase I/II open-label, sequential cohort, single ascending dose pharmacokinetic/pharmacodynamic study assessing three doses of NBI-77860. Fifteen adolescent females with classic CAH will

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be split into three cohorts and each will receive one dose of NBI-77860 at bedtime. Biomarker measurements include ACTH, 17-OHP, androgens, and cortisol levels collected the day after dosing. We expect to have data from this study in the second half of 2015.

In early 2015, NBI-77860 was granted orphan drug designation for the treatment of congenital adrenal hyperplasia. Orphan drug designation is granted by the FDA Orphan Drug Designation program for medicines intended for the safe and effective treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the United States and provides sponsors with development and commercial incentives for such designated compounds and medicines.

We have a strategic position in the CRF field through our intellectual property portfolio and relationship with experts in the endocrine and neuropsychiatric fields. We have patents covering both the receptor subtypes termed CRF_1 and CRF_2, and we have pending patent applications on small molecule organic compounds modulating the CRF receptors.

Other indications. The National Institute on Alcohol Abuse and Alcoholism is currently enrolling subjects in a Phase II clinical trial evaluating NBI-77860 in stress-induced craving in alcoholic women with high anxiety. This randomized, double-blind, placebo-controlled trial is expected to enroll 60 patients for a four-week treatment period. This study is expected to take several years to complete.

Research Programs

Our research and development focus is on addressing diseases and disorders of the central nervous and endocrine systems, which include therapeutic categories ranging from HPA disorders to stress-related disorders and neurodegenerative diseases. Central nervous system and endocrinology drug therapies are among the largest therapeutic categories, accounting for over $140 billion in worldwide drug sales according to GlobalData (2013).

VMAT2

VMAT2 inhibition results in the modulation of dopamine pathways which may also be useful for patients suffering from schizophrenia. Approximately 2.2 million people in the Unites States suffer from schizophrenia at an estimated annual cost of $62 billion. Our discovery efforts around VMAT2 inhibitors also focus on developing novel therapies for schizophrenia sufferers.

Antiepileptic Drugs

Antiepileptic drugs are utilized in the treatment of epileptic seizures by suppressing the rapid firing of neurons that initiate a seizure. Antiepileptics also have additional effects within the central nervous system that have proven beneficial in bipolar disease, neuropathic pain and essential tremor. According to Datamonitor, in 2014, worldwide sales of branded anticonvulsants approximate $5 billion.

G Protein-Coupled Receptors (GPCR)

GPCRs are the largest known gene superfamily of the human genome. Greater than thirty percent of all marketed prescription drugs act on GPCRs; which makes this class of proteins historically the most successful therapeutic target family. However, only a small fraction of the GPCR gene superfamily has been exploited. Next generation therapies derived from targeting GPCRs will be discovered through the understanding of the complex relationships of drug/receptor interactions and their subsequent impact on efficacy, downstream signaling networks and regulation.

Our GPCR research platform has met this requirement by integrating drug discovery research efforts with a suite of assays and assay systems and automated analytical techniques. This process provides an unbiased profile of GPCR pharmacological receptor/ligand interactions coupled with in vivo efficacy using discrete animal

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models allowing for rapid discovery of initial leads and advancement into preclinical and clinical development. Importantly, this design cycle is not limited to GPCR targets, but can be utilized for other proteins that play a role in human disease where current treatments or therapies are either inadequate or nonexistent.

Our Business Strategy

Our goal is to become the leading biopharmaceutical company focused on neurological and endocrine-related diseases and disorders. The following are the key elements of our business strategy:

Continuing to Advance and Build Our Product Portfolio Focused on Neurological and Endocrine-Related Diseases and Disorders. We believe that by continuing to advance and extend our product pipeline, we can mitigate some of the clinical development risks associated with drug development. We currently have multiple programs in various stages of research and development. Our two lead late-stage clinical programs are elagolix, a GnRH antagonist in Phase III development for endometriosis and Phase II clinical studies of uterine fibroids that is partnered with AbbVie, and a wholly owned VMAT2 inhibitor for the treatment of movement disorders that is currently in Phase III development. We take a portfolio approach to managing our pipeline that balances the size of the market opportunities with clear and defined clinical and regulatory paths to approval. We do this to ensure that we focus our internal development resources on innovative therapies with improved probabilities of technical and commercial success.

Maintaining Certain Commercial Rights to Our Product Portfolio to Evolve into a Fully-Integrated Pharmaceutical Company. We intend to retain commercial rights to certain products that we can effectively and efficiently develop, secure regulatory approval and economically commercialize. These include products with a concentrated prescriber base and well-defined patient population that can be accessed with an efficient patient and prescriber outreach program.

Selectively Establishing Corporate Collaborations with Global Pharmaceutical Companies to Assist in the Development of Our Products and Mitigate Financial Risk while Retaining Significant Commercial Upside. We leverage the development, regulatory and commercialization expertise of our corporate collaborators to accelerate the development of certain of our potential products, while typically retaining co-promotional rights, and at times commercial rights, in North America. We intend to further leverage our resources by selectively entering into additional strategic alliances to enhance our internal development and commercialization capabilities by licensing our technology.

Identifying Novel Drugs to Address Unmet Market Opportunities. We seek to identify and validate novel drugs on characterized targets for internal development or collaboration. For example, GnRH antagonists, compounds designed to reduce the secretions of sex steroids, may represent the first novel non-peptide, non-injectable means of treatment of endometriosis. We believe the creativity and productivity of our discovery research group will continue to be a critical component for our continued success. Research and development costs were $46.4 million, $39.2 million and $37.2 million for the years ended December 31, 2014, 2013 and 2012, respectively.

Acquiring Rights to Complementary Drug Candidates and Technologies. We plan to continue to selectively acquire rights to products in various stages of development to take advantage of our drug development capabilities.

Our Corporate Collaborations and Strategic Alliances

One of our business strategies is to utilize strategic alliances to enhance our development and commercialization capabilities. The following is a summary of our significant collaborations/alliances:

AbbVie Inc. (AbbVie). In June 2010, we announced an exclusive worldwide collaboration with AbbVie to develop and commercialize elagolix and all next-generation GnRH antagonists (collectively, GnRH Compounds) for women s and men s health. AbbVie made an upfront payment of $75 million and has agreed to make

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additional development and regulatory event based payments of up to $480 million and up to an additional $50 million in commercial event based payments. Under the terms of the agreement, AbbVie is responsible for all 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 and personnel funding through the end of 2012. We will be entitled to a percentage of worldwide sales of GnRH Compounds for the longer of ten years or the life of the related patent rights. Under the terms of our agreement with AbbVie, the collaborative development 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. 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 of sponsored development revenue.

The Mount Sinai School of Medicine of the City University of New York (Mt. Sinai). In August 1999, we entered into an agreement with Mt. Sinai pursuant to which we acquired a nonexclusive license to certain patents and patent applications related to GnRH, to develop and commercialize licensed products worldwide. Pursuant to the terms of the agreement, we have the right to grant sublicenses to third parties only with the prior written consent of Mt. Sinai. Upon entering into the agreement, we paid a $50,000 upfront fee and are required to pay an additional $10,000 annual license fee on each anniversary of the agreement. In addition, we are obligated to pay Mt. Sinai a royalty equal to 1% of net sales of licensed products. The agreement will remain in effect until the later of 15 years after the date of the first commercial sale of the first licensed product or the expiration of the last to expire of the licensed patents, unless terminated earlier at our election or for material breach by either party. Mt. Sinai also has the right to terminate the agreement if we become insolvent or bankrupt or have suspended our business operations. Pursuant to the terms of the agreement, in the event that Mt. Sinai grants a third party a license to the GnRH patents and patent applications on economic terms and conditions less favorable to Mt. Sinai than those in our agreement, we have the right to substitute the terms and conditions of the other third party license for those currently set forth in our agreement.

Intellectual Property

We seek to protect our lead compounds, compound libraries, expressed proteins, synthetic organic processes, formulations, assays, cloned targets, screening technology and other technologies by filing, or by causing to be filed on our behalf, patent applications in the United States and abroad. Additionally, we have licensed from institutions the rights to issued United States patents, pending United States patent applications, and issued and pending foreign filings. We face the risk that one or more of the above patent applications may be denied. We also face the risk that issued patents that we own or license may be challenged or circumvented or may otherwise not provide protection for any commercially viable products we develop.

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. If this occurs, we may be required to obtain licenses to patents or proprietary rights of others in order to continue with the commercialization of our products.

In addition to the granted and potential patent protection, the United States, the European Union and Japan all provide data and marketing exclusivity for new medicinal compounds. If this protection is available, no competitor may use the original applicant s data as the basis of a generic marketing application during the period of data and marketing exclusivity. This period of exclusivity is generally five years in the United States, six years in Japan and ten years in the European Union, measured from the date of FDA, or corresponding foreign, approval.

Elagolix, our small molecule GnRH antagonist currently in clinical trials for the treatment of endometriosis and uterine fibroids, is covered by six issued U.S. patents relating to composition of matter, pharmaceutical compositions, and methods of use. U.S. Patent Nos. 6,872,728, 7,179,815 and 7,462,625 are due to expire in

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2021 (not including potential patent term extensions of up to five years) while U.S. Patent Nos. 7,056,927, 7,176,211 and 7,419,983 are due to expire in 2024 (not including potential patent term extensions of up to five years).

NBI-98854, our highly selective VMAT2 inhibitor, currently in clinical trials for the treatment of tardive dyskinesia, is covered by U.S. Patent No. 8,039,627 which expires in 2029 and U.S. Patent No. 8,357,697 which expires in 2027 (not including a potential patent term extension of up to five years). NBI-98854 is also covered by European Patent No. 2,081,929 which expires in 2027.

Our CRF antagonist NBI-77860 is currently in clinical trials for the treatment of classic congenital adrenal hyperplasia and stress-related disorders. NBI-77860 is covered by U.S. Patent No. 7,879,862 which expires in 2026 (not including potential patent term extensions of up to five years).

Manufacturing and Distribution

We currently rely on, and expect to continue to rely on, contract manufacturers to produce sufficient quantities of our product candidates for use in our preclinical and clinical trials. In addition, we intend to rely on third parties to manufacture any products that we may commercialize in the future. We have established an internal pharmaceutical development group to develop manufacturing methods for our product candidates, to optimize manufacturing processes, and to select and transfer these manufacturing technologies to our suppliers. We contract with multiple manufacturers to ensure adequate product supply and to mitigate risk.

There currently are a limited number of these manufacturers. Furthermore, some of the contract manufacturers that we have identified to date only have limited experience at manufacturing, formulating, analyzing and packaging our product candidates in quantities sufficient for conducting clinical trials or for commercialization.

We currently have no distribution capabilities. In order to independently commercialize any of our product candidates, we must either internally develop distribution capabilities or make arrangements with third parties to perform these services.

Marketing and Sales

We currently have limited experience in marketing or selling pharmaceutical products. To market any of our products independently would require us to develop a sales force with technical expertise along with establishing commercial infrastructure and capabilities.

Government Regulation

Regulation by government authorities in the United States and foreign countries is a significant factor in the development, manufacture, distribution, marketing and sale of our proposed products and in our ongoing research and product development activities. All of our products will require regulatory approval by government agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous preclinical studies and clinical trials and other approval procedures of the FDA and similar regulatory authorities in foreign countries. The process of obtaining these approvals and the subsequent compliance with appropriate federal and state statutes and regulations require the expenditure of substantial time and financial resources. In the United States, various federal and state statutes and regulation also govern or influence testing, manufacturing, safety, labeling, storage, and record-keeping of human therapeutic products and their marketing. Recent federal legislation imposes additional obligations on pharmaceutical manufacturers regarding product tracking and tracing. In addition, federal and state healthcare laws restrict business practices in the pharmaceutical industry. These laws include, without limitation, federal and state 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.

