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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(Mark One)

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2015

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission file number: 0-22705

NEUROCRINE BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

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 ☑ 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 ☑

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 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 ☑ 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. ☑

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 ☑ 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 ☑

The aggregate market value of the common equity held by non-affiliates of the registrant as of June 30, 2015 totaled approximately $3,026,332,411 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, 2015. The identification of 10% or greater stockholders as of June 30, 2015 is based on Schedule 13G and amended Schedule 13G reports publicly filed before June 30, 2015. This calculation does not reflect a determination that such parties are affiliates for any other purposes.

As of February 1, 2016, there were 86,452,994 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, 2015 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,” “intends,” “estimates,” “could,” “should,” “would,” “continue,” “seeks,” “pro forma,” or “anticipates,” or other similar words (including their use in the negative), or by 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 NBI-98854 (valbenazine) a 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.

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
valbenazine (NBI-98854)	Tardive Dyskinesia	Phase III	Neurocrine/Mitsubishi Tanabe
elagolix	Uterine Fibroids	Phase III	AbbVie
valbenazine (NBI-98854)	Tourette Syndrome	Phase II	Neurocrine/Mitsubishi Tanabe
NBI-640756	Essential Tremor	Phase I	Neurocrine
Research programs:			
Endocrine (e.g. CRF1 Antagonists)	Classic Congenital Adrenal Hyperplasia	Research	Neurocrine
Neurological/Neuropsychiatric (e.g. VMAT2 Inhibitors)	Movement Disorders, Bipolar Disorder and Schizophrenia	Research	Neurocrine
CNS Disorders (Targeted by G Protein-Coupled Receptors and Ion Channels)	Epilepsy, Essential Tremor, Pain, Other Indications	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 these molecules 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.

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.

In June 2010, we entered into an exclusive worldwide collaboration with AbbVie to develop and commercialize elagolix and all next-generation non-peptide GnRH antagonists (collectively, GnRH Compounds) for women's and men's health indications. Under the terms of the agreement, AbbVie is responsible for all development, marketing and commercialization costs and has primary responsibility for all regulatory interactions with the U.S. Food and Drug Administration (FDA) related to elagolix and other GnRH Compounds covered by the collaboration. AbbVie is currently in Phase III evaluation of elagolix in two indications, endometriosis and uterine fibroids.

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 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.

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 ($\leq$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 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 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.

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.

In January 2015, AbbVie announced 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 (150mg once daily and 200mg 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 were 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 concluded in mid-2015. In July 2015, AbbVie announced that the efficacy and safety data at one year was consistent with the data witnessed at six months.

In February 2016, AbbVie announced the top-line results from the second of the two Phase III elagolix endometriosis clinical trials, the Solstice Study, a multinational study designed to evaluate the efficacy and safety of elagolix in 815 premenopausal women with endometriosis. The top-line results from this trial were consistent with those of the Violet PETAL Study; after six months of treatment, both doses of elagolix (150 mg once daily and 200 mg twice daily) met the Solstice study's co-primary endpoints of reducing scores of non-menstrual pelvic pain and menstrual pain (or dysmenorrhea) associated with endometriosis at month three, as well as month six. The observed safety profile of elagolix in the Solstice study was consistent with observations from prior studies. Among the most common adverse events were hot flush, headache, and nausea. While most adverse events were similar across treatment groups some, such as hot flush and bone mineral density loss, were dose-dependent. Overall discontinuation rates were similar across treatment groups (25.3%, 21.2%, and 19.7% for placebo, 150 mg once daily and 200 mg twice daily, respectively); discontinuations specifically due to treatment emergent adverse events were 6.1%, 4.4%, and 10.0% for placebo, 150 mg once daily and 200 mg twice daily, respectively. Patients in the Solstice study were eligible to continue on in either post-treatment follow-up or a blinded extension study for an additional six-month safety and efficacy evaluation of elagolix.

AbbVie is targeting a 2017 New Drug Application filing with the FDA for elagolix in endometriosis.

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 symptoms such as: longer, more frequent, or heavy menstrual bleeding, menstrual pain, vaginal bleeding at time other than menstruation, pain in the abdomen or lower back, pain during sex, difficulty urinating, frequent urination, constipation or rectal pain. 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 single Phase IIb clinical trial enrolled approximately 570 women with heavy uterine bleeding due to uterine fibroids at approximately 100 sites in the United States, Canada, Puerto Rico, Chile and the United Kingdom. The trial was a 24-week, randomized, double-blind, multicenter, placebo-controlled, two cohort design study that evaluated the safety and efficacy of two different elagolix treatment regimens (300mg twice daily and 600mg once daily) alone and in combination with two different strengths of hormonal add-back therapy (estradiol/norethindrone acetate). The primary endpoint of the study was an assessment of uterine blood loss after six months of treatment. Secondary efficacy endpoints included change in uterine volume, fibroid volume, and menstrual patterns. Safety assessments of bone mineral density, comparing baseline to month six, were performed via DXA scan. Patients were also followed off drug for up to six months.

Results show elagolix reduced heavy menstrual bleeding in all treatment arms. The study's primary endpoint, a composite design where subjects had to achieve a menstrual blood loss (MBL) volume of less than

80 mL as well as a 50 percent or greater reduction in MBL volume from baseline at the final study month, was met ($p<0.001$) as assessed utilizing a quantitative measure of reduction in uterine blood flow, the alkaline hematin method.

Among the most common adverse events were hot flash, headache, nausea, and vomiting. Some adverse events such as hot flash were more frequent in the elagolix only treatment arms versus the placebo and elagolix with add back therapy treatment arms. Reduction in bone mineral density associated with elagolix alone was attenuated when elagolix was co-administered with hormonal add-back therapy.

AbbVie initiated Phase III studies of elagolix in patients with uterine fibroids in early 2016. The Phase III program will include two replicate, pivotal, six-month efficacy and safety studies followed by a six-month safety and efficacy extension study. The primary endpoint in Phase III studies will be the same as that employed in the Phase IIb study: percent of subjects with reduction in uterine blood flow as measured by the alkaline hematin method.

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

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) in neurons. Specifically, dopamine enables neurotransmission among nerve cells that are involved in voluntary and involuntary motor control. Disease states such as tardive dyskinesia (TD), Tourette syndrome, Huntington's chorea, schizophrenia, 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 (valbenazine). 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 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, valbenazine should be well tolerated in patients. Valbenazine has been evaluated in multiple clinical studies to assess its safety, tolerability and efficacy. We believe that the potential efficacy and safety profile of NBI-98854 will address many of the shortcomings of current off-label treatments for TD. Finally, valbenazine 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 valbenazine 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. 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 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, during which 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 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 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.

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 valbenazine group was scored with a mean reduction from baseline of 1.3 points. Utilizing this analysis, valbenazine 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 valbenazine including the proposed Phase III development to support the registration of valbenazine in the United States as a treatment for TD. Based on the results of this meeting and the related minutes, we conducted a single placebo-controlled Phase III study of valbenazine, the Kinect 3 Study.

The Kinect 3 Study was initiated during the fourth quarter of 2014. The Kinect 3 Study is a randomized, parallel-group, double-blind, placebo-controlled clinical trial utilizing the capsule formulation of valbenazine 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 was the mean change from baseline in the AIMS as assessed by blinded central raters. The Kinect 3 Study randomized approximately 230 subjects to either placebo, once daily 40mg of valbenazine or once daily 80mg of valbenazine for 6 weeks of placebo-controlled dosing followed by an extension of active dosing through week 48.

The AIMS ratings at week 6 for the 80mg once-daily NBI-98854 ITT population was reduced 3.1 points (Least-Squares Mean) more than placebo ($p<0.0001$). In addition to the primary efficacy endpoint, the AIMS rating for the 40mg once-daily dose and the CGI-TD for both doses were also evaluated. The table below summarizes the results of the AIMS ratings and CGI-TD at week 6 for both the ITT population and a preliminary pre-specified per-protocol (PP) population, which excludes subjects whose plasma concentrations of NBI-98854 were below the lower limit of quantitation and it was determined that these subjects had not ingested the study drug.

	Week 6			
	40mg qd	p-value*	80mg qd	p-value*
AIMS Difference from Placebo				
Least-Squares Mean (ITT population)	-1.8	0.0021	-3.1	<0.0001
Least-Squares Mean (PP population)	-2.1	0.0009	-3.6	<0.0001
CGI-TD Difference from Placebo				
Least-Squares Mean (ITT population)	-0.3	0.0742	-0.3	0.0560
Least-Squares Mean (PP population)	-0.4	0.0097	-0.4	0.0122

* *Assessment of the significance of p-values based on pre-specified, fixed-sequence testing procedure*

During the six-week placebo-controlled treatment period NBI-98854 was generally well tolerated. The frequency of adverse events was similar among all treatment groups and treatment emergent adverse effects were consistent with those of prior studies. Clinical hematology, chemistry and ECG monitoring indicated no emergent safety signals. There were no drug-drug interactions identified in subjects who were utilizing a wide range of psychotropic and other concomitant medications.

The Kinect 3 Study is currently completing the 48-week safety extension portion of the study. In addition to the Kinect 3 Study, we are also conducting a separate one-year open-label safety study of 40mg once daily and 80mg once daily valbenazine (the Kinect 4 Study) which we believe will be used to support the filing of a New Drug Application (NDA) in TD that is expected in 2016.

In October 2014, the FDA granted us breakthrough therapy designation for valbenazine, for the treatment of 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.

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 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 valbenazine and based on the results of these preclinical studies, we initiated the T-Force Study in children and adolescents with Tourette syndrome in early 2015. The T-Force Study was an open-label, multiple ascending dose, pharmacokinetic and pharmacodynamic study to evaluate the safety, tolerability and exposure-response of valbenazine in children and adolescents with Tourette syndrome. A total of 28 patients were 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 was divided into two dosing groups consisting of children (ages 6-11) and adolescents (ages 12-18), and each age group was further divided into three dosing cohorts. Subsequent dose escalations for children and adolescents were based, in part, on the pharmacokinetic and safety data from the previous cohort in each age group. The Yale Global Tic Severity Scale was also assessed and after two weeks of treatment showed a mean reduction of 31% from baseline scores, with over half of the subjects considered clinical responders. Based on the results of the T-Force study, we initiated the Phase II program in Tourette syndrome.

The T-Force GREEN study is a multicenter, randomized, double-blind, placebo-controlled, multi-dose, parallel group, Phase II study to evaluate the safety, tolerability and efficacy of valbenazine in up to 90 pediatric patients with moderate to severe Tourette syndrome. Two once-daily fixed doses of NBI-98854 will be evaluated vs. placebo in a 1:1:1 randomization. The three-arm study will evaluate up to 45 children and 45 adolescents over six weeks of dosing followed by two weeks off-drug at approximately 40 study centers in the United States. The primary endpoint of this study is the change from baseline of the Yale Global Tic Severity Scale between placebo and active treatment groups at the end of week six. Tourette symptoms will also be evaluated via the Rush Video-Based Tic Rating Scale, Premonitory Urge for Tics Scale as well as Clinical Global Impression scales, among others.

We have also initiated a Phase II clinical trial of valbenazine in adults with Tourette syndrome. The T-Forward study is a randomized, double-blind, placebo-controlled, multi-dose, parallel group, study that is expected to enroll up to 90 adults with moderate to severe Tourette syndrome. Two once-daily fixed doses of NBI-98854 will be evaluated versus placebo in a 1:1:1 randomization. The three-arm study will evaluate up to 90 patients over eight weeks of dosing followed by two weeks off-drug at approximately 40 study centers in the United States to assess the safety, tolerability and efficacy of valbenazine in Tourette patients. The primary endpoint of this study is a change from baseline of placebo versus active scores utilizing the Yale Global Tic Severity Scale at the end of week 8. Tourette symptoms will also be evaluated via the Premonitory Urge for Tics Scale as well as Clinical Global Impression of Change scales, among others.

Data readouts from both of these Phase II Tourette studies are expected around year-end 2016.

NBI-640756, Essential Tremor

Essential Tremor. Essential tremor is one of the most common neurological disorders in adults, impacting an estimated 10 million individuals in the United States (International Essential Tremor Foundation). The disorder is characterized by involuntary, rhythmic, oscillatory movements that most often affect the upper limbs. As the disease progresses, tremor severity often increases and spreads to other parts of the body. Essential tremor has a significant impact on the activities of daily living often resulting in functional disability as the disease progresses and is associated with a high comorbidity rate of social phobia, depression and anxiety. Current pharmacological therapies utilized in the treatment of essential tremor include propranolol and primidone. Deep brain stimulation, an invasive procedure involving the implantation of electrodes within certain areas of the brain, is sometimes utilized for severe essential tremor.

NBI-640756 was discovered in our laboratories. We have initiated a single site, randomized, double-blind, placebo-controlled sequential dose-escalation, Phase I safety and pharmacokinetics study exploring a once-daily dose of NBI-640756 in up to 32 healthy volunteers. The study will be conducted in multiple sequential cohorts of eight subjects per cohort with top-line data expected the first-half of 2016. If this initial Phase I study is successful, we intend on initiating a multiple ascending dose study of NBI-640756 later in 2016.

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 neurological/neuropsychiatric diseases. Central nervous system and endocrinology drug therapies are among the largest therapeutic categories, accounting for over $150 billion in worldwide drug sales according to GlobalData (2014).

Endocrine: Corticotropin-Releasing Factor (CRF) Receptor$_1$ Antagonist (Classic Congenital Adrenal Hyperplasia)

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 hormone (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.

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 ACTH, 17-hydroxyprogesterone (17-OHP), androgens, 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 clinical study we initiated certain preclinical studies in juvenile rodents to permit NBI-77860 to be clinically evaluated in younger patients. The results of these preclinical studies showed certain toxicological findings that were not observed in previous animal studies. We have determined that these findings are specific to NBI-77860 and have halted all clinical development of NBI-77860.

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.

We are currently investigating two other CRF antagonist compounds in preclinical evaluations and anticipate filing an IND for at least one of these compounds as well as initiating a Phase I study during 2016.

Neurological/Neuropsychiatric: VMAT2 Inhibitors

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.