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Preclinical studies generally are conducted in laboratory animals to evaluate the potential safety and efficacy of a product. Drug developers submit the results of preclinical studies to the FDA as a part of an IND application before clinical trials can begin in humans. Typically, clinical evaluation involves a time consuming and costly three-phase process.

Phase I	Clinical trials are conducted with a small number of subjects to determine the early safety profile, maximum tolerated dose and pharmacological properties of the product in human volunteers.
Phase II	Clinical trials are conducted with groups of patients afflicted with a specific disease in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety.
Phase III	Large-scale, multi-center, comparative clinical trials are conducted with patients afflicted with a specific disease in order to determine safety and efficacy as primary support for regulatory approval by the FDA to market a product candidate for a specific disease.

The FDA closely monitors the progress of each of the three phases of clinical trials that are conducted in the United States and may, at its discretion, re-evaluate, alter, suspend or terminate the testing based upon the data accumulated to that point and the FDA s assessment of the risk/benefit ratio to the patient. To date, we have also conducted some of our clinical trials in Europe, Canada, Oceania and South Africa. Clinical trials conducted in foreign countries are also subject to oversight by regulatory authorities in those countries.

Once Phase III trials are completed, drug developers submit the results of preclinical studies and clinical trials to the FDA in the form of an New Drug Application (NDA) or a biologics licensing application for approval to commence commercial sales. The FDA may also convene an advisory committee to provide input on critical review issues associated with an NDA. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with current Good Manufacturing Practice requirements and that they are adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical trial sites to assure compliance with Good Clinical Practices.

At the conclusion of its review, the FDA may grant marketing approval or may issue a complete response letter requesting additional information if the FDA determines that the application does not meet regulatory approval criteria. FDA approvals may not be granted on a timely basis, or at all. Furthermore, the FDA may not approve the product with the desired indications, which may impair commercialization of the product.

If the FDA approves the NDA, the drug becomes available for physicians to prescribe in the United States. After approval, the drug developer must submit periodic reports to the FDA, including descriptions of any adverse reactions reported. The FDA may request post-approval clinical studies, known as Phase IV studies, in order to evaluate long-term or other effects of the drug. The FDA may also require a Risk Evaluation and Mitigation Strategy (REMS) safety management plan upon approval.

We will also have to complete an approval process similar to that in the United States in virtually every foreign target market for our products in order to commercialize our product candidates in those countries. The approval procedure and the time required for approval vary from country to country and may involve additional testing. Foreign approvals may not be granted on a timely basis, or at all. In addition, regulatory approval of prices is required in most countries other than the United States. The resulting prices may not be sufficient to generate an acceptable return to us or our corporate collaborators.

Competition

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

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biotechnology and pharmaceutical companies, research institutions, government agencies and academic institutions. 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.

Lupron Depot®, marketed by AbbVie, and Synarel® and depo-subQ provera104®, marketed by Pfizer, are products that have been approved for the treatment of endometriosis, infertility, and central precocious puberty. These drugs, and any generic alternatives, may compete with any small molecule non-peptide GnRH antagonists we, in conjunction with our collaborative partner AbbVie, develop for these indications. Approximately 130,000 hysterectomies are performed annually in the United States as a direct result of endometriosis, as well as a significant number of laparoscopic procedures to ablate endometrial explants. Our oral small molecule pharmaceutical agent, elagolix, would also compete directly with these current invasive standards of care.

We, in conjunction with our collaborative partner AbbVie, are developing elagolix for the treatment of uterine fibroids. There are no current pharmaceutical therapies approved in the United States for the chronic treatment of uterine fibroids. Lupron Depot® is approved for short-term use to improve the outcome of uterine fibroid surgery. However, approximately 250,000 hysterectomies are performed annually in the United States as a direct result of uterine fibroids, as well as myomectomies (surgery) to remove the fibroids. Our oral small molecule pharmaceutical agent, elagolix, would compete directly with these current invasive standards of care.

Our VMAT2 inhibitor, NBI-98854, is currently in clinical trials for the treatment of movement disorders, specifically TD. At present there are no approved drug therapies for TD; however, off-label treatment regimens consist of utilizing various atypical antipsychotic medications (e.g., clozapine), benzodiazepines (off-label) or botulinum toxin injections to treat the movements associated with TD. Other potential indications for our VMAT2 inhibitor are Tourette syndrome, Huntington s disease, schizophrenia and tardive dystonia. Currently, Xenazine®, marketed by Lundbeck, is approved for the chorea associated with Huntington s disease. Generic neuroleptic medications (pimozide and haloperidol) are generally utilized to control the tics associated with Tourette syndrome. Additionally, Auspex Pharmaceuticals, Inc. has recently initiated clinical trials for their VMAT2 inhibitor SD-809 for the treatment of TD and Tourette syndrome and is in Phase III development for Huntington s disease with the same compound.

Our CRF antagonist NBI-77860 is being studied in classic CAH, for which there are limited therapies. High doses of corticosteroids are the current standard of care to both correct the endogenous cortisol deficiency as well as reduce the excessive ACTH levels. However, the level of dose as well as the duration of steroid use required to suppress ACTH is well above the normal physiological level of cortisol; resulting in metabolic syndrome, bone loss, growth impairment, and Cushing s syndrome as common and serious side effects.

If one or more of these competitive products or programs are successful, it may reduce or eliminate the market for our products.

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;

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preclinical study and clinical testing experience;

manufacturing and marketing experience; and

production facilities.

Any of these competitive factors could harm our business, prospects, financial condition and results of operations, which could negatively affect our stock price.

Employees

As of December 31, 2014, we had approximately 94 full-time employees, of which 24 hold Ph.D., M.D. or equivalent degrees, and 18 others hold an M.S., M.B.A., or equivalent degrees. Of these full-time employees, 73 were engaged in, or directly support, research and development activities, and 21 were in general and administrative positions. None of our employees are represented by a collective bargaining arrangement, and we believe our relationship with our employees is good. In addition, we rely on a number of consultants to assist us in formulating our research and development strategies.

Insurance

We maintain product liability insurance for our clinical trials. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for products in development. However, 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. In addition, we may not be able to obtain commercially reasonable product liability insurance for any products approved for marketing.

Available Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge on our website at *www.neurocrine.com*, as soon as reasonably practicable after such reports are available on the Securities and Exchange Commission website at *www.sec.gov*.

Additionally, copies of our Annual Report will be made available, free of charge, upon written request.

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ITEM 1A. ***RISK FACTORS***

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 Annual Report on Form 10-K 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;
- the results may not be statistically significant;
- patient recruitment may be slower than expected;
- patients may drop out of the trials; and
- regulatory requirements may change.

These risks and uncertainties impact all of our clinical programs. Specifically, with respect to our gonadotropin-releasing hormone (GnRH) program with AbbVie Inc. (AbbVie), any of the clinical, regulatory or operational events described above could delay timelines for the completion of the Phase III endometriosis program or the Phase II uterine fibroids program, require suspension of these programs and/or obviate filings for regulatory approvals. Similarly, our VMAT2 inhibitor program will be impacted if any of the events above lead to delayed timelines for the enrollment in, or completion of, the Phase III tardive dyskinesia or the Phase I Tourette syndrome clinical trials of NBI-98854.

In addition, late stage clinical trials are often conducted with patients having the most advanced stages of disease. During the course of treatment, these patients can die or suffer other adverse medical effects for reasons that may not be related to the pharmaceutical agent being tested but which can nevertheless adversely affect clinical trial results. Any failure or substantial delay in completing clinical trials for our product candidates may severely harm our business.

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We depend on AbbVie to develop and commercialize elagolix, and may need to enter into future collaborations to develop and commercialize other 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 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. These collaborations would be subject to risks and uncertainties similar to those described above.

These issues and possible disagreements with AbbVie or any future corporate collaborators could lead to delays in the collaborative research, development or commercialization of our product candidates. Furthermore, disagreements with these parties could require or result in litigation or arbitration, which would be time-consuming and expensive. If any of these issues arise, it may delay the development and commercialization of drug candidates and, ultimately, our generation of product revenues.

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

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

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

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.

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

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

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

We may require additional funding to continue our research and product development programs, to conduct preclinical studies and clinical trials, for operating expenses and to pursue regulatory approvals for product candidates, for the costs involved in filing 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 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

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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.

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

Since our inception, we have incurred significant net losses and negative cash flow from operations. As a result of historical operating losses, we had an accumulated deficit of $826.3 million as of December 31, 2014. We do not expect to be profitable, or generate positive cash flows from operations, for the year ending December 31, 2015.

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

- seek regulatory approvals for our product candidates;
- develop, formulate, manufacture and commercialize our product candidates;
- in-license or acquire new product development opportunities;
- implement additional internal systems and infrastructure; and
- hire additional clinical, scientific and marketing personnel.

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

The price of our common stock is volatile.

The market prices for securities of biotechnology and pharmaceutical companies historically have been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Over the course of the last 12 months, the price of our common stock has ranged from approximately $12.00 per share to approximately $35.00 per share. The market price of our common stock may fluctuate in response to many factors, including:

- the results of our clinical trials;
- developments concerning new and existing collaboration agreements;
- announcements of technological innovations or new therapeutic products by us or others;

general economic and market conditions;

developments in patent or other proprietary rights;

developments related to the FDA;

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

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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

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introduction of new drugs. The CROs we contract with for execution of our clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Failure of the CROs to meet their obligations could adversely affect clinical development of our products. Moreover, these independent investigators and CROs may also have relationships with other commercial entities, some of which may compete with us. If independent investigators and CROs assist our competitors at our expense, it could harm our competitive position.

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

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

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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

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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.

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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.

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.

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

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

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

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

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

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

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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.

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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.

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ITEM 1B. ***UNRESOLVED STAFF COMMENTS***

None.

ITEM 2. ***PROPERTIES***

We lease our corporate headquarters which consists of approximately 140,000 square feet of laboratory and office space located at 12780 El Camino Real in San Diego, California. The lease expires in December 2019; however we have options to extend the term of the lease for up to two consecutive ten year periods.

We believe that our property and equipment are generally well maintained and in good operating condition.

ITEM 3. ***LEGAL PROCEEDINGS***

We are not currently a party to any material legal proceedings.

ITEM 4. ***MINE SAFETY DISCLOSURES***

None.

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PART II

ITEM 5. ***MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES***

Our common stock is traded on the NASDAQ Global Select Market under the symbol NBIX. The following table sets forth for the periods indicated the high and low sale price for our common stock. These prices do not include retail markups, markdowns or commissions.

	High	Low
Year Ended December 31, 2014		
1st Quarter	$ 20.29	$ 9.19
2nd Quarter	16.47	12.17
3rd Quarter	17.00	12.63
4th Quarter	24.86	15.20
Year Ended December 31, 2013		
1st Quarter	$ 12.44	$ 7.56
2nd Quarter	14.06	10.87
3rd Quarter	16.74	10.42
4th Quarter	11.88	8.57

As of January 30, 2015, there were approximately 62 stockholders of record of our common stock. We have not paid any cash dividends on our common stock since inception and do not anticipate paying cash dividends in the foreseeable future.

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

There were no unregistered sales of equity securities during fiscal 2014.

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Stock Performance Graph and Cumulative Total Return*

The graph below shows the cumulative total stockholder return assuming the investment of $100 on December 31, 2009 (and the reinvestment of dividends thereafter) in each of (i) Neurocrine Biosciences, Inc. s common stock, (ii) the NASDAQ Composite Index and (iii) the NASDAQ Biotechnology Index. The comparisons in the graph below are based upon historical data and are not indicative of, or intended to forecast, future performance of our common stock or Indexes.

* *The material in this section is not soliciting material , is not deemed filed with the SEC and is not to be incorporated by reference into any of our SEC filings whether made before or after the date hereof and irrespective of any general incorporation language in any such SEC filing except to the extent we specifically incorporate this section by reference.*

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ITEM 6. ***SELECTED FINANCIAL DATA***

The following selected financial data have been derived from our audited financial statements. The information set forth below is not necessarily indicative of our results of future operations and should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and the financial statements and notes thereto appearing elsewhere in this Annual Report on Form 10-K.

	2014	2013	2012	2011	2010
	(In thousands, except for net (loss) income per share data)				
STATEMENT OF COMPREHENSIVE (LOSS) INCOME DATA					
Revenues:					
Sponsored research and development	$	$	$ 18,897	$ 10,462	$ 10,938
Milestones and license fees		2,919	34,243	66,951	22,563
Total revenues		2,919	53,140	77,413	33,501
Operating expenses:					
Research and development	46,425	39,248	37,163	30,951	31,151
General and administrative	17,986	13,349	13,437	12,458	13,273
Cease-use expense			1,092	82	2,799
Total operating expenses	64,411	52,597	51,692	43,491	47,223
(Loss) income from operations	(64,411)	(49,678)	1,448	33,922	(13,722)
Other income:					
Gain on sale/disposal of assets	3,222	3,170	3,074	3,195	3,161
Other income, net	647	418	503	454	2,593
Total other income, net	3,869	3,588	3,577	3,649	5,754
Net (loss) income	$ (60,542)	$ (46,090)	$ 5,025	$ 37,571	$ (7,968)
Net (loss) income per common share:					
Basic	$ (0.81)	$ (0.69)	$ 0.08	$ 0.68	$ (0.15)
Diluted	$ (0.81)	$ (0.69)	$ 0.08	$ 0.67	$ (0.15)
Shares used in calculation of net (loss) income per common share:					
Basic	74,577	66,989	65,619	55,176	52,820
Diluted	74,577	66,989	66,946	56,347	52,820
BALANCE SHEET DATA					
Cash, cash equivalents and investments	$ 231,301	$ 145,739	$ 173,493	$ 129,103	$ 130,604
Working capital	182,539	136,763	173,618	85,366	80,274
Total assets	243,033	154,676	195,979	138,368	144,424
Long-term debt					
Accumulated deficit	(826,305)	(765,763)	(719,673)	(724,698)	(762,269)
Total stockholders equity	208,699	120,410	154,372	60,081	19,345

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ITEM 7. ***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 pertaining to, among other things, the expected continuation of our collaborative agreements, the receipt of research and development payments thereunder, the future achievement of various milestones in product development and the receipt of payments related thereto, the potential receipt of royalty payments, preclinical testing and clinical trials of potential products, the period of time that our existing capital resources will meet our funding requirements, and our financial results of operations. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various risks and uncertainties, including those set forth in this Annual Report on Form 10-K under the heading Item 1A. Risk Factors. See Forward-Looking Statements in Part I of this Annual Report on Form 10-K.

Overview

We discover and develop innovative and life-changing pharmaceuticals, in diseases with high unmet medical needs, through our novel R&D platform, focused on neurological and endocrine based diseases and disorders. Utilizing a portfolio approach to drug discovery, we have multiple small molecule drug candidates at various stages of pharmaceutical development. We develop proprietary pharmaceuticals for our pipeline, as well as collaborate with other pharmaceutical companies on our discoveries.

To date, we have not generated any revenues from the sale of products. We have funded our operations primarily through private and public offerings of our common stock and payments received under research and development collaboration agreements. While we independently develop many of our product candidates, we have entered into collaborations for several of our programs, and intend to rely on existing and future collaborators to meet funding requirements. We expect to generate future operating cash flow losses as product candidates are advanced through the various stages of clinical development. As of 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 endometriosis and Phase II clinical studies of uterine fibroids that is partnered with AbbVie Inc. (AbbVie), and a wholly owned vesicular monoamine transporter 2 (VMAT2) inhibitor for the treatment of movement disorders, currently in Phase III development. Additionally, in 2014 we advanced a third drug candidate into clinical development, our corticotropin releasing factor (CRF) receptor antagonist for the treatment of classic congenital adrenal hyperplasia (CAH). We intend to maintain certain commercial rights to our VMAT2 inhibitor and CRF antagonist programs to evolve into a fully-integrated pharmaceutical company.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations is based upon financial statements that we have prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosures. On an on-going basis, we evaluate these estimates, including those related to clinical trial accruals (research and development 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. Historically, revisions to our estimates have not resulted in a material change to the financial statements. The items in our financial statements requiring significant estimates and judgments are as follows:

Research and Development Expense

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 research and development

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efforts; as well as scientific contractor fees, preclinical and clinical trial costs, research and development 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 our independent R&D efforts as well as efforts associated with collaborations and in-licensing arrangements. In addition, we fund R&D and clinical trials at other companies and research institutions under agreements, which are generally cancelable. We review and accrue clinical trials expense based on work performed, which relies on estimates of total costs incurred based on patient enrollment, completion of studies and other events. We follow 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. Historically, revisions have not resulted in material changes to R&D expense; however a modification in the protocol of a clinical trial or cancellation of a trial could result in a charge to our results of operations.

Share-Based Compensation

We grant stock options to purchase our common stock to our employees and directors under our 2011 Equity Incentive Plan (the 2011 Plan) and grant stock options to certain employees pursuant to Employment Commencement Nonstatutory Stock Option Agreements (inducement grants). We also grant certain employees stock bonuses and restricted stock units under the 2011 Plan. Additionally, we have outstanding options that were granted under previous option plans from which we no longer make grants. Share-based compensation expense related to these equity instruments for the years ended December 31, 2014, 2013 and 2012 was $10.4 million, $6.8 million and $5.5 million, respectively.

Stock option awards and restricted stock units (RSUs) generally vest over a three to four year period and 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.

For purposes of calculating share-based compensation, we estimate the fair value of share-based compensation 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. For example, an increase in the underlying stock price results in a significant increase in the Black-Scholes option-pricing, which includes estimates such as expected term, expected volatility and interest rates.

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.

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Results of Operations for Years Ended December 31, 2014, 2013 and 2012

Revenue

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

	Year Ended December 31,		
	2014	2013	2012
		(In millions)	
Revenues under collaboration agreements:			
AbbVie	$	$	$ 46.9
GlaxoSmithKline (GSK)			0.1
Dainippon Sumitomo Pharma Co. Ltd. (DSP)		2.9	2.9
Boehringer Ingelheim			3.2
Total revenues	$	$ 2.9	$ 53.1

The decrease in revenue from the year ended December 31, 2012 to the year ended December 31, 2013 was primarily due to the completion of the collaborative development portion of the AbbVie collaboration agreement, which concluded as scheduled on December 31, 2012, and the completion of the collaborative research portion of the agreement with Boehringer Ingelheim, which was completed as planned in June 2012.

During each of the years ended December 31, 2013 and 2012, we recognized $2.9 million in revenue under our collaboration agreement with DSP from the amortization of up-front licensing fees. The up-front licensing fee was fully amortized as of December 31, 2013.

Operating Expenses

Research and Development

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

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

	Years Ended December 31,		
	2014	2013	2012
		(In millions)	
External development expense:			
elagolix	$	$	$ 2.2
VMAT2	9.0	12.3	7.9
CRF	2.8		
Other	2.6	1.5	1.5
Total external development expense	14.4	13.8	11.6
R&D personnel expense	20.2	15.4	14.5
R&D facility and depreciation expense	5.8	5.4	5.9

Other R&D expense	6.0	4.6	5.2
Total research and development expense	$ 46.4	$ 39.2	$ 37.2

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R&D expense increased from $39.2 million in 2013 to $46.4 million in 2014. This increase was primarily due to higher personnel related expenses coupled with higher early discovery and preclinical costs. The $4.8 million increase in personnel related expenses was attributable to increased R&D headcount and performance-based compensation. Additionally, $1.9 million of the increase in R&D personnel expense was due to higher share-based compensation expense. Other R&D expense increased by $1.4 million primarily due to higher laboratory related costs and external scientific consulting and testing expenses. Preclinical and manufacturing efforts related to early stage programs resulted in a $1.1 million increase in other external development expenses from 2013 to 2014. The CRF program for congenital adrenal hyperplasia was initiated in 2014, and resulted in $2.8 million of expense for the year. These increases in R&D external development expense were offset by lower VMAT2 external development expenses which decreased by $3.3 million due to this program substantially completing its Phase IIb development during 2013 and the initiation of Phase III studies later in 2014.

R&D expense increased from $37.2 million in 2012 to $39.2 million in 2013. The increase in R&D expenses from 2012 to 2013 was primarily due to higher external development expenses related to our VMAT2 program as it continued in Phase IIb development and a $0.6 million increase in share-based compensation expense. These increases were offset by a $0.9 million decrease in scientific consultants utilized to advise on multiple programs, and lower elagolix related costs as the full responsibility for that program transitioned to AbbVie in 2013.

The funding necessary to bring a drug candidate to market is subject to numerous uncertainties, which may adversely affect our liquidity and capital resources. Once a drug candidate is identified, the further development of that drug candidate can be halted or abandoned at any time due to a number of factors. These factors include, but are not limited to, funding constraints, safety or a change in market demand.

The nature and efforts required to develop our drug candidates into commercially viable products include research to identify a clinical candidate, preclinical development, clinical testing, FDA approval and commercialization. For each drug candidate that successfully completes all stages of research and development, and is commercialized, total research and development spending in the pharmaceutical industry may exceed $1 billion. Additionally, the stages of research and development can take in excess of ten years to complete for each drug candidate.

For each of our drug candidate programs, we periodically assess the scientific progress and merits of the programs to determine if continued research and development is economically viable. Certain of our programs have been terminated due to the lack of scientific progress and lack of prospects for ultimate commercialization. Because of the uncertainties associated with research and development of these programs, we may not be successful in achieving commercialization. As such, the ultimate timeline and costs to commercialize a product cannot be accurately estimated. Additionally, due to the uncertainty inherent in drug development, research and development costs are subject to considerable variation.

We expect research and development expenses to increase in 2015 as compared to 2014. We have recently initiated VMAT2 Phase III development as well as announced a new clinical program investigating our CRF antagonist NBI-77860 in congenital adrenal hyperplasia. The development efforts around these programs, coupled with higher share-based compensation expense due to increased Black-Scholes estimates and the anticipated vesting of certain performance-based restricted stock units, will result in a significant increase in research and development expenses in 2015.

General and Administrative

General and administrative expenses were $18.0 million in 2014 compared to $13.3 million in 2013 and $13.4 million in 2012. The $4.7 million increase in expenses from 2013 to 2014 resulted primarily from a $3.5 million increase in personnel related costs, of which $1.7 million was related to higher share-based compensation costs. Higher market research and professional fees accounted for $0.6 million of the increase in general and administrative expenses from 2013 to 2014.

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We expect our general and administrative expenses in 2015 to increase from 2014 expense levels due to increasing pre-commercialization activities related to our VMAT2 inhibitor for tardive dyskinesia, as well as higher share-based compensation expense primarily driven by higher Black-Scholes estimates and the anticipated vesting of certain performance-based restricted stock units.