CNS Disorders (Targeted by G Protein-Coupled Receptors and Ion Channels)

G Protein-Coupled Receptors (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. Ion channels appear to be represented by approximately 400 genes in the human genome and are currently the targets for approximately seven percent of the current marketed drugs. Next generation therapies derived from targeting GPCRs and ion channels 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, now also applied to ion channels, provides an unbiased profile of pharmacological protein/ligand interactions coupled with in vivo efficacy using discrete animal models allowing for rapid discovery of initial leads and advancement into preclinical and clinical development. Importantly, this design cycle is not limited to GPCRs or ion channel targets, but can be utilized for other recently identified 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 uterine fibroids that is partnered with AbbVie, and a VMAT2 inhibitor for the treatment of movement disorders that is currently in Phase III development for TD and in Phase II development for Tourette syndrome. 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, including valbenazine, 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 $81.5 million, $46.4 million and $39.2 million for the years ended December 31, 2015, 2014 and 2013, 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 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.

Mitsubishi Tanabe Pharma Corporation (Mitsubishi Tanabe). In March 2015, we entered into a collaboration and license agreement with Mitsubishi Tanabe for the development and commercialization of valbenazine for movement disorders in Japan and other select Asian markets. Mitsubishi Tanabe made an up-front license fee payment of $30 million and has agreed to make additional development and commercialization event-based payments totaling up to $85 million, payments for the manufacture of pharmaceutical products, and

royalties on product sales in select territories in Asia. Under the terms of the agreement, Mitsubishi Tanabe is responsible for all third-party development, marketing and commercialization costs in Japan and other select Asian markets with the exception of a single Huntington's chorea clinical trial to be performed by us, at an estimated cost of approximately $12 million, should Mitsubishi Tanabe request the clinical trial. We will be entitled to a percentage of sales of NBI-98854 in Japan and other select Asian markets for the longer of ten years or the life of the related patent rights. Mitsubishi Tanabe may terminate the agreement at its discretion upon 180 days' written notice to the Company. In such event, all NBI-98854 product rights for Japan and other select Asian markets would revert to the Company.

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. In December 2015, Mt. Sinai initiated litigation against us related to an alleged breach of our agreement (see Item 3 "Legal Proceedings" in this Form 10-K)

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 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).

Valbenazine, our highly selective VMAT2 inhibitor, currently in clinical trials for the treatment of TD and Tourette syndrome, 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.

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.

The federal Anti-Kickback Statute makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully, directly or indirectly, solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, lease of any good, facility, item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term “remuneration” has been broadly interpreted to include anything of value.

Federal false claims and false statement laws, including the federal civil False Claims Act, prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent or not provided as claimed.

The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

Also, many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, requires certain types of individuals and entities to abide by standards relating to the privacy and security of individually identifiable health information, including the adoption of administrative, physical and technical safeguards to protect such information. In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services (CMS) information related to payments or other transfers of value made to physicians and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members.

Failure to comply with these laws, where applicable, can result in significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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 NDA or a biologics license application for approval to commence commercial sales. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act (PDUFA) guidelines that are currently in effect, the FDA has a goal of ten months from the date of filing of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision.

In addition, under the Pediatric Research Equity Act of 2003 (PREA) as amended and reauthorized, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults or full or partial waivers from the pediatric data requirements.

The FDA also may require submission of a risk evaluation and mitigation strategy (REMS) plan to ensure that the benefits of the drug outweigh its risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations 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 adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with Good Clinical Practice requirements.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for FDA to reconsider the application. Even with submission of

this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and 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.

Special FDA Expedited Review and Approval Programs

The FDA has various programs, including fast track designation, accelerated approval, priority review, and breakthrough therapy designation, which are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. The FDA may review sections of the NDA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

The FDA may give a priority review designation to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. These six and ten month review periods are measured from the filing date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for fast track designation are also likely to be considered appropriate to receive a priority review.

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict

an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug may be subject to accelerated withdrawal procedures.

A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with current Good Manufacturing Practices (cGMP) requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;

- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for such drug products.

In the United States, third-party payors include federal and state healthcare programs, government authorities, private managed care providers, private health insurers and other organizations. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical drug products and medical services, in addition to questioning their safety and efficacy. Such payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Nonetheless, our product candidates may not be considered medically necessary or cost-effective.

Moreover, the process for determining whether a third-party payor will provide coverage for a drug product may be separate from the process for setting the price of a drug product or for establishing the reimbursement rate that such a payor will pay for the drug product. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

The marketability of any product candidates for which we or our collaborators receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

By way of example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the ACA, was signed into law, which intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the ACA of importance to our potential drug candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payor.

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 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 heavy menstrual bleeding associated with 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. Additionally, Esmya® (ulipristal) by Allergan Pharmaceuticals, Inc. is being evaluated in Phase III clinical trials for potential use in the treatment of heavy menstrual bleeding associated with uterine fibroids.

Our VMAT2 inhibitor, valbenazine, is currently in clinical trials for the treatment of movement disorders, specifically TD and Tourette syndrome. 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. Generic neuroleptic medications (pimozide and haloperidol) as well as Abilify® (apriprizole) are approved by the FDA to control the tics associated with Tourette syndrome. Additionally, Teva Pharmaceuticals, Inc. is conducting clinical trials for its VMAT2 inhibitor SD-809 for the treatment of TD and Tourette syndrome and has filed an NDA for the chorea associated with Huntington's disease for the same compound. Other potential indications for our VMAT2 inhibitor are Huntington's disease, schizophrenia and tardive dystonia. Currently, Xenazine®, marketed by Lundbeck, as well as its generic alternatives, are approved for the chorea associated with Huntington's disease.

NBI-640756 is currently in clinical trials for the treatment of essential tremor. Current pharmacological therapies utilized in the treatment of essential tremor include propranolol and primidone. Deep brain stimulation, an invasive procedure involving the implantation of electrodes within certain areas of the brain, is sometimes utilized for severe essential tremor. Additionally, Sage Therapeutics is conducting clinical trials for its GABA modulator SAGE-547 for essential tremor.

We are studying CRF antagonists for treating 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;
- 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, 2015, we had approximately 120 full-time employees, of which 32 hold Ph.D., M.D. or equivalent degrees, and 23 others hold an M.S., M.B.A., or equivalent degrees. Of these full-time employees, 94 were engaged in, or directly support, research and development activities, and 26 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.

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.

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 III uterine fibroids program, require suspension of these programs and/or obviate filings for regulatory approvals. Similarly, our VMAT2 inhibitor program will be impacted if any of the events above lead to delayed timelines for the enrollment in, or completion of, the Phase III tardive dyskinesia or the Tourette syndrome Phase II clinical trials of valbenazine.

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

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

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

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

- failed to gain the requisite regulatory approval of elagolix;
- did not successfully launch and commercialize elagolix;
- did not conduct its collaborative activities in a timely manner;
- did not devote sufficient time and resources to our partnered program;
- terminated its agreement with us;
- developed, either alone or with others, products that may compete with elagolix;
- disputed our respective allocations of rights to any products or technology developed during our collaboration; or
- merged with a third party that wants to terminate our agreement.

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

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

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

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

- be found ineffective or cause harmful side effects during preclinical studies or clinical trials;
- fail to receive necessary regulatory approvals on a timely basis or at all;
- be precluded from commercialization by proprietary rights of third parties;
- be difficult to manufacture on a large scale; or
- be uneconomical to commercialize or fail to achieve market acceptance.

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

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

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

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

Since our inception, we have incurred significant net losses and negative cash flow from operations. As a result of historical operating losses, we had an accumulated deficit of $915.2 million as of December 31, 2015. We do not expect to be profitable, or generate positive cash flows from operations, for the year ending December 31, 2016.

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

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

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

The price of our common stock is volatile.

The market prices for securities of biotechnology and pharmaceutical companies historically have been highly volatile, and the market for these securities has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Over the course of the last 12 months, the price of our common stock has ranged from approximately $20.00 per share to approximately $58.00 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, including economic and market conditions affecting the biotechnology industry;
- developments in patent or other proprietary rights;
- developments related to the FDA;
- future sales of our common stock by us or our stockholders;
- comments by securities analysts;
- fluctuations in our operating results;
- developments related to on-going litigation;
- 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, or violate the terms of these licenses, we could lose our rights to those technologies and drug candidates or be forced to pay damages.

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 (Mount Sinai). 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. If we were to violate any of the terms of our licenses, we could become subject to damages. For example, on December 1, 2015, Mount Sinai filed a complaint against us, seeking unspecified monetary damages, future sublicensing fees and attorney’s fees, alleging that we violated the terms of our license with Mount Sinai by entering into an exclusive worldwide collaboration with AbbVie. While we believe that we have meritorious defenses to the claims made in the complaint and intend to vigorously defend ourselves against such claims, we are not able to predict the ultimate outcome of this action. 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, no sales force, no third-party reimbursement 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 and secure adequate third-party reimbursement 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, sales and reimbursement capabilities or fail to enter into successful marketing arrangements with third parties, our product revenues will suffer.

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

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

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 current Good Manufacturing Practices and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

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

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

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

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

- continued scientific progress in our research and development programs;
- the magnitude and complexity of our research and development programs;
- progress with preclinical testing and clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in filing and pursuing patent applications, enforcing patent claims, or engaging in interference proceedings or other patent litigation;
- competing technological and market developments;
- the establishment of additional strategic alliances;
- developments related to on-going litigation;
- 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. In addition, we have previously financed capital purchases and may continue to pursue opportunities to obtain additional debt financing in the future. Additional equity or debt financing might not be available on reasonable terms, if at all. Any additional equity financings will be dilutive to our stockholders and any additional debt financings may involve operating covenants that restrict our business.

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

We are highly dependent on the principal members of our management and scientific staff. The loss of any of these people could impede the achievement of our objectives. Furthermore, recruiting and retaining qualified scientific personnel to perform research and development work in the future is critical to our success. We may be

unable to attract and retain personnel on acceptable terms given the competition among biotechnology, pharmaceutical and health care companies, universities and non-profit research institutions for experienced scientists. In addition, we rely on a significant number of consultants to assist us in formulating our research and development strategy. Our consultants may have commitments to, or advisory or consulting agreements with, other entities that may limit their availability to us.

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

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

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

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available. 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.

Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available regardless of whether they are approved by the FDA for that particular use.

Government authorities and other third-party payors are developing increasingly sophisticated methods of controlling healthcare costs, such as by limiting coverage and the amount of reimbursement for particular medications. Further, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

There may also be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

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 availability of coverage and adequate reimbursement for 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.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current Good Manufacturing Practices for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- product injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

If we receive regulatory approval from the FDA for any of our product candidates, we could face liability if a regulatory authority determines that we are promoting any such product for "off-label" uses.

A company may not promote "off-label" uses for its drug products. An off-label use is the use of a product for an indication that is not described in the product's FDA-approved label in the United States or for uses in other jurisdictions that differ from those approved by the applicable regulatory agencies. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. A company that is found to have promoted off-label use of its product may be subject to significant liability, including civil and criminal sanctions. If we begin marketing any of our product candidates, we intend to comply with the requirements and restrictions of the FDA and other regulatory agencies with respect to our promotion of our products, but we cannot be sure that the FDA or other regulatory agencies will agree that we have not violated their restrictions. As a result, we may be subject to criminal and civil liability. In addition, our management's attention could be diverted to handle any such alleged violations. A significant number of companies have been the target of inquiries and investigations by various U.S. federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys' Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission and various state Attorneys General offices. These investigations have alleged violations of various U.S. federal and state laws and regulations, including claims asserting antitrust violations, violations of the federal False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a *qui tam* suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects, and reputation.

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

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

Additionally, in March 2010, the ACA was signed into law, which was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the ACA of importance to our potential drug candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

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, essential tremor, classic congenital adrenal hyperplasia, 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, marketing and distribution experience; and
- production facilities.

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

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

- obtain patent protection for our products;
- preserve our trade secrets;
- prevent third parties from infringing upon our proprietary rights; and
- operate without infringing upon the proprietary rights of others, both in the United States and internationally.

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

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

In addition, although we own a number of patents, the issuance of a patent is not conclusive as to its validity or enforceability, and third parties may challenge the validity or enforceability of our patents. We cannot assure you how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court or in other proceedings. It is possible that a competitor may successfully challenge our patents or that challenges will result in limitations of their coverage. Moreover, competitors may infringe our patents or successfully avoid them through design innovation. To prevent infringement or unauthorized use, we may need to file infringement claims, which are expensive and time-consuming. In addition, in an infringement proceeding a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology.

Interference proceedings declared by the United States Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patent applications or those of our licensors. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and be a distraction to management. We cannot assure you that we will be able to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

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

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

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

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

Breakthrough therapy designation for valbenazine for the treatment of tardive dyskinesia may not lead to a faster development or regulatory review or approval process.

A breakthrough therapy is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Products designated as breakthrough therapies by the FDA may also be eligible for priority review if supported by clinical data at the time the NDA is submitted to FDA.

Designation as a breakthrough therapy is within the discretion of the FDA. The receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, the FDA may later decide that the product candidate no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

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.

Such laws include:

- the federal Anti-Kickback Statute which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal false claims and civil monetary penalties laws, including the civil False Claims Act, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, which also imposes obligations, including mandatory contractual terms, on certain types of individuals and entities, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to report annually to CMS information related to payments or other transfers of value made to physicians and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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.

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

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

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

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

ITEM 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***

On December 1, 2015, Icahn School of Medicine at Mount Sinai (Mount Sinai) filed a complaint against us in the United States District Court for the Southern District of New York: *Icahn School of Medicine at Mount Sinai v. Neurocrine Biosciences, Inc.*, Case No. 1:15-cv-09414. In the complaint, Mount Sinai alleges that we, by entering into an exclusive worldwide collaboration with AbbVie Inc. to develop and commercialize next-generation gonadotropin-releasing hormone antagonists, breached our license agreement with Mount Sinai dated August 27, 1999. Mount Sinai is seeking unspecified monetary damages, future sublicensing fees and attorney's fees. We believe that we have meritorious defenses to the claims made in the complaint and intend to vigorously defend ourselves against such claims, but we are not able to predict the ultimate outcome of this action.