Cease-use Expense

During 2012, we recognized $1.1 million in net cease-use expense related to our corporate headquarters, as a result of entering certain sublease agreements.

Net (Loss) Income

Our net loss for 2014 was $60.5 million, or $0.81 net loss per common share, net loss for 2013 was $46.1 million, or $0.69 net loss per common share, and net income for 2012 was $5.0 million, or $0.08 net income per fully diluted share.

The increase in our net loss from 2013 to 2014 was a result of the above mentioned higher expenses coupled with a $2.9 million decrease in revenue.

The change to a net loss in 2013 from a net income position in 2012 was primarily the result of revenue recognized under multiple collaboration agreements. During 2012, we recorded an aggregate of $50.1 million in revenue under our AbbVie and Boehringer Ingelheim collaboration agreements, the final year of the collaborative portion of these agreements.

We expect to have a net loss in 2015, primarily due to higher R&D expenses resulting from the progress of our VMAT2 inhibitor into Phase III and the addition of the congenital adrenal hyperplasia clinical program. Additionally, preparation for commercialization of NBI-98854 for tardive dyskinesia will lead to an increase in general and administrative expenses. We also expect an increase in share-based compensation expense due to higher Black-Scholes valuations related to 2015 equity grants and the anticipated vesting of certain performance-based restricted stock units in 2015.

Liquidity and Capital Resources

At December 31, 2014, our cash, cash equivalents, and investments totaled $231.3 million compared with $145.7 million at December 31, 2013.

Net cash used in operating activities during 2014 was $47.1 million compared to $29.6 million in 2013. The $17.5 million change is primarily due to the increase in net loss coupled with a decrease in receivables of approximately $14.1 million from 2012 receivables that were collected during the first quarter of 2013.

Net cash used in operating activities during 2013 was $29.6 million compared to $35.3 million in 2012. The $5.7 million change is primarily related to $14.1 million in accounts receivable at December 31, 2012 which was received during 2013, offset by higher R&D expenses in 2013 primarily due to expanded efforts on our VMAT2 program.

Net cash used in investing activities was $105.4 million in 2014 compared to net cash provided by investing activities of $5.3 million in 2013 and net cash used in investing activities of $34.8 million 2012. The fluctuation in net cash used in investing activities resulted primarily from the timing differences in investment purchases, sales and maturities, and the fluctuation of our portfolio mix between cash equivalents and short-term investment holdings. The average term to maturity in our investment portfolio is less than one year.

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Net cash provided by financing activities during 2014 was $138.7 million compared to $5.3 million and $83.7 million in 2013 and 2012, respectively. Cash provided by financing activities included approximately $133.2 million and $83.0 million from our public offering of common stock in February 2014 and January 2012, respectively. During 2014, 2013 and 2012 stock option exercises yielded $5.6 million, $5.3 million and $0.7 million, respectively, in cash proceeds. We had no outstanding debt at December 31, 2014.

Equity Financing. 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 shares were sold pursuant to a shelf registration statement with the Securities and Exchange Commission (SEC). The net proceeds generated from this transaction, after underwriting discounts and commissions and offering costs, were approximately $133.2 million.

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

Shelf Registration Statements. In 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 December 31, 2014, we had sold 8.0 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 December 31, 2014, we had not sold any shares under this shelf registration statement.

Factors That May Affect Future Financial Condition and Liquidity

We anticipate increases in expenditures as we continue to expand our research and development activities. Because of our limited financial resources, our strategies to develop some of our programs include collaborative agreements with major pharmaceutical companies and sales of our common stock in both public and private offerings. Our collaborative agreements typically include a partial recovery of our research costs through license fees, contract research funding and milestone revenues. Our collaborators are also financially and managerially responsible for clinical development and commercialization. In these cases, the estimated completion date would largely be under the control of the collaborator. We cannot forecast, with any degree of certainty, which other proprietary products or indications, if any, will be subject to future collaborative arrangements, in whole or in part, and how such arrangements would affect our capital requirements.

Our inlicensed, research and clinical development agreements are generally cancelable with written notice within 180 days or less. In addition to the minimum payments due under inlicense and research agreements, we may be required to pay up to approximately $17 million in milestone payments, plus sales royalties, in the event that all scientific research under these agreements is successful.

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business. We are not aware of any such proceedings or claims that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations.

We lease our office and research laboratories under an operating lease with an initial term that expires at the end of 2019. Additionally, our facility lease agreement calls for us to maintain $50 million in cash and investments at all times, or to increase our security deposit by $5 million.

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As of December 31, 2014, the total estimated future annual minimum lease payments under our non-cancelable operating lease obligations are as follows *(in thousands):*

	Payment Amount
Year ending:	
2015	$ 7,385
2016	7,606
2017	7,834
2018	8,070
2019	8,311
Thereafter	
Total future minimum lease payments	$ 39,206

The funding necessary to execute our business strategies is subject to numerous uncertainties, which may adversely affect our liquidity and capital resources. Completion of clinical trials may take several years or more, but the length of time generally varies substantially according to the type, complexity, novelty and intended use of a product candidate. It is also important to note that if a clinical candidate is identified, the further development of that candidate can be halted or abandoned at any time due to a number of factors. These factors include, but are not limited to, funding constraints, safety or a change in market demand.

An important element of our business strategy is to pursue the research and development of a diverse range of product candidates for a variety of disease indications. We pursue this goal through proprietary research and development as well as searching for new technologies for licensing opportunities. This allows us to diversify against risks associated with our research and development spending. To the extent we are unable to maintain a diverse and broad range of product candidates, our dependence on the success of one or a few product candidates would increase.

The nature and efforts required to develop our product candidates into commercially viable products include research to identify a clinical candidate, preclinical development, clinical testing, FDA approval and commercialization. For each drug candidate that successfully completes all stages of research and development, and is commercialized, total research and development spending in the pharmaceutical industry may exceed $1 billion. Additionally, the stages of research and development can take in excess of ten years to complete for each drug candidate.

We test our potential product candidates in numerous preclinical studies to identify disease indications for which our product candidates may show efficacy. We may conduct multiple clinical trials to cover a variety of indications for each product candidate. As we obtain results from trials, we may elect to discontinue clinical trials for certain product candidates or for certain indications in order to focus our resources on more promising product candidates or indications. The duration and the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during the clinical trial protocol, including, among others, the following:

- we or the FDA or similar foreign regulatory authorities may suspend the trials;
- we may discover that a product candidate may cause harmful side effects;
- patient recruitment may be slower than expected; and
- patients may drop out of the trials.

For each of our programs, we periodically assess the scientific progress and merits of the programs to determine if continued research and development is economically viable. Certain of our programs have been

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terminated due to the lack of scientific progress and lack of prospects for ultimate commercialization. Because of the uncertainties associated with research and development of these programs, we may not be successful in achieving commercialization. As such, the ultimate timeline and costs to commercialize a product cannot be accurately estimated.

Our product candidates have not yet achieved FDA regulatory approval, which is required before we can market them as therapeutic products in the United States. In order to proceed to subsequent clinical trial stages and to ultimately achieve regulatory approval, the FDA must conclude that our clinical data establish safety and efficacy. We must satisfy the requirements of similar regulatory authorities in foreign countries in order to market products in those countries. The results from preclinical testing and early clinical trials may not be predictive of results in later clinical trials. It is possible for a candidate to show promising results in clinical trials, but subsequently fail to establish sufficient safety and efficacy data necessary to obtain regulatory approvals.

As a result of the uncertainties discussed above, among others, the duration and completion costs of our research and development projects are difficult to estimate and are subject to considerable variation. Our inability to complete our research and development projects in a timely manner or our failure to enter into collaborative agreements, when appropriate, could significantly increase our capital requirements and could adversely impact our liquidity. These uncertainties could force us to seek additional, external sources of financing from time to time in order to continue with our business strategy. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

We also may be required to make further substantial expenditures if unforeseen difficulties arise in other areas of our business. In particular, our future capital requirements will depend on many factors, including:

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

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, we cannot guarantee that our existing capital resources and anticipated revenues will be sufficient to conduct and complete all of our research and development programs as planned.

We will require additional funding to continue our research and product development programs, to conduct preclinical studies and clinical trials, for operating expenses, to pursue regulatory approvals for our product candidates, for the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims, if any, for the cost of product in-licensing and for 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

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involve operating covenants that may restrict our business. If adequate funds are not available through these means, we may be required to curtail significantly one or more of our research or development programs or obtain funds through arrangements with collaborators or others. This may require us to relinquish rights to certain of our technologies or product candidates. To the extent that we are unable to obtain third-party funding for such expenses, we expect that increased expenses will result in increased cash flow losses from operations. We cannot assure you that we will successfully develop our products under development or that our products, if successfully developed, will generate revenues sufficient to enable us to earn a profit.

Interest Rate Risk

We are exposed to interest rate risk on our short-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 were to have occurred on December 31, 2014, 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, we have concluded that we do not have a material financial market risk exposure.

New Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board (FASB) issued guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. The guidance is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013, with an option for early adoption. The adoption of this guidance did not have a material impact on our consolidated financial statements.

In May 2014, the FASB amended the existing accounting standards for revenue recognition. The amendments are based on the principle that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for said goods or services. We are required to adopt the amendments beginning in 2017. Early adoption is not permitted. The amendments may be applied retrospectively to each prior period presented or retrospectively with the cumulative effect recognized as of the date of initial application. We are currently evaluating the impact that these amendments will have on our consolidated financial statements.

ITEM 7A. ***QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK***

Information required by this item is contained in Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations Interest Rate Risk. Such information is incorporated herein by reference.

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ITEM 8. ***FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA***

NEUROCRINE BIOSCIENCES, INC.

INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of

Neurocrine Biosciences, Inc.

We have audited the accompanying consolidated balance sheets of Neurocrine Biosciences, Inc. as of December 31, 2014 and 2013, and the related consolidated statements of comprehensive (loss) income, stockholders equity and cash flows for each of the three years in the period ended December 31, 2014. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Neurocrine Biosciences, Inc. at December 31, 2014 and 2013, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Neurocrine Biosciences, Inc. s internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 9, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California

February 9, 2015

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NEUROCRINE BIOSCIENCES, INC.

Consolidated Balance Sheets

(In thousands, except for par value and share totals)

	December 31, 2014	2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,014	$ 44,789
Short-term investments, available-for-sale	162,795	100,950
Other current assets	4,394	2,723
Total current assets	198,203	148,462
Property and equipment, net	2,507	1,771
Long-term investments, available-for-sale	37,492	
Restricted cash	4,831	4,443
Total assets	$ 243,033	$ 154,676
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 246	$ 101
Accrued liabilities	11,508	7,955
Current portion of deferred rent	119	
Current portion of cease-use liability	467	416
Current portion of deferred gain on sale of real estate	3,324	3,227
Total current liabilities	15,664	11,699
Deferred gain on sale of real estate	14,322	17,645
Deferred rent	1,877	1,982
Cease-use liability	2,211	2,680
Other liabilities	260	260
Total liabilities	34,334	34,266
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 76,465,942 and 67,351,195 at December 31, 2014 and 2013, respectively	76	67
Additional paid-in capital	1,035,205	886,101
Accumulated other comprehensive (loss) gain	(277)	5
Accumulated deficit	(826,305)	(765,763)
Total stockholders equity	208,699	120,410
Total liabilities and stockholders equity	$ 243,033	$ 154,676

See accompanying notes.

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NEUROCRINE BIOSCIENCES, INC.