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

None.

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, 2015		
1st Quarter	$45.36	$19.68
2nd Quarter	49.49	32.67
3rd Quarter	56.97	33.61
4th Quarter	58.46	37.76

As of February 1, 2016, there were approximately 56 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.

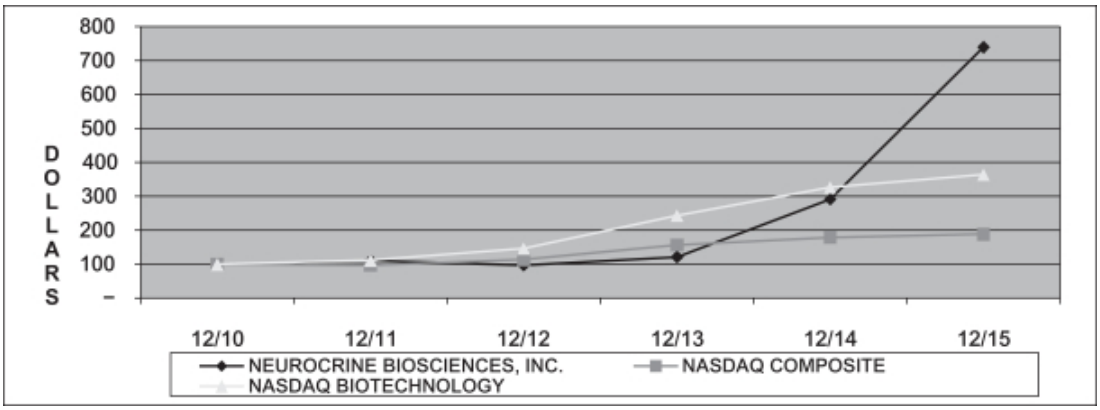
Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

There were no unregistered sales of equity securities during fiscal 2015.

Stock Performance Graph and Cumulative Total Return*

The graph below shows the cumulative total stockholder return assuming the investment of $100 on December 31, 2010 (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.*

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.

	2015	2014	2013	2012	2011
	(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
Milestones and license fees	19,769	—	2,919	34,243	66,951
Total revenues	19,769	—	2,919	53,140	77,413
Operating expenses:					
Research and development	81,491	46,425	39,248	37,163	30,951
General and administrative	32,480	17,986	13,349	13,437	12,458
Cease-use expense	—	—	—	1,092	82
Total operating expenses	113,971	64,411	52,597	51,692	43,491
(Loss) income from operations	(94,202)	(64,411)	(49,678)	1,448	33,922
Other income:					
Gain on sale/disposal of assets	3,334	3,222	3,170	3,074	3,195
Other income, net	1,939	647	418	503	454
Total other income, net	5,273	3,869	3,588	3,577	3,649
Net (loss) income	$ (88,929)	$ (60,542)	$ (46,090)	$ 5,025	$ 37,571
Net (loss) income per common share:					
Basic	$ (1.05)	$ (0.81)	$ (0.69)	$ 0.08	$ 0.68
Diluted	$ (1.05)	$ (0.81)	$ (0.69)	$ 0.08	$ 0.67
Shares used in calculation of net (loss) income per common share:					
Basic	84,496	74,577	66,989	65,619	55,176
Diluted	84,496	74,577	66,989	66,946	56,347
BALANCE SHEET DATA					
Cash, cash equivalents and investments	$ 461,679	$ 231,301	$ 145,739	$ 173,493	$ 129,103
Working capital	358,359	182,539	136,763	173,618	85,366
Total assets	474,785	243,033	154,676	195,979	138,368
Long-term debt	—	—	—	—	—
Accumulated deficit	(915,234)	(826,305)	(765,763)	(719,673)	(724,698)
Total stockholders' equity	424,454	208,699	120,410	154,372	60,081

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 research and development (R&D) platform, focused on neurological and endocrine based diseases and disorders. Utilizing a portfolio approach to drug discovery, we have multiple small molecule drug candidates at various stages of pharmaceutical development. We develop proprietary pharmaceuticals for our pipeline, as well as collaborate with other pharmaceutical companies on our discoveries.

To date, we have not generated any revenues from the sale of products. We have funded our operations primarily through private and public offerings of our common stock and payments received under 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, 2015, we had an accumulated deficit of $915.2 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 uterine fibroids that is partnered with AbbVie Inc. (AbbVie), and a vesicular monoamine transporter 2 (VMAT2) inhibitor for the treatment of movement disorders, currently in Phase III development for tardive dyskinesia and Phase II development for Tourette syndrome. We intend to maintain certain commercial rights to our VMAT2 inhibitor program 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 revenue recognition, 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:

Revenue Recognition

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

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

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

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

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

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

Revenues from development milestones are accounted for in accordance with the Revenue Recognition – Milestone Method Topic of the Financial Accounting Standards Board (FASB) ASC (Milestone Method). Milestones are recognized when earned, as evidenced by written acknowledgment from the collaborator or other persuasive evidence that the milestone has been achieved, provided that the milestone event is substantive. A milestone event is considered to be substantive if its achievability was not reasonably assured at the inception of the agreement and our efforts led to the achievement of the milestone or the milestone was due upon the occurrence of a specific outcome resulting from our performance. We assesses whether a milestone is substantive at the inception of each agreement. For payments payable on achievement of milestones that do not meet all of the conditions to be considered substantive, we recognize the portion of the payment allocable to delivered items as revenue when the specific milestone is achieved, and the contingency is removed.

Prior to the revised multiple element guidance described above, adopted by us on January 1, 2011, upfront, nonrefundable payments for license fees, grants, and advance payments for sponsored research revenues received in excess of amounts earned were classified as deferred revenue and recognized as income over the contract or development period.

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

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

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

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

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

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

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

AbbVie Inc. (AbbVie). In June 2010, 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 agreed to make additional

development and regulatory event-based payments of up to $480 million and up to an additional $50 million in commercial event-based payments. We assessed event-based payments under the revised authoritative guidance for research and development milestones and determined that event-based payments prior to commencement of a Phase III clinical study, as defined in the agreement, meet the definition of a milestone in accordance with authoritative guidance as (i) they are events that can only be achieved in part on our past performance, (ii) there is substantive uncertainty at the date the arrangement was entered into that the event will be achieved and (iii) they result in additional payments being due to us. Development and regulatory event-based payments subsequent to the commencement of a Phase III clinical study, however, currently do not meet these criteria as their achievement is based on the performance of AbbVie. As of December 31, 2015, $500 million remains outstanding in future event-based payments under the agreement. However, none of the remaining event-based payments meet the definition of a milestone in accordance with authoritative accounting guidance.

Under the terms of the agreement, AbbVie is responsible for all third-party development, marketing and commercialization costs. We received funding for certain internal collaboration expenses, which included reimbursement from AbbVie for internal and external expenses related to the GnRH Compounds, through the end of 2012. We will be entitled to a percentage of worldwide sales of GnRH Compounds for the longer of ten years or the life of the related patent rights. Under the terms of our agreement with AbbVie, the collaboration effort between the parties to advance GnRH Compounds towards commercialization was governed by a joint development committee with representatives from both us and AbbVie. Our participation in the joint development committee was determined to be a substantive deliverable under the contract, and therefore, the upfront payment was deferred and recognized over the term of the joint development committee, which was completed, as scheduled, in December 2012. AbbVie may terminate the collaboration at its discretion upon 180 days' written notice to us. In such event, we would be entitled to specified payments for ongoing clinical development and related activities and all GnRH Compound product rights would revert to us.

Research and Development Expense

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 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, 2015, 2014 and 2013 was $28.4 million, $10.4 million and $6.8 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; upon which expense is then recognized ratably over the expected performance period. Because the performance based criteria for vesting for the PRSUs was not immediately probable, no associated expense was recorded for the year ended December 31, 2014. During 2015, we recognized approximately $8.8 million in expense related to PRSUs as it became probable that the pre-defined performance conditions would be met mainly due to the Phase III results of the Kinect 3 clinical study. Unrecognized estimated compensation expense related to these PRSUs will continue to be recognized ratably over the remaining estimated expected performance period.

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.

Results of Operations for Years Ended December 31, 2015, 2014 and 2013

Revenue

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

	Year Ended December 31,		
	2015	2014	2013
	(In millions)		
Revenues under collaboration agreements:			
Mitsubishi Tanabe Pharma, Inc.	$19.8	$—	$ —
Dainippon Sumitomo Pharma Co. Ltd. (DSP)	—	—	2.9
Total revenues	$19.8	$—	$2.9

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

During the year ended December 31, 2013, we recognized $2.9 million in revenue under our collaboration agreement with Dainippon Sumitomo Pharma Co. Ltd. from the amortization of up-front licensing fees. The up-front licensing fee under this collaboration agreement 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 R&D costs separately for each of our drug candidates. We review our R&D expenses by focusing on four categories: external development, personnel, facility and depreciation, and other. External development expenses consist of costs associated with our external preclinical and clinical trials, including pharmaceutical development and manufacturing. Personnel expenses include salaries and wages, share-based compensation, payroll taxes and benefits for those individuals involved in ongoing research and development efforts. Other R&D 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,		
	2015	2014	2013
	(In millions)		
External development expense:			
VMAT2	$29.3	$ 9.0	$12.3
CRF	3.3	2.8	—
Other	1.2	2.6	1.5
Total external development expense	33.8	14.4	13.8
R&D personnel expense	32.8	20.2	15.4
R&D facility and depreciation expense	6.0	5.8	5.4
Other R&D expense	8.9	6.0	4.6
Total research and development expense	$81.5	$46.4	$39.2

R&D expense increased from $46.4 million in 2014 to $81.5 million in 2015. The $35.1 million increase in R&D expense was due in part to a $19.4 million increase in external development expenses primarily related to our VMAT2 Phase III clinical program, which was initiated during the second half of 2014. Approximately $12.6 million of the increase in R&D expense was due to higher R&D personnel related expense. Share-based compensation expense increased by approximately $7.9 million from 2014 to 2015; approximately $4.2 million of which was related to PRSUs recognized during 2015. An increase in R&D headcount and other personnel related costs accounted for the balance of the increase in personnel expense. Other R&D expense also increased by $2.9 million from 2014 to 2015 primarily due to external consulting expenses as we expanded our efforts on the NDA for valbenazine in tardive dyskinesia.

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.

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 R&D, and is commercialized, total R&D spending in the pharmaceutical industry may exceed $2 billion. Additionally, the stages of R&D 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 R&D 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 R&D 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, R&D costs are subject to considerable variation.

We expect research and development expenses to increase in 2016 as compared to 2015. We have recently initiated VMAT2 Phase II development in Tourette syndrome as well as announced a new clinical program investigating NBI-640756 in essential tremor. Additionally, we expect to file a new IND application in 2016 for another drug candidate. The development efforts around these programs, increased headcount to support these programs, coupled with higher share-based compensation expense due to increased Black-Scholes estimates and the expensing of certain RSUs and PRSUs, will result in an increase in R&D expense in 2016.

General and Administrative

General and administrative expenses were $32.5 million in 2015 compared to $18.0 million in 2014 and $13.3 million in 2013. The majority of this $14.5 million increase in expenses from 2014 to 2015 was due to higher personnel related expenses. Share-based compensation expense increased by approximately $10.1 million from 2014 to 2015; approximately $4.6 million of which was related to PRSUs expense recognized in 2015. An increase in headcount and other personnel related costs accounted for approximately $2.1 million of additional increase in personnel expense. Higher market research, licensing and other professional fees accounted for approximately $1.9 million of the increase in general and administrative expenses from 2014 to 2015.

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.

We expect our general and administrative expenses in 2016 to increase significantly from 2015 expense levels due to increasing pre-commercialization activities related to our VMAT2 inhibitor for tardive dyskinesia.

Net Loss

Our net loss for 2015 was $88.9 million, or $1.05 net loss per common share, our net loss for 2014 was $60.5 million, or $0.81 net loss per common share, and our net loss for 2013 was $46.1 million, or $0.69 net loss per common share.

The increase in our net loss from 2014 to 2015 was a result of the above mentioned higher overall expenses offset partially by an increase in revenue of approximately $19.8 million from the Mitsubishi Tanabe agreement.

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

We expect to have a net loss in 2016, primarily due to significantly higher general and administrative expenses as we prepare for commercialization of valbenazine in tardive dyskinesia. R&D expenses will also increase due to our expanded clinical pipeline and early stage R&D efforts. Revenue is also expected to decrease modestly in 2016.

Liquidity and Capital Resources

At December 31, 2015, our cash, cash equivalents, and investments totaled $461.7 million compared with $231.3 million at December 31, 2014.

Net cash used in operating activities during 2015 was $38.0 million compared to $47.1 million in 2014. The $9.1 million change in cash flows from operating activities is primarily due to an increase in operating expenses of approximately $49.6 million; of which approximately $18.0 million consisted of non-cash share-based compensation expense. This increase in operating expenses was offset by a $30 million up-front payment from Mitsubishi Tanabe received in the second quarter of 2015, and an increase in current accounts payable and accrued liabilities of approximately $9.8 million.

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 investing activities was $195.8 million in 2015 compared to net cash used in investing activities of $105.4 million in 2014 and net cash provided by investing activities of $5.3 million in 2013. 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.

Net cash provided by financing activities during 2015 was $277.0 million compared to $138.7 million and $5.3 million in 2014 and 2013, respectively. Cash provided by financing activities included approximately $270.7 and $133.2 million from our public offering of common stock in February 2015 and 2014, respectively. During 2014, 2013 and 2012 stock option exercises yielded $6.3 million, $5.6 million and $5.3 million, respectively, in cash proceeds. We had no outstanding debt at December 31, 2015.

Equity Financing. In February 2015, we completed a public offering of common stock in which we sold 8.0 million shares of our common stock at an offering price of $36.00 per share. The 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 $270.7 million.

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

Shelf Registration Statement. 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, 2015, we had sold 16.0 million 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 R&D 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. On December 1, 2015, Icahn School of Medicine at Mount Sinai (Mount Sinai) filed a complaint against us in the United States District Court for the Southern District of New York: *Icahn School of Medicine at Mount Sinai v. Neurocrine Biosciences, Inc.*, Case No. 1:15-cv-09414. In the complaint, Mount Sinai alleges that we, by entering into an exclusive worldwide collaboration with AbbVie to develop and commercialize GnRH antagonists breached our license agreement with Mount Sinai dated August 27, 1999. Mount Sinai is seeking unspecified monetary damages, future sublicensing fees and attorney's fees. We believe that we have meritorious defenses to the claims made in the complaint and intend to vigorously defend ourselves against such claims, but are not able to predict the ultimate outcome of this action.

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.

As of December 31, 2015, the total estimated future annual minimum lease payments under our non-cancelable operating lease obligations are as follows *(in thousands):*

	Payment Amount
Year ending:	
2016	$ 7,606
2017	7,834
2018	8,070
2019	8,311
2020 and thereafter	—
Total future minimum lease payments	$31,821

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.

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 R&D, and is commercialized, total R&D spending in the pharmaceutical industry may exceed $2 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 R&D 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 R&D 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 R&D projects are difficult to estimate and are subject to considerable variation. Our inability to complete our R&D 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 R&D programs;
- the magnitude of our R&D 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;
- developments related to on-going litigation;
- 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 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, 2015, this change would not have had a material effect on the fair value of our investment portfolio as of that date. Due to the short holding period of our investments, we have concluded that we do not have a material financial market risk exposure.

New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued an Accounting Standards Update (ASU), “Revenue from Contracts with Customers,” which outlines a comprehensive revenue recognition model and supersedes most current revenue recognition guidance. The new standard requires a company to recognize revenue upon transfer of goods or services to a customer at an amount that reflects the expected consideration to be received in exchange for those goods or services. The ASU defines a five-step approach for recognizing revenue, which may require a company to use more judgment and make more estimates than under the current guidance. The ASU as currently issued will be effective for us starting in 2018. The new standard allows for two methods of adoption: (a) full retrospective adoption, meaning the standard is applied to all periods presented, or (b) modified retrospective adoption, meaning the cumulative effect of applying the new standard is recognized as an adjustment to the opening retained earnings balance. We are in the process of determining the adoption method we will implement as well as the effects the adoption will have on our consolidated financial statements.

In November 2015, the FASB issued an ASU, “Income Taxes: Balance Sheet Classification of Deferred Taxes,” which ASU eliminates the current requirement for organizations to present deferred tax assets and liabilities as current and noncurrent in a classified balance sheet. Instead, organizations will be required to classify all deferred tax assets and liabilities as noncurrent. This ASU applies to all organizations that present a classified balance sheet. The ASU is effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. We adopted this standard as of December 31, 2015 with retroactive application.

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.

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

NEUROCRINE BIOSCIENCES, INC.
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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, 2015 and 2014, and the related consolidated statements of comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2015. 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, 2015 and 2014, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, 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, 2015, 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 11, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 11, 2016

NEUROCRINE BIOSCIENCES, INC.

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

	December 31, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 74,195	$ 31,014
Short-term investments, available-for-sale	304,996	162,795
Other current assets	4,883	4,394
Total current assets	384,074	198,203
Property and equipment, net	3,432	2,507
Long-term investments, available-for-sale	82,488	37,492
Restricted cash	4,791	4,831
Total assets	$ 474,785	$ 243,033
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,561	$ 246
Accrued liabilities	19,034	11,508
Current portion of deferred rent	269	119
Current portion of cease-use liability	428	467
Current portion of deferred gain on sale of real estate	3,423	3,324
Total current liabilities	25,715	15,664
Deferred gain on sale of real estate	10,898	14,322
Deferred revenue	10,231	—
Deferred rent	1,711	1,877
Cease-use liability	1,555	2,211
Other liabilities	221	260
Total liabilities	50,331	34,334
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value; 110,000,000 shares authorized; issued and outstanding shares were 86,262,594 and 76,465,942 at December 31, 2015 and 2014, respectively	86	76
Additional paid-in capital	1,340,579	1,035,205
Accumulated other comprehensive loss	(977)	(277)
Accumulated deficit	(915,234)	(826,305)
Total stockholders' equity	424,454	208,699
Total liabilities and stockholders' equity	$ 474,785	$ 243,033

See accompanying notes.

NEUROCRINE BIOSCIENCES, INC.

Consolidated Statements of Comprehensive Loss
(In thousands, except net loss per share data)

	Year Ended December 31,		
	2015	2014	2013
Revenues:			
Milestones and license fees	$ 19,769	$ —	$ 2,919
Total revenues	19,769	—	2,919
Operating expenses:			
Research and development	81,491	46,425	39,248
General and administrative	32,480	17,986	13,349
Total operating expenses	113,971	64,411	52,597
Loss from operations	(94,202)	(64,411)	(49,678)
Other income:			
Gain (loss) on sale/disposal of assets	9	(4)	37
Deferred gain on real estate	3,325	3,226	3,133
Investment income, net	1,928	629	402
Other income, net	11	18	16
Total other income	5,273	3,869	3,588
Net loss	$ (88,929)	$ (60,542)	$ (46,090)
Net loss per common share:			
Basic	$ (1.05)	$ (0.81)	$ (0.69)
Diluted	$ (1.05)	$ (0.81)	$ (0.69)
Shares used in the calculation of net loss per common share:			
Basic	84,496	74,577	66,989
Diluted	84,496	74,577	66,989
Other comprehensive loss:			
Net loss	$ (88,929)	$ (60,542)	$ (46,090)
Net unrealized (losses) gains on available-for-sale securities	(700)	(282)	7
Comprehensive loss	$ (89,629)	$ (60,824)	$ (46,083)

See accompanying notes.

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, 2012	66,447	$ 66	$ 873,981	$ (2)	$ (719,673)	$ 154,372
Net income	—	—	—	—	(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
Net loss	—	—	—	—	(88,929)	(88,929)
Unrealized losses on investments	—	—	—	(700)	—	(700)
Share-based compensation	—	—	28,392	—	—	28,392
Issuance of common stock for restricted share units vested	503	1	—	—	—	1
Issuance of common stock for option exercises	1,308	1	6,303	—	—	6,304
Issuance of common stock, net of offering costs	7,986	8	270,679	—	—	270,687
BALANCE AT DECEMBER 31, 2015	86,263	$ 86	$1,340,579	$ (977)	$ (915,234)	$ 424,454

See accompanying notes.

NEUROCRINE BIOSCIENCES, INC.

Consolidated Statements of Cash Flows
(In thousands)

	Years Ended December 31,		
	2015	2014	2013
CASH FLOW FROM OPERATING ACTIVITIES			
Net loss	$ (88,929)	$ (60,542)	$ (46,090)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,009	827	671
Gain on sale of assets, net	(3,334)	(3,222)	(3,170)
Cease-use expense	(85)	—	—
Deferred revenues	10,231	—	(2,919)
Deferred rent	(16)	14	142
Amortization of premiums on investments	6,032	3,792	2,843
Non-cash share-based compensation expense	28,392	10,382	6,819
Change in operating assets and liabilities:			
Accounts receivable and other assets	(489)	(1,671)	13,528
Cease-use liability	(610)	(418)	(590)
Other liabilities	(39)	—	108
Accounts payable and accrued liabilities	9,841	3,698	(949)
Net cash used in operating activities	(37,997)	(47,140)	(29,607)
CASH FLOW FROM INVESTING ACTIVITIES			
Purchases of investments	(449,052)	(257,544)	(145,328)
Sales/maturities of investments	255,123	154,133	151,281
Deposits and restricted cash	40	(388)	(108)
Proceeds from sales of property and equipment	9	45	40
Purchases of property and equipment	(1,934)	(1,612)	(545)
Net cash (used in) provided by investing activities	(195,814)	(105,366)	5,340
CASH FLOW FROM FINANCING ACTIVITIES			
Issuance of common stock	276,992	138,731	5,302
Net cash provided by financing activities	276,992	138,731	5,302
Net change in cash and cash equivalents	43,181	(13,775)	(18,965)
Cash and cash equivalents at beginning of the year	31,014	44,789	63,754
Cash and cash equivalents at end of the year	$ 74,195	$ 31,014	$ 44,789
SUPPLEMENTAL DISCLOSURES			
Taxes paid	$ —	$ —	$ —

See accompanying notes.

NEUROCRINE BIOSCIENCES, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2015

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 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 was inactive for all periods presented. The Company also has two wholly-owned Irish subsidiaries, Neurocrine Therapeutics, Ltd. and Neurocrine Europe, Ltd. which were formed in December 2014, both of which are inactive.

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. 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. Collaborative R&D agreements accounted for all of the Company's revenue for all periods presented.

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.

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 ratably over the performance period once the pre-defined performance based criteria for vesting becomes probable.

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,		
	2015	2014	2013
Interest income	$1,928	$ 629	$ 400
Realized gains, net	—	—	2
Total	$1,928	$ 629	$ 402

Net Loss Per Share. The Company computes basic net loss 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.

Due to the Company's net loss position in 2015, 2014 and 2013, approximately 4.1 million, 2.9 million and 2.1 million, respectively, of common share equivalents were excluded from the diluted common shares outstanding. For the years ended December 31, 2015, 2014 and 2013, there were employee stock options, calculated on a weighted average basis, to purchase 0.1 million, 1.0 million, and 0.3 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, which outlines a comprehensive revenue recognition model and supersedes most current revenue recognition guidance. The new standard requires a company to recognize revenue upon transfer of goods or services to a customer at an amount that reflects the expected consideration to be received in exchange for those goods or services. The amended guidance defines a five-step approach for recognizing revenue, which may require a company to use more judgment and make more estimates than under the current guidance. The amended guidance as currently issued will be effective for the Company starting in 2018. The new standard allows for two methods of adoption: (a) full retrospective adoption, meaning the standard is applied to all periods presented, or (b) modified retrospective adoption, meaning the cumulative effect of applying the new standard is recognized as an adjustment to the opening retained earnings balance. The Company is in the process of determining the adoption method it will implement, as well as the effects the adoption will have on its consolidated financial statements.

In November 2015, the FASB issued an ASU, "Income Taxes: Balance Sheet Classification of Deferred Taxes," which ASU eliminates the current requirement for organizations to present deferred tax assets and liabilities as current and noncurrent in a classified balance sheet. Instead, organizations will be required to classify all deferred tax assets and liabilities as noncurrent. This ASU applies to all organizations that present a classified balance sheet. The ASU is effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. The Company has adopted this standard as of December 31, 2015 with retroactive application.

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

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

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

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

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

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

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

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

Prior to the revised multiple element guidance described above, adopted by the Company on January 1, 2011, upfront, nonrefundable payments for license fees, grants, and advance payments for sponsored research revenues received in excess of amounts earned were classified as deferred revenue and recognized as income over the contract or development period. Revenues from development milestones are accounted for in accordance with the Revenue Recognition – Milestone Method Topic of the FASB ASC (Milestone Method). Milestones are recognized when earned, as evidenced by written acknowledgment from the collaborator or other persuasive evidence that the milestone has been achieved, provided that the milestone event is substantive. A milestone event is considered to be substantive if its achievability was not reasonably assured at the inception of the agreement and the Company's efforts led to the achievement of the milestone or the milestone was due upon the occurrence of a specific outcome resulting from the Company's performance. The Company assesses whether a milestone is substantive at the inception of each agreement.

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

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

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

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

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

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

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

AbbVie Inc. (*AbbVie)*. In June 2010, the Company announced an exclusive worldwide collaboration with AbbVie, to develop and commercialize elagolix and all next-generation 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, of which $30 million has been received to date, 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. As of December 31, 2015, $500 million remains outstanding in future event based payments under the agreement as the performance is based solely on AbbVie. 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 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. 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. There was no revenue recognized in 2015, 2014 or 2013 related to this collaboration.

NOTE 3. INVESTMENTS

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

Investments at December 31, 2015 and 2014 consisted of the following (in thousands):

	Years Ended December 31,	
	2015	2014
Certificates of deposit	$ 10,078	$ 17,438
Commercial paper	23,955	7,498
Corporate debt securities	323,219	174,323
Securities of government-sponsored entities	30,232	1,028
Total investments	$ 387,484	$ 200,287

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

	Contractual Maturity (in years)	Amortized Cost	Gross Unrealized Gains(1)	Gross Unrealized Losses(1)	Aggregate Estimated Fair Value
December 31, 2015:					
Classified as current assets:					
Certificates of deposit	Less than 1	$ 9,120	$ 1	$ (1)	$ 9,120
Commercial paper	Less than 1	23,965	1	(11)	23,955
Corporate debt securities	Less than 1	254,592	1	(414)	254,179
Securities of government-sponsored entities	Less than 1	17,762	1	(21)	17,742
Total short-term available-for-sale securities		$305,439	$ 4	$ (447)	$304,996
Classified as non-current assets:					
Certificates of deposit	1 to 2	$ 960	$ —	$ (2)	$ 958
Corporate debt securities	1 to 2	69,528	—	(488)	69,040
Securities of government-sponsored entities	1 to 2	12,534	—	(44)	12,490
Total long-term available-for-sale securities		$ 83,022	$ —	$ (534)	$ 82,488
December 31, 2014:					
Classified as current assets:					
Certificates of deposit	Less than 1	$ 9,072	$ —	$ (6)	$ 9,066
Commercial paper	Less than 1	7,497	1	—	7,498
Corporate debt securities	Less than 1	145,321	5	(123)	145,203
Securities of government-sponsored entities	Less than 1	1,029	—	(1)	1,028
Total short-term available-for-sale securities		$162,919	$ 6	$ (130)	$162,795
Classified as non-current assets:					
Certificates of deposit	1 to 2	$ 8,400	$ —	$ (28)	$ 8,372
Corporate debt securities	1 to 2	29,245	—	(125)	29,120
Total long-term available-for-sale securities		$ 37,645	$ —	$ (153)	$ 37,492

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

The following table presents gross unrealized losses and fair value for those available-for-sale investments that were in an unrealized loss position as of December 31, 2015 and 2014, aggregated by investment category and length of time that individual securities have been in a continuous 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, 2015:						
Certificates of deposit	$ 5,517	$ (3)	$ —	$ —	$ 5,517	$ (3)
Commercial paper	16,959	(11)	—	—	16,959	(11)
Corporate debt securities	310,160	(880)	5,521	(22)	315,681	(902)
Securities of government-sponsored entities	25,913	(65)	—	—	25,913	(65)
Total	$358,549	$ (959)	$ 5,521	$ (22)	$364,070	$ (981)
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)

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, 2015 and 2014.