Consolidated Statements of Comprehensive (Loss) Income

(In thousands, except net (loss) income per share data)

	Year Ended December 31,		
	2014	2013	2012
Revenues:			
Sponsored research and development	$	$	$ 18,897
Milestones and license fees		2,919	34,243
Total revenues		2,919	53,140
Operating expenses:			
Research and development	46,425	39,248	37,163
General and administrative	17,986	13,349	13,437
Cease-use expense			1,092
Total operating expenses	64,411	52,597	51,692
(Loss) income from operations	(64,411)	(49,678)	1,448
Other income:			
(Loss) gain on sale/disposal of assets	(4)	37	32
Deferred gain on real estate	3,226	3,133	3,042
Investment income, net	629	402	489
Other income, net	18	16	14
Total other income	3,869	3,588	3,577
Net (loss) income	$ (60,542)	$ (46,090)	$ 5,025
Net (loss) income per common share:			
Basic	$ (0.81)	$ (0.69)	$ 0.08
Diluted	$ (0.81)	$ (0.69)	$ 0.08
Shares used in the calculation of net (loss) income per common share:			
Basic	74,577	66,989	65,619
Diluted	74,577	66,989	66,946
Other comprehensive (loss) income:			
Net (loss) income	$ (60,542)	$ (46,090)	$ 5,025
Net unrealized (losses) gains on available-for-sale securities	(282)	7	85
Comprehensive (loss) income	$ (60,824)	$ (46,083)	$ 5,110

See accompanying notes.

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NEUROCRINE BIOSCIENCES, INC.

Consolidated Statements of Stockholders Equity

(In thousands)

	Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive (Loss) Gain	Accumulated Deficit	Total Stockholders Equity
	Shares	Amount				
BALANCE AT DECEMBER 31, 2011	55,263	$ 55	$ 784,811	$ (87)	$ (724,698)	$ 60,081
Net income					5,025	5,025
Unrealized gains on investments				85		85
Share-based compensation			5,479			5,479
Issuance of common stock for restricted share units vested	50					
Issuance of common stock for option exercises	209		731			731
Issuance of common stock, net of offering costs	10,925	11	82,960			82,971
BALANCE AT DECEMBER 31, 2012	66,447	$ 66	$ 873,981	$ (2)	$ (719,673)	$ 154,372
Net loss					(46,090)	(46,090)
Unrealized gains on investments				7		7
Share-based compensation			6,819			6,819
Issuance of common stock for option exercises	904	1	5,301			5,302
BALANCE AT DECEMBER 31, 2013	67,351	$ 67	$ 886,101	$ 5	$ (765,763)	$ 120,410
Net loss					(60,542)	(60,542)
Unrealized losses on investments				(282)		(282)
Share-based compensation			10,382			10,382
Issuance of common stock for restricted share units vested	93					
Issuance of common stock for option exercises	1,022	1	5,559			5,560
Issuance of common stock, net of offering costs	8,000	8	133,163			133,171
BALANCE AT DECEMBER 31, 2014	76,466	$ 76	$ 1,035,205	$ (277)	$ (826,305)	$ 208,699

See accompanying notes.

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NEUROCRINE BIOSCIENCES, INC.

Consolidated Statements of Cash Flows

(In thousands)

	Years Ended December 31,		
	2014	**2013**	**2012**
CASH FLOW FROM OPERATING ACTIVITIES			
Net (loss) income	$ (60,542)	$ (46,090)	$ 5,025
Adjustments to reconcile net (loss) income to net cash used in operating activities:			
Depreciation and amortization	827	671	657
Gain on sale of assets, net	(3,222)	(3,170)	(3,074)
Cease-use expense			1,092
Deferred revenues		(2,919)	(34,242)
Deferred rent	14	142	305
Amortization of premiums on investments	3,792	2,843	3,135
Non-cash share-based compensation expense	10,382	6,819	5,479
Change in operating assets and liabilities:			
Accounts receivable and other assets	(1,671)	13,528	(12,878)
Cease-use liability	(418)	(590)	(263)
Other liabilities		108	27
Accounts payable and accrued liabilities	3,698	(949)	(557)
Net cash used in operating activities	(47,140)	(29,607)	(35,294)
CASH FLOW FROM INVESTING ACTIVITIES			
Purchases of investments	(257,544)	(145,328)	(166,313)
Sales/maturities of investments	154,133	151,281	132,520
Deposits and restricted cash	(388)	(108)	(29)
Proceeds from sales of property and equipment	45	40	32
Purchases of property and equipment	(1,612)	(545)	(971)
Net cash (used in) provided by investing activities	(105,366)	5,340	(34,761)
CASH FLOW FROM FINANCING ACTIVITIES			
Issuance of common stock	138,731	5,302	83,702
Net cash provided by financing activities	138,731	5,302	83,702
Net change in cash and cash equivalents	(13,775)	(18,965)	13,647
Cash and cash equivalents at beginning of the year	44,789	63,754	50,107
Cash and cash equivalents at end of the year	$ 31,014	$ 44,789	$ 63,754
SUPPLEMENTAL DISCLOSURES			
Taxes paid	$	$	$

See accompanying notes.

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NEUROCRINE BIOSCIENCES, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2014

NOTE 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Business Activities. 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 wholly owned vesicular monoamine transporter 2 (VMAT2) inhibitor for the treatment of movement disorders.

Neurocrine Continental, Inc., is a Delaware corporation and a wholly owned subsidiary of the Company and is inactive. The Company also has two wholly-owned Irish subsidiaries, Neurocrine Therapeutics, Ltd. and Neurocrine Europe, Ltd. which were formed during December 2014.

Principles of Consolidation. The consolidated financial statements include the accounts of Neurocrine as well as its wholly owned subsidiaries. The Company does not have any significant interests in any variable interest entities. All intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (GAAP) requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the accompanying notes. Actual results could differ from those estimates.

Cash Equivalents. The Company considers all highly liquid investments that are readily convertible into cash and have an original maturity of three months or less at the time of purchase to be cash equivalents.

Short-Term and Long-Term Investments Available-for-Sale. Certain investments are classified as available-for-sale and, in accordance with authoritative guidance, are carried at fair value, with the unrealized gains and losses reported in other comprehensive (loss) income. 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 investment income. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income or expense. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in investment income.

Concentration of Credit Risk. Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents and investments. The Company has established guidelines to limit its exposure to credit risk by placing investments with high credit quality financial institutions, diversifying its investment portfolio and placing investments with maturities that maintain safety and liquidity.

Collaboration Agreements. During the years ended December 31, 2013 and 2012 collaborative R&D agreements accounted for all of the Company s revenue.

Property and Equipment. Property and equipment are stated at cost and depreciated over the estimated useful lives of the assets using the straight-line method. Equipment is depreciated over an average estimated useful life of three to seven years. Leasehold improvements are depreciated over the shorter of their estimated useful lives or the remaining lease term.

Industry Segment and Geographic Information. The Company operates in a single industry segment the discovery and development of therapeutics for the treatment of neurological and endocrine based diseases and disorders. The Company had no foreign based operations during any of the years presented.

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Impairment of Long-Lived Assets. The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. If indicators of impairment exist, the Company assesses the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If the carrying amount is not recoverable, the Company measures the amount of any impairment by comparing the carrying value of the asset to the present value of the expected future cash flows associated with the use of the asset.

Fair Value of Financial Instruments. Financial instruments, including cash and cash equivalents, accounts receivable, accounts payable, and accrued liabilities, are carried at cost, which management believes approximates fair value because of the short-term maturity of these instruments.

Research and Development Expenses. 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.

Share-Based Compensation. The Company estimates the fair value of stock options using the Black-Scholes option pricing model on the date of grant. Restricted stock units are valued based on the closing price of the Company s common stock on the date of grant. The fair value of equity instruments expected to vest are recognized and amortized on a straight-line basis over the requisite service period of the award, which is generally three to four years; however, certain provisions in the Company s equity compensation plans provide for shorter vesting periods under certain circumstances. Additionally, the Company has granted certain performance-based equity awards that vest upon the achievement of certain pre-defined Company-specific performance criteria. Expense related to these performance-based equity awards is generally recognized upon achievement of the specific performance criteria.

Investment Income, net. Investment income, net is comprised of interest and dividends earned on cash, cash equivalents and investments as well as gains and losses realized from activity in the Company s investment portfolio. The following table presents certain information related to the components of investment income (in thousands):

	Years Ended December 31,		
	2014	2013	2012
Interest income	629	400	489
Realized gains, net		2	
Total	$ 629	$ 402	$ 489

Net (Loss) Income Per Share. The Company computes basic net (loss) income per share using the weighted average number of common shares outstanding during the period. Diluted net income per share is based upon the weighted average number of common shares and potentially dilutive securities (common share equivalents) outstanding during the period. Common share equivalents outstanding, determined using the treasury stock method, are comprised of shares that may be issued under the Company s stock option agreements. Common share equivalents are excluded from the diluted net loss per share calculation because of their anti-dilutive effect.

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Due to the net loss position in 2014 and 2013, approximately 2.9 million and 2.1 million, respectively, of common share equivalents were excluded from the diluted common shares outstanding. At December 31, 2012, the Company had approximately 1.3 million of additional common share equivalents outstanding that were included in the diluted income per share calculation. For the years ended December 31, 2014, 2013 and 2012, there were employee stock options, calculated on a weighted average basis, to purchase 1.0 million, 0.3 million and 2.2 million shares of our common stock with an exercise price greater than the average market price of the underlying common shares.

Impact of Recently Issued Accounting Standards. In May 2014, the Financial Accounting Standards Board (FASB) amended the existing accounting standards for revenue recognition. The amendments are based on the principle that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for said goods or services. The Company is required to adopt the amendments beginning in 2017. Early adoption is not permitted. The amendments may be applied retrospectively to each prior period presented or retrospectively with the cumulative effect recognized as of the date of initial application. The Company is currently evaluating the impact that these amendments will have on its consolidated financial statements.

In July 2013, the FASB issued guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. The guidance is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013, with an option for early adoption. The adoption of this guidance did not have a material impact on the Company s consolidated financial statements.

NOTE 2. REVENUE RECOGNITION AND SIGNIFICANT COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENTS

Revenue Recognition Policy. Revenues under collaborative agreements and grants are recognized as research costs are incurred over the period specified in the related agreement or as the services are performed. These agreements are on a best-efforts basis, do not require scientific achievement as a performance obligation and provide for payment to be made when costs are incurred or the services are performed. All fees are nonrefundable to the collaborators. Prior to the revised multiple element guidance adopted by the Company on January 1, 2011, upfront, nonrefundable payments for license fees, grants, and advance payments for sponsored research revenues received in excess of amounts earned were classified as deferred revenue and recognized as income over the contract or development period. Estimating the duration of the development period includes continual assessment of development stages and regulatory requirements. If and when the Company enters into a new collaboration agreement or materially modifies an existing collaboration agreement, the Company will be required to apply the new multiple element guidance. Milestone payments are recognized as revenue upon achievement of pre-defined scientific events, which require substantive effort, and for which achievement of the milestone was not readily assured at the inception of the agreement.

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 has agreed to make additional development and regulatory event based payments of up to $480 million and up to an additional $50 million in commercial event based payments. The Company has assessed event based payments under the revised authoritative guidance for research and development milestones and determined that event based payments prior to commencement of a Phase III clinical study, as defined in the agreement, meet the definition of a milestone in accordance with authoritative guidance as (1) they are events that can only be achieved in part on the Company s past performance, (2) there is substantive uncertainty at the date the arrangement was entered into that the event will be achieved and (3) they result in additional payments being due to the Company. Development and regulatory event based payments subsequent to the commencement of a Phase III clinical study, however, currently do not meet these criteria as their achievement is based on the performance of AbbVie.