The Company's assets which are measured at fair value on a recurring basis as of December 31, 2015 and 2014 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, 2015:				
Classified as current assets:				
Cash and money market funds	$ 69.5	$ 69.5	$ —	$ —
Certificates of deposit	9.1	9.1	—	—
Commercial paper	24.0	—	24.0	—
Securities of government-sponsored entities	17.7	—	17.7	—
Corporate debt securities	259.0	—	259.0	—
Subtotal	379.3	78.6	300.7	—
Classified as long-term assets:				
Certificates of deposit	5.7	5.7	—	—
Securities of government-sponsored entities	12.5	—	12.5	—
Corporate debt securities	69.0	—	69.0	—
Total	466.5	84.3	382.2	—
Less cash, cash equivalents and restricted cash	(79.0)	(74.2)	(4.8)	—
Total investments	$ 387.5	$ 10.1	$ 377.4	$ —
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	$ —

NOTE 5. PROPERTY AND EQUIPMENT

Property and equipment, net, at December 31, 2015 and 2014 consisted of the following (in thousands):

	2015	2014
Tenant improvements	1,335	1,226
Furniture and fixtures	837	819
Equipment	28,121	29,208
	30,293	31,253
Less accumulated depreciation	(26,861)	(28,746)
Property and equipment, net	$ 3,432	$ 2,507

For each of the years ended December 31, 2015, 2014 and 2013, depreciation expense was $1.0 million, $0.8 million and $0.7 million, respectively. During 2015, 2014 and 2013, the Company recognized a gain/(loss) of approximately $9,000, ($4,000) and $37,000, respectively, related to disposal of capital equipment.

NOTE 6. ACCRUED LIABILITIES

Accrued liabilities at December 31, 2015 and 2014 consisted of the following (in thousands):

	2015	2014
Accrued employee related costs	$ 7,358	$ 6,520
Accrued development costs	7,359	1,706
Other accrued liabilities	4,317	3,282
	$19,034	$11,508

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) 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, 2015, 2014 and 2013, the Company recognized $3.3 million, $3.2 million and $3.1 million, respectively, of the deferred gain and will recognize the remaining $14.3 million of the deferred gain over the initial Lease term which will expire at the end of 2019.

Under the terms of the Lease and the Amendments, the Company pays base annual rent (subject to an annual fixed percentage increase), plus a 3.5% annual management fee, property taxes and other normal and necessary expenses associated with the Lease such as utilities, repairs and maintenance. In lieu of a cash security deposit under the Lease, Wells Fargo Bank, N.A. issued on the Company’s behalf a letter of credit in the amount of $4.6 million, which is secured by a deposit of equal amount with the same bank. The Company also has the right to extend the Lease for two consecutive ten-year terms.

As of December 31, 2015, the Company has two sublease agreements for approximately 30,000 square feet of the Rear Building. These subleases are expected to result in approximately $1.1 million of rental income in 2016 with this sublease rental income being recorded as an offset to rent expense. The income generated under

these subleases is lower than the Company's financial obligation under the Lease for the Rear Building, as determined on a per square foot basis. Consequently, at the inception of such a sublease, or in association with an amendment to such sublease, the Company is required to record a cease-use liability for the net present value of the estimated difference between the expected income to be generated under the subleases and future subleases and the Lease obligation over the remaining term of the Lease for the space that is occupied by the subtenant. The subleases provide various options to extend for additional one-year renewal periods. The current terms each of these two subleases expire in February 2017 and March 2018.

The following table sets forth changes to the accrued cease-use liability during 2015 and 2014 (in thousands):

	Years Ended December 31,	
	2015	2014
Beginning balance	$2,678	$3,096
Change in estimate	(85)	—
Payments	(610)	(418)
Ending balance	$1,983	$2,678

Rent Expense. Gross rent expense was $5.9 million for each of the years ended December 31, 2015, 2014 and 2013, 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.

As of December 31, 2015, the total estimated future annual minimum lease payments under the Company's non-cancelable building lease for the years ending after December 31, 2015 were as follows (in thousands):

	Payment Amount
2016	$ 7,606
2017	7,834
2018	8,070
2019	8,311
2020 and thereafter	—
Total future minimum lease payments	$ 31,821

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. On December 1, 2015, Icahn School of Medicine at Mount Sinai (Mount Sinai) filed a complaint against the Company in the United States District Court for the Southern District of New York: *Icahn School of Medicine at Mount Sinai v. Neurocrine Biosciences, Inc.*, Case No. 1:15-cv-09414. In the complaint, Mount Sinai alleges that the Company, by entering into an exclusive worldwide collaboration with AbbVie to develop and commercialize next-generation gonadotropin-releasing hormone antagonists, breached its license agreement with Mount Sinai dated August 27, 1999. Mount Sinai is seeking unspecified monetary damages, future sublicensing fees and attorney's fees. The Company believes that it has meritorious defenses to the claims made in the complaint and intend to vigorously defend itself against such claims, but is not able to predict the ultimate outcome of this action.

The Company is not aware of any other 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 13.5 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 2015 and 2014, 120,000 and 160,000 stock options, respectively, and during 2015 50,000 RSUs were granted pursuant to such inducement plan. These stock option grants have a four year vesting period and the RSUs have a three year cliff vesting. The Company currently has approximately 0.3 million in stock options and RSUs outstanding under this inducement plan.

As of December 31, 2015, approximately 6.2 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 12.8 million shares of common stock reserved for such issuance as of December 31, 2015.

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 for all share-based compensation arrangements is as follows (in thousands):

	Years Ended December 31,		
	2015	2014	2013
General and administrative expense	$15,281	$ 5,167	$3,516
Research and development expense	13,111	5,215	3,303
Share-based compensation expense	$28,392	$10,382	$6,819

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, 2015, 2014 and 2013 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, 2015:

	Years Ended December 31,		
	2015	2014	2013
Risk-free interest rate	1.7%	2.2%	1.4%
Expected volatility of common stock	66%	71%	76%
Dividend yield	0.0%	0.0%	0.0%
Expected option term	6.6 years	7.2 years	7.3 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. 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 2015 based on historical experience. Pre-vesting forfeitures for awards with annual vesting terms were also estimated at 0% in 2015 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, 2015, 2014 and 2013, estimated as of the grant date using the Black-Scholes option valuation model, were $23.24, $12.57 and $6.55, respectively.

A summary of the status of the Company's stock options as of December 31, 2015, 2014 and 2013 and of changes in options outstanding under the plans during the three years ended December 31, 2015 is as follows (in thousands, except for weighted average exercise price data):

	2015		2014		2013	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding at January 1	5,750	$ 9.31	5,853	$ 7.54	6,166	$ 7.62
Granted	1,159	37.21	1,089	18.41	771	9.24
Exercised	(1,315)	5.01	(1,135)	6.50	(904)	5.96
Canceled	(87)	46.08	(57)	56.83	(180)	25.68
Outstanding at December 31	5,507	$ 15.63	5,750	$ 9.31	5,853	$ 7.54

Options outstanding at December 31, 2015 have a weighted average remaining contractual term of 6.8 years.

For the year ended December 31, 2015, share-based compensation expense related to stock options was $13.6 million. As of December 31, 2015, there was approximately $28.0 million of unamortized compensation cost related to stock options, which is expected to be recognized over a weighted average remaining vesting period of approximately 2.6 years. As of December 31, 2015, there were approximately 3.8 million options exercisable with a weighted average exercise price of $10.44 and a weighted-average remaining contractual term of 6.1 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, 2015, 2014, and 2013 was $43.6 million, $14.3 million and $6.0 million, respectively. As of December 31, 2015, the total intrinsic value of options outstanding and exercisable was $225.4 million and $177.0 million, respectively. Cash received from stock option exercises for the years ended December 31, 2015, 2014 and 2013 was $6.3 million, $5.6 million and $5.3 million, respectively.

Restricted Stock Units. 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 2015. The effect of past restructurings has been excluded from the historical review of employee turnover. For the year ended December 31, 2015, 2014 and 2013, share-based compensation expense related to RSUs was $6.0 million, $2.6 million, and $0.8 million, respectively. As of December 31, 2015, there was approximately $16.2 million of unamortized compensation cost related to RSUs, which is expected to be recognized over a weighted average remaining vesting period of approximately 2.7 years.

The total intrinsic value of RSUs converted into common shares during the years ended December 31, 2015, 2014 and 2013 was $5.7 million, $1.7 million, and $0, 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, 2015 was $51.5 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, 2015, 2014 and 2013 and of changes in RSUs outstanding under the plans for the three years ended December 31, 2015 is as follows (in thousands, except for weighted average grant date fair value per unit):

	2015		2014		2013	
	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
Outstanding at January 1	669	$ 15.01	373	$ 8.65	—	$ —
Granted	448	33.62	389	19.59	379	8.65
Cancelled	(16)	20.83	—	—	(6)	8.65
Converted into common shares	(191)	14.24	(93)	8.65	—	—
Outstanding at December 31	910	$ 24.23	669	$ 15.01	373	$ 8.65

Performance-Based Restricted Stock Units. During the years ended December 31, 2015 and 2014, the Company granted 50,000 and 475,000 PRSUs, respectively, that vest based on the achievement of certain pre-defined Company-specific performance criteria and expire approximately five years from the grant date. Because the performance based criteria for vesting for the PRSUs was not immediately probable, no associated expense was recorded for the PRSUs during the year ended December 31, 2014. During 2015, the Company recognized approximately $8.8 million in expense related to PRSUs as it became probable that the pre-defined performance conditions would be met mainly due to the Phase III results of the Kinect 3 clinical study. At December 31, 2015, the total unrecognized estimated compensation expense related to these PRSUs was $2.2 million and will be recognized ratably over the remaining expected performance period. The total intrinsic value of PRSUs converted into common shares during the year ended December 31, 2015 was $14.9 million. The total intrinsic value of PRSUs outstanding at December 31, 2015 was $12.0 million based on the Company's closing stock price on that date.

NOTE 9. STOCKHOLDERS' EQUITY

Equity Financing

In February 2015, the Company completed a public offering of common stock in which the Company sold approximately 8.0 million shares of its common stock at an offering price of $36.00 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 $270.7 million.

In February 2014, the Company completed a public offering of common stock in which the Company sold 8.0 million shares of its common stock at an offering price of $17.75 per share. The shares were sold pursuant to a shelf registration statement previously filed with the SEC. The net proceeds generated from this transaction, after underwriting discounts and commissions and offering costs, were approximately $133.2 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, 2015, the Company had sold approximately 16.0 million shares of its common stock under this shelf registration statement.

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, 2015 or December 31, 2014, and has not recognized interest and/or penalties in the statement of comprehensive loss for the year ended December 31, 2015.

The Company is subject to taxation in the United States and various state jurisdictions. The Company's tax years for 1998 (federal)/2002 (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, 2015, the Company had deferred tax assets of $382.4 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 R&D 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, 2015.

At December 31, 2015, the Company had Federal and California income tax net operating loss carry forwards of approximately $736.0 million and $567.3 million, respectively. The Federal tax loss carry forwards will begin to expire in 2021, unless previously utilized.

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

Year	Amount
2016	116,600
2017	51,900
2018	140,600
2028 and beyond	258,100

In addition, the Company has Federal and California R&D tax credit carry forwards of $38.2 million and $27.2 million, respectively. The Federal R&D tax credit carry forwards begin expiring in 2018 and will continue to expire unless utilized. The California R&D tax credit carryforwards carry forward indefinitely. The Company also has Federal Alternative Minimum Tax credit carryforwards of approximately $213,000, which will carry forward indefinitely. At December 31, 2015, approximately $77.0 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, 2015 and 2014 are listed below. A valuation allowance of $382.4 million and $367.1 million at December 31, 2015 and 2014, 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):

	2015	2014
Deferred tax assets:		
Net operating losses	$ 257,900	$ 260,600
Research and development credits	33,500	29,000
Capitalized research and development	58,900	45,700
Share-based compensation expense	10,900	6,900
Deferred revenue	4,300	800
Deferred gain on sales leaseback	5,000	7,200
Intangibles	6,900	10,600
Cease-use expense	700	1,100
Fixed assets	400	500
Other	3,900	4,700
Total deferred tax assets	382,400	367,100
Valuation allowance	(382,400)	(367,100)
Net deferred tax assets	$ —	$ —

The provision for income taxes on earnings subject to income taxes differs from the statutory Federal rate at December 31, 2015, 2014 and 2013, due to the following (in thousands):

	2015	2014	2013
Federal income taxes at 35%	$(31,126)	$(21,190)	$(16,131)
State income tax, net of Federal benefit	2	(3,410)	(2,611)
Tax effect on non-deductible expenses	172	10	7
Share-based compensation expense	201	91	215
Change in tax rate	10,773	—	—
Expired tax attributes	5,594	315	151
Research credits	(6,638)	(1,882)	(3,458)
Change in valuation allowance	15,029	25,366	20,504
Uncertain tax positions	5,940	621	1,283
Other	53	79	40
	$ —	$ —	$ —

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

	2015	2014	2013
Balance as of the beginning of the year	$23,854	$23,131	$21,672
Increases related to prior year tax positions	6,636	47	543
Increases related to current year tax positions	2,584	676	916
Expiration of the statute of limitations for the assessment of taxes	—	—	—
Balance as of the end of the year	$33,074	$23,854	$23,131

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 $6.6 and $2.6 million for prior year tax positions and current year tax positions, respectively, as reflected in the tabular rollforward above.

As of December 31, 2015, the Company had $26.2 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 $0.4 million, $0.3 million and $0.3 million for the years ended December 31, 2015, 2014 and 2013, respectively.

NOTE 12. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

The following is a summary of the quarterly results of the Company for the years ended December 31, 2015 and 2014 *(unaudited, in thousands, except for per share data)*:

	Year Ended December 31,				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Year Ended December 31
2015:					
Revenues	$ 19,769	$ —	$ —	$ —	$ 19,769
Operating expenses	22,057	25,322	35,844	30,748	113,971
Net loss	(1,192)	(23,987)	(34,435)	(29,315)	(88,929)
Net loss per share:					
Basic and Diluted	$ (0.01)	$ (0.28)	$ (0.40)	$ (0.34)	$ (1.05)
Shares used in the calculation of net loss per share:					
Basic and Diluted	80,349	85,518	85,856	86,184	84,496
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

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.

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, 2015. 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, 2015, 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.

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, 2015, 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, 2015, 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, 2015 and 2014, and the related consolidated statements of comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2015 of Neurocrine Biosciences, Inc. and our report dated February 11, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 11, 2016

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

None.

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 2016 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2015. 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 2016 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2015. 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 2016 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2015. 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 2016 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2015. 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 2016 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2015. Such information is incorporated herein by reference.

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, 2015 and 2014

Consolidated Statements of Comprehensive Loss for the years ended December 31, 2015, 2014 and 2013

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2015, 2014 and 2013

Consolidated Statements of Cash Flows for the years ended December 31, 2015, 2014 and 2013

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(11)
3.2	Certificate of Amendment to Certificate of Incorporation(11)
3.3	Bylaws, as amended(11)
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.(8)
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.(13)
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.(9)
10.8**	Amended and Restated Employment Agreement effective August 1, 2007 between the Company and Timothy P. Coughlin.(3)
10.9**	Amended and Restated Employment Agreement effective August 6, 2007 between the Company and Christopher F. O'Brien M.D.(6)

Exhibit Number	Description
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.(12)
10.13*	Collaboration Agreement dated June 15, 2010, by and between Abbott International Luxembourg S.a.r.l. and the Company as amended on August 31, 2011.
10.14**	Form of Amendment to Employment Agreement for executive officers.(10)
10.15**	Neurocrine Biosciences, Inc. Inducement Plan, as amended, Form of Stock Option Grant Notice and Option Agreement for use thereunder.(2)
10.16	Collaboration and License Agreement dated March 31, 2015 between Mitsubishi Tanabe Pharma Corporation and the Company.(14)
10.17	First Amendment to Collaboration and License Agreement Dated August 31, 2011 between the Company and Abbott International Luxemburg S.a.r.l.(15)
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 July 29, 2015
(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 Current Report on Form 8-K filed on January 18, 2012
(9) Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed on July 26, 2013
(10) Incorporated by reference to the Company's Annual Report on Form 10-K filed on February 10, 2011
(11) Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K dated October 2, 2015, and Exhibits 3.1, 3.2 and 3.3 to the Company's Annual Report on From 10-K filed on February 8, 2013

(12) Incorporated by reference to the Company's Current Report on Form 8-K filed on June 1, 2015
(13) Incorporated by reference to the Company's Annual Report on Form 10-K filed on February 9, 2015
(14) Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed on April 30, 2015
(15) Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed on October 31, 2011.
* 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 11, 2016

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 Kevin C. Gorman	President, Chief Executive Officer and Director (Principal Executive Officer)	February 11, 2016
/s/ Timothy P. Coughlin Timothy P. Coughlin	Chief Financial Officer (Principal Financial and Accounting Officer)	February 11, 2016
/s/ William H. Rastetter William H. Rastetter	Chairman of the Board of Directors	February 11, 2016
/s/ Gary A. Lyons Gary A. Lyons	Director	February 11, 2016
/s/ W. Thomas Mitchell W. Thomas Mitchell	Director	February 11, 2016
/s/ Joseph A. Mollica Joseph A. Mollica	Director	February 11, 2016
/s/ George J. Morrow George J. Morrow	Director	February 11, 2016
/s/ Corinne H. Nevinny Corinne H. Nevinny	Director	February 11, 2016
/s/ Richard F. Pops Richard F. Pops	Director	February 11, 2016
/s/ Alfred W. Sandrock, Jr. Alfred W. Sandrock, Jr.	Director	February 11, 2016
/s/ Stephen A. Sherwin Stephen A. Sherwin	Director	February 11, 2016

Exhibit 10.13

*****Text Omitted and Filed Separately with the Securities and Exchange Commission. Confidential Treatment Requested Under 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2**

COLLABORATION AGREEMENT

dated June 15, 2010

by and between

Abbott International Luxembourg S.à r.l.

and

Neurocrine Biosciences, Inc.

EXHIBIT INDEX

A – *Elagolix*

B – Follow-on Compounds

C – Neurocrine Patent Rights

D – Third Party Development Contracts

E – Third Party Manufacturing Contracts

F – Transition Plan

G – Collaborative Development Plan

H – Alternative Dispute Resolution

I – Press Release

COLLABORATION AGREEMENT

COLLABORATION AND LICENSE AGREEMENT (the "***Agreement***") dated as of June 15, 2010 ("***Effective Date***") by and between Abbott International Luxembourg S.à r.l., a corporation organized and existing under the laws of Luxembourg, with offices at 26, Boulevard Royal, L-2449 Luxembourg ("***Abbott***") and Neurocrine Biosciences, Inc., a corporation organized and existing under the laws of Delaware with offices at 12780 El Camino Real, San Diego, California 92130 ("***Neurocrine***").

WHEREAS, Neurocrine has a proprietary research and development program in the field of Non-peptide GnRH Antagonists (as defined below) and in connection therewith has identified proprietary drug candidates for development and commercialization.

WHEREAS, Abbott is engaged in research, development and commercialization of pharmaceuticals and would like to collaborate with Neurocrine in the field of Non-peptide GnRH Antagonists.

WHEREAS, the Parties would like to set forth the terms and conditions pursuant to which the Parties will collaborate in connection with the research, development and commercialization of Products in the Territory (as both terms are defined below), and with respect to certain other matters as described herein.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, the Parties agree as follows:

ARTICLE ONE - DEFINITIONS

Capitalized terms not otherwise defined herein will have the definitions set forth below.

1.1 **"Abbott Patent Rights"** means the Patent Rights covering Abbott Technology.

1.2 **"Abbott Quarter"** means the calendar quarters ending March 31, June 30, September 30 and December 31 each year.

1.3 **"Abbott Technology"** means Technology reasonably necessary or directly useful to research, develop, make, have made, use, sell, offer for sale, import and/or otherwise exploit Compounds and Products in the Field of Use, including synthetic processes to manufacture Compounds and all related chemical and biological data: (i) Controlled by Abbott during the Term but, excluding Program Technology, and is actually utilized by Abbott, in Abbott's sole discretion, in the Development or Commercialization of Compounds or Products.

1.4 **"Abbott Year"** means the twelve (12) month period commencing on January 1 of any calendar year.

1.5 **"**[…***…]**"** means […***…].

1.6 **"Affiliate"** means any entity directly or indirectly controlled by, controlling, able to control, or under common control with, a Party to this Agreement, but only for so long as such control shall continue. For purposes of this definition, "control" (including, with correlative meanings, "controlled by", "controlling" and "under common control with") means possession, direct or indirect, of (a) the power to direct or cause direction of the management and policies of an entity

(whether through ownership of securities or partnership or other ownership interests, by contract or otherwise), or (b) at least fifty percent (50%) of the voting securities (whether directly or pursuant to any option, warrant or other similar arrangement) or other comparable equity interests. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity. Neither of the Parties to this Agreement shall be deemed to be an "Affiliate" of the other solely as a result of their entering into this Agreement.

1.7 **"Assigned Third Party Development Contracts"** means those contracts set forth on Exhibit D assigned to Abbott as set forth in Section 6.5 (*Assignment of Third Party Development Contracts*).

1.8 **"Assigned Third Party Manufacturing Contracts"** means those contracts set forth on Exhibit E assigned to Abbott as set forth in Section 6.6 (*Assignment of Third Party Manufacturing Contracts*).

1.9 **"Bankruptcy Code"** means 11 U.S.C. §§ 101-1532, as amended.

1.10 **"**[…***…]**"** means […***…].

1.11 **"Change of Control"** means (i) a merger, consolidation or reorganization of Neurocrine with a Third Party which results in the voting securities of Neurocrine outstanding immediately prior thereto ceasing to represent more than fifty percent (50%) of the voting power of the then combined entity, (ii) a Third Party(ies) becoming the beneficial owner(s) of more than fifty percent (50%) of the combined voting power of the outstanding securities of Neurocrine or (iii) the sale or transfer to a Third Party of all or substantially all of the assets of Neurocrine. Notwithstanding the foregoing, the merger, consolidation or reorganization of Neurocrine with another entity in which […***…] is the surviving entity and with respect to which […***…], will not constitute a Change of Control.

1.12 **"Collaboration"** means the collaboration between Neurocrine and Abbott related to the Transition Program and Collaborative Development Program.

1.13 **"Collaborative Development Program"** means the collaborative development program to be conducted by Abbott and Neurocrine as set forth in Article Seven, as further described in the Collaborative Development Plan.

1.14 **"Collaborative Development Plan"** means the plan describing the overall plan, budget, goals and activities to be undertaken by the Parties in the Collaborative Development Program, as agreed to by the Parties in writing concurrently with the execution of this Agreement and set forth on Exhibit G, and as may be updated from time to time pursuant to Section 7.2(b) (*Collaborative Development Plan and Budget, Amendments*).

1.15 **"Combination Product(s)"** means any product which contains, in addition to a Product, one or more other therapeutically active ingredients that are proprietary to Abbott and not within the scope of the Neurocrine Patent Rights and/or Program Patent Rights.

1.16 **"Commercialization"** or **"Commercialize"** means any and all activities directed to the offering for sale and sale of a Product, after Regulatory Approval has been obtained, including activities related to marketing, promoting, distributing, importing, selling and offering to sell Product and/or conducting post-marketing human clinical studies with respect to any Indication with respect to

which Regulatory Approval has been received or for a use that is subject of an investigator-initiated study program, and interacting with Regulatory Authorities regarding the foregoing. When used as a verb, "to Commercialize" and "Commercializing" means to engage in Commercialization and "Commercialized" has a corresponding meaning.

1.17 **"Commercially Reasonable Efforts"** means with respect to activities of a Party in the discovery, Development or the Commercialization of a particular Product, the efforts and resources typically used by that Party in the development of product candidates or the commercialization of products of comparable market potential taking into account all relevant factors including, as applicable and without limitations, stage of development, mechanism of action, efficacy and safety relative to competitive products in the marketplace, actual or anticipated labeling, the nature and extent of market exclusivity (including patent coverage and regulatory exclusivity), cost, actual or projected profitability (provided […***…]) and likelihood of obtaining marketing approval. Commercially Reasonable Efforts will be determined on a market-by-market and indication-by-indication basis, and it is anticipated that the level of effort will be different for different markets and will change over time reflecting changes in the status of the Product and the markets involved.

1.18 **"Compound(s)"** means (a) *Elagolix*, (b) the Follow-on Compounds, (c) all complexes, mixtures or other combinations, prodrugs, esters, metabolites, solvates, enantiomers, salt forms, polymorphs, racemates and stereoisomers of the foregoing; and (d) all derivatives of the foregoing containing one or more atoms substituted with an isotope.

1.19 **"Confidential Information"** means with respect to each Party, all materials, trade secrets or other information or data in connection with and pursuant to this Agreement, including without limitation, any data, proprietary information and materials (whether or not patentable, or protectable as a trade secret) regarding a Party's Technology, products, business information or objectives, which is disclosed orally, visually in writing or other form by a Party to the other Party. Confidential Information does not include such materials, trade secrets or other information or data which the receiving Party can demonstrate by competent evidence:

a) was known by the receiving Party or its Affiliates or Sublicensees prior to its date of disclosure to the receiving Party; or

b) is in the public domain by use and/or publication before its receipt from the disclosing Party or thereafter enters the public domain through no fault of the receiving Party or its Affiliates or Sublicensees; or

c) either before or after the date of the disclosure to the receiving Party or its Affiliates or Sublicensees is lawfully disclosed to the receiving Party by a Third Party(ies) not in violation of any obligation to the disclosing Party; or

d) is independently developed by or for the receiving Party or its Affiliates or Sublicensees without reference to` or reliance upon the Confidential Information.

All confidential information disclosed prior to the Effective Date by one Party to the other Party under or pursuant to the confidentiality agreements between the Parties dated […***…], that is not excluded by subsections (a)-(d) above shall be deemed "Confidential Information" of the disclosing Party.

1.20 **"Control"** or **"Controlled"** means with respect to Technology or Patent Rights, ownership by the applicable Party or possession (whether by license, covenant not to sue or otherwise) of the ability

to grant licenses, sublicenses or access, other than pursuant to this Agreement, without […***…] the violation of the terms of any agreement or other arrangement with, or rights of, any Third Party existing on or after the Effective Date and during the Term.

1.21 **"Default"** means with respect to a Party that (i) any representation or warranty of such Party set forth herein shall have been untrue in any material respect when made or (ii) such Party shall have failed to perform any material obligation set forth in this Agreement.

1.22 **"Development"** or **"Develop"** means, with respect to each Product, all non-clinical and clinical activities designed to obtain Regulatory Approval of such Product in accordance with this Agreement up to and including the obtaining of Regulatory Approval of such Product, including regulatory toxicology studies, statistical analysis and report writing, clinical trial design and operations, preparing and filing Regulatory Filings, and all regulatory affairs related to the foregoing. When used as a verb, "Developing" means to engage in Development and "Developed" has a corresponding meaning.

1.23 **"Diagnostic Use"** means use solely for diagnosis, prediction, detection or imaging of any disease, disorder, state, or condition where: the Product (i) is packaged, labeled and sold solely for diagnosis, prediction, detection or imaging of any disease, disorder, state or condition and (ii) does not on its own or in combination with another product(s) rely on the pharmacodynamic effect of a Non-peptide GnRH Antagonist for its use or application.

1.24 **"Effective Date"** means the date first written above.

1.25 **"*Elagolix*"** means the compound known as NBI-56418, as further described and set forth on Exhibit A.

1.26 **"EMA"** means European Medicines Agency or any successor agency(ies) or authority having substantially the same function.