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As of December 31, 2014, $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. 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. 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. During 2012, the Company recorded $13.1 million in revenue related to completion of the collaborative development period which is included as part of sponsored research and development revenue.

There was no revenue recognized in 2014 or 2013 related to this collaboration. During the year ended December 31, 2012 the Company recognized $46.9 million in revenue under the AbbVie collaboration agreement, $29.1 million from the amortization of up-front license fees and $17.8 million from sponsored research and development.

Dainippon Sumitomo Pharma Co., Ltd. *(DSP).* In October 2007, the Company entered into an exclusive license agreement with DSP, under which the Company licensed rights to indiplon to DSP and agreed to collaborate with DSP on the development and commercialization of indiplon in Japan. Pursuant to the license agreement, among other things, the Company received an up-front license fee of $20 million. The Company is also eligible to receive additional event based payments upon specified future events related to the development and commercialization of indiplon in Japan. Should all event based payments be achieved, the Company may be entitled to payments totaling an additional $115 million. Event based payments under the DSP agreement do not meet the criteria of a milestone in accordance with the authoritative guidance as they are based on the performance of DSP. Additionally, the Company is entitled to royalties from DSP on future sales of indiplon in Japan. For each of the years ended December 31, 2013 and 2012, the Company recognized into revenue $2.9 million of the upfront license fee under the DSP agreement. All performance obligations pursuant to the contract were completed during 2013.

NOTE 3. INVESTMENTS

Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in comprehensive (loss) income. 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 investment income. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income or expense. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in investment income.

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Investments at December 31, 2014 and 2013 consisted of the following (in thousands):

	Years Ended December 31,	
	2014	2013
Certificates of deposit	$ 17,438	$ 11,012
Commercial paper	7,498	4,997
Corporate debt securities	174,323	77,441
Securities of government-sponsored entities	1,028	7,500
Total investments	$ 200,287	$ 100,950

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
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
December 31, 2013:					
Classified as current assets:					
Certificates of deposit	Less than 1	$ 11,018	$ 1	$ (7)	$ 11,012
Commercial paper	Less than 1	4,997			4,997
Corporate debt securities	Less than 1	77,430	19	(8)	77,441
Securities of government-sponsored entities	Less than 1	7,500			7,500
Total short-term available-for-sale securities		$ 100,945	$ 20	$ (15)	$ 100,950

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

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The following table presents certain information related to sales and maturities of available-for-sale investments (in thousands):

	Year Ended December 31,		
	2014	2013	2012
Proceeds from sales/maturities of available-for-sale securities	$ 154,133	$ 151,283	$ 132,520
Gross realized gains on sales of available-for-sale securities		2	
Gross realized losses on sales of available-for-sale securities			
Gains reclassified out of accumulated other comprehensive (loss) income into earnings			

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
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)
December 31, 2013:						
Certificates of deposit	$ 9,802	$ (7)	$	$	$ 9,802	$ (7)
Corporate debt securities	29,919	(8)			29,919	(8)
Total	$ 39,721	$ (15)	$	$	$ 39,721	$ (15)

NOTE 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 years ended December 31, 2014 and 2013.

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The Company s assets which are measured at fair value on a recurring basis as of December 31, 2014 and 2013 were determined using the inputs described above (in millions):

		Fair Value Measurements Using		
	Carrying Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
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	$
December 31, 2013:				
Classified as current assets:				
Cash and money market funds	$ 34.9	$ 34.9	$	$
Certificates of deposit	11.0	11.0		
Commercial paper	5.0		5.0	
Securities of government-sponsored entities	7.5		7.5	
Corporate debt securities	87.4		87.4	
Subtotal	145.8	45.9	99.9	
Classified as long-term assets:				
Certificates of deposit	4.4	4.4		
Total	150.2	50.3	99.9	
Less cash, cash equivalents and restricted cash	(49.2)	(39.3)	(9.9)	
Total investments	$ 101.0	$ 11.0	$ 90.0	$

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NOTE 5. PROPERTY AND EQUIPMENT

Property and equipment, net, at December 31, 2014 and 2013 consisted of the following (in thousands):

	2014	2013
Tenant improvements	1,226	1,195
Furniture and fixtures	819	819
Equipment	29,208	28,089
	31,253	30,103
Less accumulated depreciation	(28,746)	(28,332)
Property and equipment, net	$ 2,507	$ 1,771

For each of the years ended December 31, 2014, 2013 and 2012, depreciation expense was $0.8 million, $0.7 million and $0.7 million, respectively. During 2014, 2013 and 2012, the Company recognized a (loss) gain of approximately ($4,000), $37,000 and $32,000, respectively, related to disposal of capital equipment.

NOTE 6. ACCRUED LIABILITIES

Accrued liabilities at December 31, 2014 and 2013 consisted of the following (in thousands):

	2014	2013
Accrued employee related costs	$ 6,520	$ 3,403
Accrued development costs	1,706	1,387
Other accrued liabilities	3,282	3,165
	$ 11,508	$ 7,955

NOTE 7. COMMITMENTS AND CONTINGENCIES

Real Estate. In December 2007, the Company closed the sale of its facility and associated real property for a purchase price of $109 million. Concurrent with the sale, the Company retired the entire $47.7 million in mortgage debt previously outstanding with respect to the facility and associated real property, and received cash of $61.0 million net of transaction costs and debt retirement.

Upon the closing of the sale of the facility and associated real property, the Company entered into a lease agreement (Lease) with DMH Campus Investors, LLC (DMH) whereby it leased back for an initial term of 12 years its corporate headquarters comprised of two buildings located at 12790 El Camino Real (Front Building) and 12780 El Camino Real (Rear Building) in San Diego, California. The Company also entered into a series of lease amendments (Amendments), beginning in late 2008, through which it vacated the Front Building, but continues to occupy the Rear Building. The ultimate result of this real estate sale was a net gain of $39.1 million which was deferred in accordance with authoritative guidance. For the years ended December 31, 2014, 2013 and 2012, the Company recognized $3.2 million, $3.1 million and $3.0 million, respectively, of the deferred gain and will recognize the remaining $17.6 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

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of $4.6 million, which is secured by a deposit of equal amount with the same bank. The Company also has the right to extend the Lease for two consecutive ten-year terms.

In December 2010, the Company entered into a sublease agreement (Sublease) for approximately 16,000 square feet of the Rear Building. The Sublease is expected to result in approximately $0.6 million of rental income per year over the three year term of the Sublease and is recorded as an offset to rent expense. The Sublease provides an option to extend for two one-year renewal periods. The income generated under the Sublease is lower than the Company s financial obligation under the Lease for the Rear Building with DMH, as determined on a per square foot basis. Consequently, at December 31, 2010 the Company was required to record a cease-use liability for the net present value estimated difference between the expected income to be generated under the Sublease and future subleases and the Lease obligation over the remaining term of the Lease for the space that is occupied by the subtenant. This transaction resulted in $2.5 million of gross cease-use expense, and a reversal of $173,000 in associated deferred rent, being recorded in December 2010. In August 2012, the Company extended the terms of the Sublease and increased the leased square footage to approximately 17,000 square feet. This transaction resulted in approximately $150,000 of gross cease-use expense, and a reversal of $15,000 in associated deferred rent, being recorded in September 2012.

In September 2011, the Company entered into a second sublease agreement (Second Sublease) for approximately 3,300 square feet of space in the Rear Building. The Second Sublease is expected to result in approximately $0.1 million in rental income per year over the three year term and is recorded as an offset to rent expense. The Second Sublease provides an option to extend for a one-year renewal period which was exercised in 2013. Similar to the Sublease, the Second Sublease resulted in $0.3 million of gross cease-use expense, and a reversal of $47,000 in associated deferred rent, being recorded in September 2011.

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

The following table sets forth changes to the accrued cease-use liability during 2014 and 2013 (in thousands):

	Years Ended December 31,	
	2014	2013
Beginning balance	$ 3,096	$ 3,686
Payments	(418)	(590)
Ending balance	$ 2,678	$ 3,096

Rent Expense. Rent expense was $5.9 million for each of the years ended December 31, 2014, 2013 and 2012, respectively. For financial reporting purposes, the Company recognizes rent expense on a straight-line basis over the term of the lease. Accordingly, rent expense recognized in excess of rent paid is reflected as a liability in the accompanying consolidated balance sheets.

Lease Commitments. The Company leases its office and research laboratories under an operating lease with an initial term of twelve years, expiring at the end of 2019. Additionally, the Company s facility lease agreement calls for it to maintain $50 million in cash and investments at all times, or to increase the security deposit by $5 million.

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As of December 31, 2014, the total estimated future annual minimum lease payments under the Company s non-cancelable building lease for the years ending after December 31, 2014 were as follows (in thousands):

	Payment Amount
2015	$ 7,385
2016	7,606
2017	7,834
2018	8,070
2019	8,311
Thereafter	
Total future minimum lease payments	$ 39,206

Product Liability. The Company s business exposes it to liability risks from its potential drug products. A successful product liability claim or series of claims brought against the Company could result in payment of significant amounts of money and divert management s attention from running the business. The Company may not be able to maintain insurance on acceptable terms, or the insurance may not provide adequate protection in the case of a product liability claim. To the extent that product liability insurance, if available, does not cover potential claims, the Company would be required to self-insure the risks associated with such claims. The Company believes that it carries reasonably adequate insurance for product liability claims.

Licensing and Research Agreements. The Company has entered into inlicensing agreements with various universities and research organizations, which are generally cancelable at the option of the Company with terms ranging from 0-180 days written notice. Under the terms of these agreements, the Company has received licenses to research tools, know-how and technology claimed, in certain patents or patent applications. The Company is required to pay fees, milestones and/or royalties on future sales of products employing the technology or falling under claims of a patent, and some of the agreements require minimum royalty payments. Some of the agreements also require the Company to pay expenses arising from the prosecution and maintenance of the patents covering the inlicensed technology. The Company continually reassesses the value of the license agreements and cancels them when research efforts are discontinued on these programs. If all inlicensed and research candidates are successfully developed, the Company may be required to pay milestone payments of approximately $17 million over the lives of these agreements, in addition to royalties on sales of the affected products at rates ranging up to 5%. Due to the uncertainties of the development process, the timing and probability of the milestone and royalty payments cannot be accurately estimated.

Litigation. From time to time, the Company may be subject to legal proceedings and claims in the ordinary course of business. The Company is not aware of any such proceedings or claims that it believes will have, individually or in the aggregate, a material adverse effect on its business, financial condition or results of operations.

NOTE 8. SHARE-BASED COMPENSATION

Share-Based Compensation Plans. In May 2011, the Company adopted the Neurocrine Biosciences, Inc. 2011 Equity Incentive Plan (the 2011 Plan) pursuant to which 8.5 million shares of Company common stock are authorized for issuance. The 2011 Plan provides for the grant of stock options that qualify as incentive stock options under Section 422 of the Internal Revenue Code of 1986, as amended (the Code), nonstatutory stock options, restricted stock awards, restricted stock unit awards (RSUs), stock appreciation rights, performance stock awards, performance-based restricted stock units (PRSUs) and other forms of equity compensation.

The Company also issues stock options under the Neurocrine Biosciences, Inc. Inducement Plan to certain executive level employees. During 2014, 160,000 stock options were granted pursuant to such inducement plan. These stock option grants have a four year vesting period. The Company currently has approximately 0.2 million in stock options outstanding under such inducement plans.

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As of December 31, 2014, approximately 2.7 million remained available for future grant awards under the 2011 Plan. Only share awards made under the 2011 Plan that are subsequently cancelled due to forfeiture or expiration are returned to the share pool available for future grants.