1.27 **"End of Phase II Meeting(s)"** means the meeting(s) between the sponsor of an investigational drug and the FDA following completion of a key set of Phase II clinical studies in which it is determined whether it is safe to proceed to Phase III, Phase III program and protocols are evaluated and additional information necessary to support a marketing application for the uses under investigation are decided.

1.28 **"Endometriosis"** means the condition in which endometrial glands and stroma are present in a location outside of the uterus, including its signs and symptoms, which include, but are not limited to, pain associated with such condition.

1.29 **"FDA"** means the U.S. Food and Drug Administration of the United States Department of Health and Human Services or any successor agency(ies) or authority having substantially the same function.

1.30 **"Field of Use"** means all Therapeutic Uses and Diagnostic Uses.

1.31 **"First Commercial Sale"** means with respect to each Product granted Regulatory Approval for commercial sale by applicable Regulatory Authorities, the first transfer by Abbott, its Affiliates or Sublicensees of the Product to a Third Party in exchange for cash or some equivalent to which value can be assigned. A sale by Abbott to an Affiliate or Sublicensee will not constitute a First Commercial Sale unless the Affiliate or Sublicensee is the last entity in the distribution chain and

provided further that any sale on a cost reimbursement basis for use in a clinical trial will not constitute a First Commercial Sale.

1.32 **"Follow-on Compound"** means any of (i) […***…], and […***…] as set forth on Exhibit B (ii) and all non-peptide synthetic organic chemical compounds which are encompassed, generically or specifically, by (a) […***…].

1.33 **"Force Majeure"** means any occurrence beyond the reasonable control of a Party that prevents or substantially interferes with the performance by the Party of any of its obligations hereunder, if such occurs by reason of any act of God, flood, fire, explosion, earthquake, strike, lockout, labor dispute, casualty or accident; or war, revolution, civil commotion, acts of terrorism, acts of public enemies, blockage or embargo; or any injunction, Law, order, proclamation, regulation, ordinance, demand or requirement of any Governmental Authority; or breakdown of plant, inability to procure or use materials, labor, equipment, transportation, or energy sufficient to meet manufacturing needs without the necessity of allocation; or any other cause whatsoever, whether similar or dissimilar to those above enumerated, beyond the reasonable control of such Party, if and only if the Party affected shall have used reasonable efforts to avoid such occurrence and to remedy it promptly if it shall have occurred.

1.34 **"FTE"** means a full time equivalent Neurocrine employee consisting of a total of approximately […***…] hours per year of work in accordance with Neurocrine's time allocation practices (including normal vacations, sick-days and holidays for Neurocrine employees).

1.35 **"Generic Product(s)"** means any pharmaceutical product that (i) is sold by a Third Party that is not a licensee or Sublicensee of Abbott or its Affiliates, or any of their licensees or Sublicensees under a marketing authorization granted by a Regulatory Authority to such Third Party, and (ii) contains the same Compound as an active pharmaceutical ingredient as the relevant Product and (x) for purposes of the United States, is approved in reliance on the prior approval of a Product as determined by the FDA, or (y) for purposes of a country outside the United States, is approved in reliance on the prior approval of a Product as determined by the applicable Regulatory Authority. On a country by country basis, a Product licensed or produced by Abbott (e.g. an authorized generic product) will not constitute a Generic Product.

1.36 **"Generic Competition"** means, on a country by country and Product by Product basis, that the following conditions are met: (x) one or more Third Parties is selling a Generic Product in a country during […***…], and (y) the […***…] of such Generic Products sold in such country by the Third Party(ies) in such […***…] is […***…] sold in that country by Abbott, its Affiliates and Sublicensees. Unless otherwise agreed by the Parties, the […***…] of each Generic Product sold during […***…] shall be deemed to be the volume of sales of the Generic Product in such country in that […***…] as reported by IMS America Ltd. of Plymouth Meeting, Pennsylvania ("***IMS***") or any successor to IMS or any other independent sales auditing firm reasonably agreed upon by the Parties.

1.37 **"GnRH Receptor"** means […***…].

1.38 **"Governmental Authority"** means any court, agency, department, authority or other instrumentality of any national, state, county, city or other political subdivision.

1.39 **"IND"** means an investigational new drug application filed with the FDA pursuant to 21 CFR 312 or the foreign equivalent for authorization to commence human clinical trials of a product, including all supplements and amendments that may be filed with respect to the foregoing.

1.40 **"Indication"** means an individual, separate and distinct disease or clinical condition with respect to which at least one adequate and well controlled study is required to support inclusion of such disease or condition in the indication statement of a Regulatory Authority approved package insert for a Product. The Parties agree that: (i) prevention of a disease or medical condition shall not be a separate indication from treatment of the same disease or medical condition; (ii) the treatment and prevention of separate varieties of the same disease or medical condition shall not be a separate indication; and (iii) the treatment or prevention of the same disease or medical condition in a different population shall not be a separate indication (e.g., adult and pediatric) unless in each of (i)-(iii) above, at least one adequate and well controlled study is required to support inclusion of such disease or condition in the indication statement of a Regulatory Authority approved package insert for a Product. Furthermore, a label enhancement or elaboration or expansion of an approved Indication is not a separate Indication even if one or more studies are performed to receive such enhancement or elaboration.

1.41 **"Initiation"** means, with respect to a human clinical trial, dosing of the first subject in a Phase I, Phase II or Phase III clinical study, as applicable, pursuant to a clinical protocol of the specified clinical trial.

1.42 **"Invention"** means any information, composition of matter, or article of manufacture that is discovered, developed, generated, made, conceived and/or reduced to practice by or on behalf of a Party (or its Affiliate) through performance of activities conducted pursuant to the Collaboration. Inventorship of Inventions will be determined in accordance with United States patent laws and ownership shall be determined in accordance with this Agreement.

1.43 **"Law"** or **"Laws"** means all laws, statutes, rules, codes, regulations, orders, decrees, judgments and/or ordinances of any Governmental Authority.

1.44 **"MAA"** means a Marketing Authorization Application covering a Product filed with the EMA, required for marketing approval of a pharmaceutical product.

1.45 **"Major European Country"** means […***…].

1.46 **"Milestones"** means those payments to be made by Abbott to Neurocrine upon the occurrence of certain events as set forth in Article Four.

1.47 **"NDA"** means a New Drug Application covering a Product filed with the FDA pursuant to 21 CFR 314, required for marketing approval of a pharmaceutical product and/or a supplemental NDA (sNDA).

1.48 **"Net Sales"** means the total amount billed or invoiced on sales of Product by Abbott, its Affiliates and/or Sublicensees in the Territory to Third Parties (for example, wholesalers or distributors) in bona fide arm's length transactions, less the following deductions (specifically excluding any royalty payments made by Abbott, its Affiliates and/or Sublicensees to Licensor), in each case related specifically to the Product and actually allowed and taken by such Third Parties and not otherwise recovered by or reimbursed to Abbott, its Affiliates and/or Sublicensees:

a) trade, cash and quantity discounts;

b) price reductions or rebates, retroactive or otherwise, imposed by, negotiated with or otherwise paid to Governmental Authorities;

c) taxes on sales (such as sales, value added or use taxes) to the extent added to the sale price and set forth separately as such in the total amount invoiced;

d) freight, insurance and other transportation charges to the extent added to the sale price and set forth separately as such in the total amount invoiced, as well as any fees for services provided by wholesalers and warehousing chains related to the distribution of the Product;

e) amounts repaid or credited by reason of rejections, defects, one percent (1%) return goods allowance, recalls or returns, or because of retroactive price reductions, including, but not limited to, rebates or wholesaler charge backs;

f) the portion of administrative fees paid during the relevant time period to group purchasing organizations, pharmaceutical benefit managers and/or Medicare Prescription Drug Plans relating specifically to the Product; and

g) any consideration actually paid or payable for any Delivery System related to a billed or invoiced sale of a Product, where for purposes of this Net Sales definition, a "Delivery System" means any delivery system comprising equipment, instrumentation, one or more devices or other components designed to assist in the administration of a Product.

Net Sales shall include the amount or fair market value of all other consideration received by Abbott, its Affiliates and/or Sublicensees in respect of the Product, whether such consideration is in cash, payment in kind, exchange or other form. For purposes of determining Net Sales, Net Sales shall not include transfers or dispositions for charitable, promotional, pre-clinical, clinical, regulatory or governmental purposes. Net sales shall not include sales between or among Abbott, its Affiliates and/or Sublicensees.

Subject to the above, Net Sales shall be calculated in accordance with the standard internal policies and procedures of Abbott, its Affiliates and/or Sublicensees, which must be in accordance with generally accepted accounting principles ("***GAAP***").

For purposes of calculating Net Sales, all Net Sales shall be converted into United States Dollars using Abbott, its Affiliates and/or Sublicensees' standard conversion methodology consistent with GAAP. The standard conversion methodology is based on monthly averages (the spot rate at the end of the month immediately prior to the reporting month plus the spot rate at the end of the reporting month, divided by two) using open market rates.

In the event that a Product is sold in the form of a Combination Product, the Net Sales for such Combination Product will be […***…]:

a) […***…].

b) […***…].

c) […***…].

d) […***…].

1.49 **"Neurocrine Patent Rights"** means the Patent Rights covering Neurocrine Technology, as set forth on Exhibit C.

1.50 **"Neurocrine Technology"** means all Technology Controlled by Neurocrine: (i) on the Effective Date or during the Term, that is reasonably necessary or directly useful to research, develop, make, have made, use, sell, offer for sale, import and/or otherwise exploit Compounds (including Compounds contained in Product(s)) in the Field of Use, including synthetic processes to manufacture Compounds and all related chemical and biological data and/or (ii) on the Effective Date, that is reasonably necessary or directly useful to research, develop, make, have made, use, sell, offer for sale, import and/or otherwise exploit Products in the Field of Use that is not otherwise covered by (i). Neurocrine Technology will specifically not include Neurocrine's rights under the Receptor License.

1.51 **"Non-peptide GnRH Antagonists"** means […***…]. "Non-peptide GnRH Antagonists" excludes […***…].

1.52 **"Patent Rights"** means the rights and interest in and to all issued patents and pending patent applications in any country, including, all divisionals, continuations, renewals, continuations-in-part, patents of addition, substitutions, reexaminations, supplementary protection certificates and the like, extensions, registration or confirmation patents and reissues thereof.

1.53 **"Phase I"** means a human clinical trial in any country of a product in any country, the principal purpose of which is a preliminary determination of safety or pharmacokinetics in healthy individuals or patients or similar clinical study prescribed by the Regulatory Authorities, from time to time, pursuant to applicable law or otherwise, including for example the trials referred to in 21 C.F.R. §312.21(a).

1.54 **"Phase II"** means a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(b) conducted to study the effectiveness and establish the dose range of a Product for a particular Indication in patients with the disease or condition under study, including Phase IIa studies.

1.55 "**Phase IIb**" means a Phase II study in any country, the principal purpose of which is to explore the dose relationship of a Product against some efficacy measure for the Indication in patients with the disease or Indication under study.

1.56 **"Phase III"** means an expanded human clinical study in any country on a sufficient number of subjects that is designated to establish that such product is safe and efficacious for its intended use, and to determine warnings, precautions, and adverse reactions, if any, that are associated with such product in the dosage range to be prescribed, which trial is designed to result in Regulatory Approval of such product, including all tests, studies, or a similar clinical study prescribed by the Regulatory Authorities, from time to time, pursuant to applicable law or otherwise, including for example the trials referred to in 21 C.F.R.§312.21(c).

1.57 **"PMDA"** means Japan's Pharmaceuticals and Medical Devices Agency or any successor agency(ies) or authority having substantially the same function.

1.58 **"Product(s)"** means a product or product candidate that contains one or more Compounds, including all formulations and dosages of such Compound, all processes and delivery systems that incorporate such Compound, and any Combination Product. For the purposes of this Agreement, […***…] will constitute a single Product.

1.59 **"Program Patent Rights"** means the Patent Rights covering the Program Technology.

1.60 **"Program Technology"** means any and all Technology conceived, reduced to practice, made or developed, […***…], by employees of […***…] and/or others acting on behalf of […***…] in performance of the Collaborative Development Program or Transition Program that is necessary or useful to research, develop, make, have made, use, sell, offer for sale, import and/or otherwise exploit Compounds and Products in the Field of Use.

1.61 **"Receptor License"** means Non-exclusive License Agreement dated August 27, 1999, by and between Neurocrine and The Mount Sinai School of Medicine of the City University of New York regarding the human GnRH receptor.

1.62 **"Regulatory Approval"** means all the technical, medical and scientific licenses, registrations, authorizations and approvals (including, approvals of NDAs and equivalents, supplements and amendments, pre- and post- approvals, pricing and third party reimbursement approvals where required, and labeling approvals) of any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other Governmental Authority, necessary for the manufacture, distribution, marketing, promotion, offer for sale, use, import, export or sale of Product(s) in a regulatory jurisdiction.

1.63 **"Regulatory Authorities"** means any applicable government regulatory authority involved in granting approvals for the manufacturing, marketing, reimbursement and/or pricing of a product in the Territory, including the FDA, EMA and PMDA.

1.64 **"Regulatory Filings"** means, collectively, INDs, MAAs, NDAs and/or any other related, equivalent or comparable filings as may be required by Regulatory Authorities to obtain Regulatory Approvals relating to the Products.

1.65 **"Royalties"** means those royalties payable by Abbott to Neurocrine pursuant to Article Four of this Agreement.

1.66 **"Rest of World Territory"** means worldwide excluding the United States Territory.

1.67 **"**[…***…]**"** means […***…].

1.68 **"Sublicensee"** means any Third Party to whom Abbott has granted a sublicense of the license rights granted to Abbott under this Agreement.

1.69 **"Technology"** means all proprietary data, information, and materials (including Inventions, know-how, trade secrets, experimental data, formula, market research data, expert opinions, experimental procedures, pre-clinical and clinical data, regulatory data and filings and other confidential and/or proprietary information, molecules, assays, reagents, compounds, compositions, human or animal tissue, samples or specimens).

1.70 **"Territory"** means United States Territory and Rest of World Territory.