The Company issues new shares upon the exercise of stock options, the issuance of stock bonus awards and vesting of RSUs and PRSUs, and has 9.5 million shares of common stock reserved for such issuance as of December 31, 2014.

Vesting Provisions of Share-Based Compensation. Stock options generally have terms from seven to ten years from the date of grant, and generally vest over a three to four-year period. The maximum contractual term for all options granted from the 2011 Plan is ten years. RSUs granted under the 2011 Plan generally have vesting periods of four years. PRSUs granted under the 2011 Plan vest based on the achievement of certain pre-defined Company-specific performance criteria and expire five years from the grant date.

Share-Based Compensation. The compensation cost that has been included in the statement of comprehensive (loss) income for all share-based compensation arrangements is as follows (in thousands):

	Years Ended December 31,		
	2014	2013	2012
General and administrative expense	$ 5,167	$ 3,516	$ 2,746
Research and development expense	5,215	3,303	2,733
Share-based compensation expense	$ 10,382	$ 6,819	$ 5,479

Authoritative guidance requires that cash flows resulting from tax deductions in excess of the cumulative compensation cost recognized for options exercised be classified as cash inflows provided by financing activities and cash outflows used in operating activities. Due to the Company s net tax loss position, no tax benefits have been recognized in the consolidated statements of cash flows.

Stock Options. The exercise price of all options granted during the years ended December 31, 2014, 2013 and 2012 was equal to the closing price of the Company s common stock on the date of grant. The estimated fair value of each option award granted was determined on the date of grant using the Black-Scholes option-pricing valuation model with the following weighted-average assumptions for option grants during the three years ended December 31, 2014:

	Years Ended December 31,		
	2014	2013	2012
Risk-free interest rate	2.2%	1.4%	1.3%
Expected volatility of common stock	71%	76%	79%
Dividend yield	0.0%	0.0%	0.0%
Expected option term	7.2 years	7.3 years	6.8 years

The Company estimates the fair value of stock options using a Black-Scholes option-pricing model on the date of grant. The fair value of equity instruments that are ultimately expected to vest, net of estimated forfeitures, are recognized and amortized on a straight-line basis over the requisite service period. The Black-Scholes option-pricing model incorporates various and highly sensitive assumptions including expected volatility, expected term and interest rates. The expected volatility is based on the historical volatility of the Company s common stock over the most recent period commensurate with the estimated expected term of the Company s stock options. The expected option term is estimated based on historical experience as well as the status of the employee. For example, directors and officers have a longer expected option term than all other employees. Additionally, grants of stock options during the past three years have a contractual life of ten years,

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versus seven years for older option grants, and the vesting period for these same option grants has been extended to four years, which together have resulted in an increase in the expected option term. 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.

Authoritative guidance requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Pre-vesting forfeitures for awards with monthly vesting terms were estimated to be 0% in 2014 based on historical experience. Pre-vesting forfeitures for awards with annual vesting terms were also estimated at 0% in 2014 based on historical employee turnover experience. The effect of past restructurings has been excluded from the historical review of employee turnover. The effect of pre-vesting forfeitures for awards has historically been negligible on the Company s recorded expense. The Company s determination of fair value is affected by the Company s stock price as well as a number of assumptions that require judgment. The weighted-average fair values of options granted during the years ended December 31, 2014, 2013 and 2012, estimated as of the grant date using the Black-Scholes option valuation model, were $12.57, $6.55 and $6.05, respectively.

A summary of the status of the Company s stock options as of December 31, 2014, 2013 and 2012 and of changes in options outstanding under the plans during the three years ended December 31, 2014 is as follows (in thousands, except for weighted average exercise price data):

	2014		2013		2012	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding at January 1	5,853	$ 7.54	6,166	$ 7.62	5,315	$ 8.82
Granted/amended	1,089	18.41	771	9.24	1,446	8.50
Exercised	(1,135)	6.50	(904)	5.96	(209)	3.49
Canceled	(57)	56.83	(180)	25.68	(386)	29.66
Outstanding at December 31	5,750	$ 9.31	5,853	$ 7.54	6,166	$ 7.62

Options outstanding at December 31, 2014 have a weighted average remaining contractual term of 6.4 years.

For the year ended December 31, 2014, share-based compensation expense related to stock options was $7.8 million. As of December 31, 2014, there was approximately $14.7 million of unamortized compensation cost related to stock options, which is expected to be recognized over a weighted average remaining vesting period of approximately 2.7 years. As of December 31, 2014, there were approximately 4.2 million options exercisable with a weighted average exercise price of $7.55 and a weighted-average remaining contractual term of 5.6 years. The total intrinsic value, which is the amount by which the exercise price was exceeded by the sale price of the Company s common stock on the date of sale, of stock option exercises during the years ended December 31, 2014, 2013, and 2012 was $14.3 million, $6.0 million and $943,000, respectively. As of December 31, 2014, the total intrinsic value of options outstanding and exercisable was $77.1 million and $64.3 million, respectively. Cash received from stock option exercises for the years ended December 31, 2014, 2013 and 2012 was $5.6 million, $5.3 million and $0.7 million, respectively.

Restricted Stock Units. Certain employees receive RSUs under the 2011 Plan. The fair value of RSUs is based on the closing sale price of the Company s common stock on the date of issuance. The total number of RSUs expected to vest is adjusted by estimated forfeiture rates, which has been based on historical experience of equity awards and historical employee turnover experience. The effect of pre-vesting forfeitures for awards has historically been negligible on the Company s recorded expense and was estimated at 0% in 2014. The effect of

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past restructurings has been excluded from the historical review of employee turnover. For the year ended December 31, 2014, 2013 and 2012, share-based compensation expense related to RSUs was $2.6 million, $0.8 million, and $0, respectively. As of December 31, 2014, there was approximately $7.5 million of unamortized compensation cost related to RSUs, which is expected to be recognized over a weighted average remaining vesting period of approximately 2.9 years.

The total intrinsic value of RSUs converted into common shares during the years ended December 31, 2014, 2013 and 2012 was $1.7 million, $0, and $0.4 million, respectively. The RSUs, at the election of eligible employees, may be subject to deferred delivery arrangement. The total intrinsic value of RSUs outstanding at December 31, 2014 was $15.0 million based on the Company s closing stock price on that date.

A summary of the status of the Company s RSUs as of December 31, 2014, 2013 and 2012 and of changes in RSUs outstanding under the plans for the three years ended December 31, 2014 is as follows (in thousands, except for weighted average grant date fair value per unit):

	2014		2013		2012	
	Number of Units	Weighted Average Grant Date Fair Value per Unit	Number of Units	Weighted Average Grant Date Fair Value per Unit	Number of Units	Weighted Average Grant Date Fair Value per Unit
Restricted stock units outstanding at January 1	373	$ 8.65		$	50	$ 5.88
Restricted stock units granted	389	19.59	379	8.65		
Restricted stock units cancelled			(6)	8.65		
Restricted stock units converted into common shares	(93)	8.65			(50)	5.88
Restricted stock units outstanding at December 31	669	$ 15.01	373	$ 8.65		$

Performance-Based Restricted Stock Units. During the year ended December 31, 2014, the Company granted approximately 0.5 million PRSUs that vest based on the achievement of certain pre-defined Company-specific performance criteria and expire five years from the grant date. As the performance based criteria for vesting for the PRSUs is not currently probable, no associated expense has been recorded for the PRSUs during the year ended December 31, 2014. The total unrecognized estimated compensation expense related to these PRSUs is $9.3 million and is expected to be recognized when the performance condition have been achieved, which is when these events will become probable. The total intrinsic value of PRSUs outstanding at December 31, 2014 was $10.6 million based on the Company s closing stock price on that date.

NOTE 9. STOCKHOLDERS EQUITY

Equity Financing

In February 2014, the Company completed a public offering of common stock in which the Company sold 8.0 million shares of our common stock at an offering price of $17.75 per share. The shares were sold pursuant to an automatic shelf registration statement filed with the Securities and Exchange Commission (SEC). The net proceeds generated from this transaction, after underwriting discounts and commissions and offering costs, were approximately $133.2 million.

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

Shelf Registration Statement

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 December 31, 2014, the Company had sold 8.0 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. The specific terms of future offerings, if any, under the shelf registration statement would be established at the time of such offerings.

NOTE 10. INCOME TAXES

Under the FASB s accounting guidance related to uncertain tax positions, among other things, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, the guidance provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

The Company s policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties on the Company s consolidated balance sheets at December 31, 2014 or December 31, 2013, and has not recognized interest and/or penalties in the statement of comprehensive (loss) income for the year ended December 31, 2014.

The Company is subject to taxation in the United States and various state jurisdictions. The Company s tax years for 1998 (federal)/1997 (California) and forward are subject to examination by the United States and California tax authorities due to the carry forward of unutilized net operating losses and R&D credits.

At December 31, 2014, the Company had deferred tax assets of $367.1 million. Due to uncertainties surrounding the Company s ability to generate future taxable income to realize these assets, a full valuation has been established to offset the net deferred tax asset. Additionally, the future utilization of the Company s net operating loss and research and development credit carry forwards to offset future taxable income may be subject to an annual limitation, pursuant to Internal Revenue Code Sections 382 and 383, as a result of ownership changes that could occur in the future. The Company has determined that no ownership changes have occurred through December 31, 2014.

At December 31, 2014, the Company had Federal and California income tax net operating loss carry forwards of approximately $668.3 million and $652.8 million, respectively. The Federal tax loss carry forwards will begin to expire in 2021, unless previously utilized.

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The California net operating loss carry forwards will expire as follows (in thousands):

Year	Amount
2015	68,500
2016	113,400
2017	72,100
2018	140,600
2028 and beyond	258,200

In addition, the Company has Federal and California R&D tax credit carry forwards of $33.9 million and $23.6 million, respectively. The Federal research and development tax credit carry forwards begin expiring in 2018 and will continue to expire unless utilized. The California research and development tax credit carryforwards carry forward indefinitely. The Company also has Federal Alternative Minimum Tax credit carryforwards of approximately $227,000, which will carry forward indefinitely. At December 31, 2014, approximately $26.5 million of the net operating loss carry forwards relate to stock option exercises, which will result in an increase to additional paid-in capital and a decrease in income taxes payable at the time when the tax loss carryforwards are utilized.

Significant components of the Company s deferred tax assets as of December 31, 2014 and 2013 are listed below. A valuation allowance of $367.1 million and $341.7 million at December 31, 2014 and 2013, respectively, has been recognized to offset the deferred tax assets as realization of such assets is uncertain. Amounts are shown as of December 31 as of each respective year (in thousands):

	2014	2013
Deferred tax assets:		
Net operating losses	$ 260,600	$ 246,500
Research and development credits	29,000	27,700
Capitalized research and development	45,700	34,500
Share-based compensation expense	6,900	5,200
Deferred revenue	800	800
Deferred gain on sales leaseback	7,200	8,500
Intangibles	10,600	13,200
Cease-use expense	1,100	1,300
Fixed assets	500	300
Other	4,700	3,700
Total deferred tax assets	367,100	341,700
Valuation allowance	(367,100)	(341,700)
Net deferred tax assets	$	$

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The provision for income taxes on earnings subject to income taxes differs from the statutory Federal rate at December 31, 2014, 2013 and 2012, due to the following (in thousands):

	2014	2013	2012
Federal income taxes at 35%	$ (21,190)	$ (16,131)	$ 1,759
State income tax, net of Federal benefit	(3,410)	(2,611)	406
Tax effect on non-deductible expenses	10	7	9
Share-based compensation expense	91	215	1,154
Expired tax attributes	315	151	327
Research credits	(1,882)	(3,458)	(428)
Change in valuation allowance	25,366	20,504	(4,061)
Uncertain tax positions	621	1,283	876
Other	79	40	(42)
	$	$	$

The following table summarizes the activity related to our unrecognized tax benefits (in thousands):

	2014	2013	2012
Balance as of the beginning of the year	$ 23,131	$ 21,672	$ 20,237
Increases related to prior year tax positions	47	543	1,434
Increases related to current year tax positions	676	916	165
Expiration of the statute of limitations for the assessment of taxes			(164)
Balance as of the end of the year	$ 23,854	$ 23,131	$ 21,672

The Company, under authoritative guidance, excluded those deferred tax assets that are not more likely than not to be sustained under the technical merits of the tax position. These unrecognized tax benefits totaled $47,000 and $0.7 million for prior year tax positions and current year tax positions, respectively, as reflected in the tabular rollforward above.

As of December 31, 2014, the Company had $20.2 million of unrecognized tax benefits that, if recognized and realized, would effect the effective tax rate.

In the next twelve months, the Company does not expect a significant change in their unrecognized tax benefits.

NOTE 11. RETIREMENT PLAN

The Company has a 401(k) defined contribution savings plan (401(k) Plan). The 401(k) Plan is for the benefit of all qualifying employees and permits voluntary contributions by employees up to 60% of base salary limited by the IRS-imposed maximum. Employer contributions were $0.3 million, $0.3 million and $0.2 million for the years ended December 31, 2014, 2013 and 2012, respectively.

NOTE 12. SUBSEQUENT EVENTS

The Company evaluated all subsequent events that have occurred after the date of the accompanying financial statements and determined that there were no events or transactions occurring during this subsequent event reporting period which require recognition or disclosure in the Company s financial statements, other than as disclosed below.

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NOTE 13. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

The following is a summary of the quarterly results of the Company for the years ended December 31, 2014 and 2013 *(unaudited, in thousands, except for per share data)*:

	Year Ended December 31,				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Year Ended December 31
2014:					
Revenues	$	$	$	$	$
Operating expenses	12,725	14,361	16,857	20,468	64,411
Net loss	(11,842)	(13,381)	(15,875)	(19,444)	(60,542)
Net loss per share:					
Basic and Diluted	$ (0.17)	$ (0.18)	$ (0.21)	$ (0.26)	$ (0.81)
Shares used in the calculation of net loss per share:					
Basic and Diluted	70,260	75,879	75,948	76,139	74,577
2013:					
Revenues	$ 730	$ 730	$ 729	$ 730	$ 2,919
Operating expenses	13,705	13,897	12,735	12,260	52,597
Net loss	(12,075)	(12,242)	(11,131)	(10,642)	(46,090)
Net loss per share:					
Basic and Diluted	$ (0.18)	$ (0.18)	$ (0.17)	$ (0.16)	$ (0.69)
Shares used in the calculation of net loss per share:					
Basic and Diluted	66,600	66,799	67,199	67,346	66,989

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ITEM 9. ***CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE***
Not applicable.

ITEM 9A. ***CONTROLS AND PROCEDURES***
We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports 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 year 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.

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Management s Report on Internal Control Over Financial Reporting

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

(1) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

(2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and

(3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk. Management is responsible for establishing and maintaining adequate internal control over financial reporting for the company.

Management has used the framework set forth in the report entitled Internal Control-Integrated Framework (2013 framework) published by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), known as COSO, to evaluate the effectiveness of our internal control over financial reporting. Based on this assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2014. Ernst & Young, LLP, our independent registered public accounting firm, has issued an attestation report on our internal control over financial reporting as of December 31, 2014, which is included herein.

There has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of

Neurocrine Biosciences, Inc.

We have audited Neurocrine Biosciences, Inc. s internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). Neurocrine Biosciences, Inc. s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management s Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Neurocrine Biosciences, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Neurocrine Biosciences, Inc. as of December 31, 2014 and 2013, and the related consolidated statements of comprehensive (loss) income, stockholders equity and cash flows for each of the three years in the period ended December 31, 2014 of Neurocrine Biosciences, Inc. and our report dated February 9, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California

February 9, 2015

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ITEM 9B. ***OTHER INFORMATION***

None.

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PART III

ITEM 10. ***DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE***

Information required by this item will be contained in our Definitive Proxy Statement for our 2015 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2014. Such information is incorporated herein by reference.

We have adopted a code of ethics that applies to our Chief Executive Officer, Chief Financial Officer, and to all of our other officers, directors, employees and agents. The code of ethics is available at the Corporate Governance section of the Investors page on our website at www.neurocrine.com. We intend to disclose future amendments to, or waivers from, certain provisions of our code of ethics on the above website within four business days following the date of such amendment or waiver.

ITEM 11. ***EXECUTIVE COMPENSATION***

Information required by this item will be contained in our Definitive Proxy Statement for our 2015 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2014. Such information is incorporated herein by reference.

ITEM 12. ***SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS***

Information required by this item will be contained in our Definitive Proxy Statement for our 2015 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2014. Such information is incorporated herein by reference.

ITEM 13. ***CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE***

Information required by this item will be contained in our Definitive Proxy Statement for our 2015 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2014. Such information is incorporated herein by reference.

ITEM 14. ***PRINCIPAL ACCOUNTANT FEES AND SERVICES***

Information required by this item will be contained in our Definitive Proxy Statement for our 2015 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2014. Such information is incorporated herein by reference.

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PART IV

ITEM 15. ***EXHIBITS, FINANCIAL STATEMENT SCHEDULES***
(a) Documents filed as part of this report.

1. List of Financial Statements. The following are included in Item 8 of this report:

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2014 and 2013

Consolidated Statements of Comprehensive (Loss) Income for the years ended December 31, 2014, 2013 and 2012

Consolidated Statements of Stockholders Equity for the years ended December 31, 2014, 2013 and 2012

Consolidated Statements of Cash Flows for the years ended December 31, 2014, 2013 and 2012

Notes to the Consolidated Financial Statements (includes unaudited Selected Quarterly Financial Data)

2. List of all Financial Statement schedules. All schedules are omitted because they are not applicable or the required information is shown in the Financial Statements or notes thereto.

3. List of Exhibits required by Item 601 of Regulation S-K. See part (b) below.

(b) Exhibits. The following exhibits are filed as part of, or incorporated by reference into, this report:

Exhibit

Number	**Description**
3.1	Certificate of Incorporation(13)
3.2	Certificate of Amendment to Certificate of Incorporation(13)
3.3	Bylaws, as amended(13)
4.1	Form of Common Stock Certificate(1)
10.1**	Neurocrine Biosciences, Inc. 2003 Incentive Stock Plan, as amended and form of stock option agreement and restricted stock unit agreement.(7)
10.2**	Form of Indemnity Agreement entered into between the Company and its officers and directors.(5)
10.3**	Employment Commencement Nonstatutory Stock Option Agreement dated October 31, 2005 between the Company and Christopher O Brien.(4)
10.4	Amended and Restated Lease dated November 1, 2011 between the Company and Kilroy Realty, L.P.(9)
10.5	Letter of Credit dated December 3, 2007, issued by Wells Fargo Bank, N.A. for the benefit of Kilroy Realty, L.P., as amended on November 20, 2014.
10.6**	Amended and Restated Employment Agreement effective August 1, 2007 between the Company and Kevin C. Gorman, Ph.D.(3)
10.7	License agreement dated August 27, 1999 between the Company and the Mount Sinai School of Medicine of the City University of New York.(11)

10.8**	Amended and Restated Employment Agreement effective August 1, 2007 between the Company and Timothy P. Coughlin.(3)

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Exhibit

Number	Description
10.9**	Amended and Restated Employment Agreement effective August 6, 2007 between the Company and Christopher F. O Brien M.D.(6)
10.10**	Amended and Restated Employment Agreement effective August 23, 2007 between the Company and Dimitri E. Grigoriadis, Ph.D.(6)
10.11**	Amended and Restated Employment Agreement effective August 14, 2007 between the Company and Haig Bozigian, Ph.D.(6)
10.12**	2011 Equity Incentive Plan, as amended, Form of Stock Option Grant Notice and Option Agreement for use thereunder, and Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement for use thereunder.(14)
10.13*	Collaboration Agreement dated June 15, 2010, by and between Abbott International Luxembourg S.a.r.l. and the Company.(8)
10.14*	First Amendment to Collaboration and License Agreement dated August 31, 2011 between the Company and Abbott International Luxembourg S.à. r.l.(10)
10.15**	Form of Amendment to Employment Agreement for executive officers.(12)
10.16**	Neurocrine Biosciences, Inc. Inducement Plan, as amended, Form of Stock Option Grant Notice and Option Agreement for use thereunder.(2)
21.1	Subsidiaries of the Company
23.1	Consent of Independent Registered Public Accounting Firm
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 Registration Statement on Form S-1 (Registration No. 333-03172)
(2) Incorporated by reference to the Company s Quarterly Report on Form 10-Q filed on November 4, 2014
(3) Incorporated by reference to the Company s Quarterly Report on Form 10-Q filed on August 3, 2007
(4) Incorporated by reference to the Company s Current Report on Form 8-K filed on November 1, 2005
(5) Incorporated by reference to the Company s Current Report on Form 8-K filed on September 1, 2009
(6) Incorporated by reference to the Company s Annual Report on Form 10-K filed on February 11, 2008
(7) Incorporated by reference to the Company s Quarterly Report on Form 10-Q filed on July 30, 2009
(8) Incorporated by reference to the Company s Quarterly Report on Form 10-Q filed on July 29, 2010

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(9) Incorporated by reference to the Company s Current Report on Form 8-K filed on January 18, 2012
(10) Incorporated by reference to the Company s Quarterly Report on Form 10-Q filed on October 31, 2011
(11) Incorporated by reference to the Company s Quarterly Report on Form 10-Q filed on July 26, 2013
(12) Incorporated by reference to the Company s Annual Report on Form 10-K filed on February 10, 2011
(13) Incorporated by reference to the Company s Annual Report on Form 10-K filed on February 8, 2013
(14) Incorporated by reference to the Company s Quarterly Report on Form 10-Q filed on August 6, 2014
* Confidential treatment has been granted with respect to certain portions of the exhibit.
** Management contract or compensatory plan or arrangement.
*** These certifications are being furnished solely to accompany this annual 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.

(c) Financial Statement Schedules. See Item 15(a)(2) above.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

A Delaware Corporation

By: /s/ Kevin C. Gorman
Kevin C. Gorman
President and Chief Executive Officer

Date: February 9, 2015

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Kevin C. Gorman	President, Chief Executive Officer	February 9, 2015
Kevin C. Gorman	and Director	
	(Principal Executive Officer)	
/s/ Timothy P. Coughlin	Chief Financial Officer	February 9, 2015
Timothy P. Coughlin	(Principal Financial and Accounting Officer)	
/s/ William H. Rastetter	Chairman of the Board of Directors	February 9, 2015
William H. Rastetter		
/s/ Gary A. Lyons	Director	February 9, 2015
Gary A. Lyons		
/s/ W. Thomas Mitchell	Director	February 9, 2015
W. Thomas Mitchell		
/s/ Joseph A. Mollica	Director	February 9, 2015
Joseph A. Mollica		
/s/ Corinne H. Nevinny	Director	February 9, 2015
Corinne H. Nevinny		
/s/ Richard F. Pops	Director	February 9, 2015

Richard F. Pops		
/s/ Stephen A. Sherwin	Director	February 9, 2015
Stephen A. Sherwin		