1.71 **"Therapeutic Use"** means use(s) for any disease, disorder, state or condition in humans or animals, other than a Diagnostic Use.

1.72 **"Third Party(ies)"** means any person or party other than Neurocrine, Abbott and their respective Affiliates.

1.73 **"Third Party Development Contracts"** means all contracts in effect on the Effective Date between Neurocrine and Third Party contractors pursuant to which Neurocrine has contracted for pre-clinical and/or clinical services for Products as set forth on Exhibit D, true and complete copies of which have been made available to Abbott prior to the date hereof.

1.74 **"Third Party License Payments"** means […***…] payments payable by Abbott, its Affiliates or Sublicensees to a Third Party (or multiple Third Parties) […***…] to obtain rights under the Third Party Patent Rights to make, have made, use, offer for sale, sell and/or import such Products.

1.75 **"Third Party Manufacturing Contracts"** means all contracts in effect on the Effective Date between Neurocrine and Third Party contract manufacturers pursuant to which Neurocrine has contracted for manufacturing services for Products as set forth on Exhibit E, true and complete copies of which have been made available to Abbott prior to the date hereof.

1.76 **"Trademarks"** means any proprietary names selected by Abbott for commercialization of Products in the Territory.

1.77 **"Transition Plan"** means the plan describing the Development activities to be conducted by Neurocrine including (i) the timetable for transferring to Abbott various assets related to the Compounds and the Products, including the Development and manufacture thereof, and (ii) the activities to be undertaken by Neurocrine in the Transition Program, as agreed to by the Parties in writing concurrently with the execution of this Agreement and set forth on Exhibit F as may be updated from time to time pursuant to Section 6.1(c) (*Transition Program; Transition Plan*).

1.78 **"Transition Program"** means the Product development, regulatory and manufacturing activities to be conducted by Neurocrine pursuant to Article Six, as described in further detail in the Transition Plan.

1.79 **"United States Territory"** means the United States of America.

1.80 **"Uterine Fibroids"** means the condition in which a benign (non-cancerous) tumor originates from the smooth muscle layer (myometrium) and the accompanying connective tissue of the uterus, including its signs and symptoms, which include, but are not limited to, heavy bleeding during menstruation, dysmenorrhea, dyspareunia, pressure related symptoms, and urinary frequency and urgency.

1.81 **"Valid Claim"** means a claim of any issued and unexpired patent included within the Neurocrine Patent Rights and/or Program Patent Rights whose enforceability has not been effected by one or more of any of the following: (1) irretrievable lapse, revocation or abandonment and/or (2) holding of unenforceability or invalidity by a decision of a court or other appropriate body of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and/or (3) disclaimer or admission of invalidity or unenforceability through reissue or re-examination or opposition, nullity action or invalidation suit response or otherwise.

1.82 **Additional Definitions**. Each of the following definitions is set forth in the Section of this Agreement indicated below:

DEFINITION	SECTION
Agreement	Preamble
Abbott	Preamble
Neurocrine	Preamble
GAAP	"Net Sales"
Exclusivity Period	2.3
License Fee	4.1
JDC	5.3
Alliance Manager	5.5
Assigned Third Party Development Contracts	6.5
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Manufacturing Technology Transfer	8.4
Paragraph IV Notice	12.5
Neurocrine Indemnified Party	10.1
Liability	10.1
Abbott Indemnified Party	10.2
Indemnified Party	10.3
Indemnifying Party	10.3
Term	11.1(a)
Notifying Party	11.4(a)
Adverse Ruling	11.4(a)(1)
Insolvent Party	11.5

1.83 **Construction**. In construing this Agreement, unless expressly specified otherwise:

(a) references to Articles, Sections, Exhibits and Schedules are to articles and sections of, and exhibits and schedules to, this Agreement;

(b) except where the context otherwise requires, use of either gender includes the other gender, and use of the singular includes the plural and vice versa;

(c) any list or examples following the word "including" shall be interpreted without limitation to the generality of the preceding words;

(d) except where the context otherwise requires, the word "or" is used in the inclusive sense; and

(e) all references to "dollars" or "$" herein means United States of America Dollars.

ARTICLE TWO - REPRESENTATIONS AND WARRANTIES AND COVENANTS

2.1 **Mutual Representations and Warranties.** Neurocrine and Abbott each hereby represents and warrants, to the other as of the Effective Date of this Agreement, as follows:

a) Organization. It is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation and has all requisite power and authority, corporate and otherwise, to execute, deliver and perform this Agreement.

b) Authorization. The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action and will not violate (a) such Party's certificate of incorporation or by-laws, (b) any agreement, instrument or contractual obligation to which such Party is bound in any material respect, (c) any requirement of applicable Law, or (d) any order, writ, judgment, injunction, decree, determination or award of any court or governmental agency presently in effect applicable to such Party.

c) Binding Agreement. Assuming due authorization, execution and delivery on the part of the other Party, this Agreement constitutes a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its respective terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium and similar Laws relating to or affecting creditors generally or by general equitable principles (regardless of whether such enforceability is considered in a proceeding in equity or at Law).

d) No Inconsistent Obligation. It is not under any obligation, contractual or otherwise, to any Third Party that conflict with or is inconsistent in any respect with the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder.

2.2 **Additional Neurocrine Representations and Warranties.** Neurocrine hereby represents and warrants as of the Effective Date as follows:

a) The status of all Neurocrine Patent Rights listed on Exhibit C are properly stated as to their filing status or issuance and, to Neurocrine's knowledge, no issued patents which are part of Neurocrine Patent Rights listed on Exhibit C are invalid or unenforceable. All Neurocrine Patent Rights that (a) contain one or more claims that cover any Compound or Product (including its manufacture or its formulation or a method of its delivery or of its use); and (b) to the best of Neurocrine's knowledge are necessary for Abbott to exercise the licenses granted to it pursuant to Article Three and (c) that are existing on the Effective Date, are listed on Exhibit C.

b) There are no claims, judgment or settlements against Neurocrine pending, or to Neurocrine's knowledge, threatened that invalidate or seek to invalidate the Neurocrine Patent Rights.

c) Except as required […***…], Neurocrine has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the Neurocrine Patent Rights in manner inconsistent with the terms hereof.

d) Except as required by […***…], to Neurocrine's knowledge, it is the sole and exclusive owner of the Neurocrine Patent Rights all of which are free and clear of any liens, charges and encumbrances, and no other person, corporate or other private entity, or governmental entity or subdivision thereof, has or shall have any claim of ownership whatsoever with respect to the Neurocrine Patent Rights.

e) To Neurocrine's knowledge and except […***…], Neurocrine has complied with all requirements of […***…], where applicable, with respect to Neurocrine Patent Rights.

f) Neurocrine has disclosed or made available to Abbott all material information known to Neurocrine regarding the Neurocrine Patent Rights and Neurocrine Technology.

g) To Neurocrine's knowledge, Neurocrine has sufficient legal and/or beneficial title under the Neurocrine Patent Rights and Neurocrine Technology necessary to grant the rights contained in and to carry out its obligations under this Agreement.

h) Subject to Sections 6.2(b) and 7.3(b), Neurocrine shall maintain all Third Party Development Contracts, Third Party Manufacturing Contracts, and the […***…] in full force and effect and will not, without Abbott's prior written consent, terminate or otherwise modify the terms of such Third Party Development Contracts, Third Party Manufacturing Contracts, or the […***…].

2.3 **Exclusive Collaborative Effort.** Subject to Abbott's sublicensing rights hereunder, and except where the Parties shall mutually agree otherwise (in which event, for avoidance of doubt, such activities to which the Parties shall have agreed will be considered part of the Collaboration), Neurocrine and Abbott shall not, and shall cause their respective Affiliates and Sublicensees not to, other than pursuant to this Agreement, independently, or in collaboration with any Third Parties, engage in […***…] prior to the earlier of (a) […***…] or (b) […***…] (the "***Exclusivity Period***"); provided, however, that nothing in this Agreement shall (i) restrict […***…], or (ii) preclude either Party […***…], provided that the Party making such […***…]. If either Party (or its Affiliates) breaches this Section 2.3 due to an acquisition of or merger with all or substantially all of the business or assets of a Third Party, such acquiring Party shall not be in breach of this Section 2.3 so long as such acquiring Party (or its Affiliate) […***…] after the closing of such acquisition or merger.

2.4 **Commercially Reasonable Efforts.** Abbott will use Commercially Reasonable Efforts to Develop and Commercialize […***…]. Neurocrine and Abbott shall each use Commercially Reasonable Efforts to perform their respective obligations hereunder. In addition, Abbott agrees to comply with the […***…], if and as applicable, in relation to this Agreement.

2.5 **Conduct of Activities.** Each Party will conduct, and shall use Commercially Reasonable Efforts to cause its Affiliates to conduct, those activities allocated to such Party under this Agreement in

compliance in all material respects with applicable Laws of the country in which such activities are conducted.

2.6 **Disclaimer.** EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES, AND EACH PARTY HEREBY DISCLAIMS, ANY OTHER REPRESENTATION OR WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO THE SUBJECT MATTER OF THIS AGREEMENT, INCLUDING, ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NON-INFRINGEMENT, INCLUDING WITHOUT LIMITATION NEUROCRINE PATENT RIGHTS AND NEUROCRINE TECHNOLOGY. ADDITIONALLY, EXCEPT AS EXPRESSLY PROVIDED HEREIN, NEUROCRINE MAKES NO REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT THE MANUFACTURE, USE OR SALE OF ANY PRODUCT WILL NOT INFRINGE THE INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY.

ARTICLE THREE - LICENSE GRANTS; RETAINED RIGHTS

3.1 **License.** Subject to the terms of this Agreement, Neurocrine and its Affiliates hereby grants to Abbott, and Abbott hereby accepts, an exclusive worldwide license, with the right to sublicense through multiple tiers, under the Neurocrine Technology and Neurocrine Patent Rights, in each case, to research, develop, make, have made, use, sell, offer for sale, import and/or otherwise exploit Compounds and Products in the Field of Use in the Territory.

3.2 **License Grant to Neurocrine for the Collaboration.** Abbott hereby grants to Neurocrine a non-exclusive license, without the right to sublicense, under Patent Rights and Technology Controlled by Abbott solely for use in connection with Neurocrine's conduct of the Collaboration. Nothing set forth herein will limit Abbott's right to use for all purposes, any Abbott Technology or Abbott Patent Rights.

3.3 **Retention of Rights**. Notwithstanding the exclusive licenses granted to Abbott pursuant to Section 3.1 (*License*), Neurocrine retains the right to practice under the Neurocrine Technology and Neurocrine Patent Rights to perform (and to sublicense Third Parties to perform) its obligations under this Agreement (including the manufacture and supply of Compound and Product to Abbott). Subject to Section 2.3, Neurocrine also retains: (i) a […***…] license in the […***…], to use the Neurocrine Technology (including Neurocrine Patent Rights) for […***…] and (ii) exclusive rights for all purposes outside the scope of the licenses granted in Section 3.1; provided that any activity Neurocrine would undertake in relation to the retention of rights hereunder that […***…], shall require Abbott's prior written consent before undertaking such activity.

3.4 **License Grant to Neurocrine under Program Technology.** Subject to Section 2.3, Abbott grants Neurocrine a […***…] license […***…], to use the Program Technology (including Program Patent Rights) […***…] for: (i) […***…] and (ii) for any purpose outside the scope of the licenses granted in Section 3.1; provided that any activity Neurocrine would undertake in relation to the grant of rights hereunder that […***…], shall require Abbott's prior written consent before undertaking such activity.

3.5 **No Implied Licenses**. Except as expressly set forth in this Agreement, neither Party grants any license under its intellectual property rights to the other Party.

3.6 **Exclusions.** For avoidance of doubt, the licenses granted to Abbott under this Agreement shall not include any rights for Abbott to research, develop, make, have made, use, sell, offer for sale and/or import any proprietary compound of Neurocrine that is not a Compound. Notwithstanding anything to the contrary in this Agreement, for the Term of Royalty set forth in Section 4.6, Neurocrine shall not, alone or with or through (i) its Affiliates or (ii) any Third Party: Develop, Commercialize, offer for sale, sell and/or otherwise commercially exploit Compounds or Products in the Field of Use in the Territory.

ARTICLE FOUR - ROYALTIES, MILESTONES AND PAYMENT PROVISIONS

4.1 **License Fee.** In consideration of the licenses granted to Abbott hereunder and the disclosure to Abbott of Neurocrine Technology, Abbott shall pay to Neurocrine a non-refundable, non-creditable license fee equal to seventy five million dollars ($75 MM) ("***License Fee***"). The License Fee shall be paid to Neurocrine within […***…] days after the Effective Date of this Agreement.

4.2 **Milestones.** Abbott will pay to Neurocrine […***…] Milestones for achievement of the events set forth below. Abbott will notify Neurocrine within […***…] days of achievement of each Milestone event and the related Milestone payment will be made to Neurocrine within […***…] days of achievement of the event.

a) *Elagolix*. In consideration for the license rights granted by Neurocrine to Abbott, on an […***…], Abbott will pay to Neurocrine the Milestones set forth below for *Elagolix*:

ELAGOLIX EVENT*	[…***…]	[…***…]
Acceptance of SPA by FDA following agreement on protocols during the End of Phase II Meeting(s) with the FDA	$20 MM	N/A
Initiation of […***…]	[…***…]	[…***…]
Initiation of first Phase IIa study	N/A	$10 MM
Initiation of […***…]	[…***…]	[…***…]
Acceptance of […***…]	[…***…]	[…***…]

*** Confidential Treatment Requested

First Regulatory Approval of […***…]	[…***…]	[…***…]
First filing of […***…]	[…***…]	[…***…]
First Regulatory Approval of […***…]	[…***…]	[…***…]
First filing of […***…]	[…***…]	[…***…]
First Regulatory Approval of […***…]	[…***…]	[…***…]

Total Milestones payable under this Section 4.2(a) shall not exceed […***…].

In the event that a Product is discontinued in the course of development for […***…], only those Milestones that have not been paid at the time the Product has been discontinued shall be payable for a future Product achieving the Milestone Event.

* Once a Product achieves a Milestone for […***…], it will be deemed to have achieved all earlier Milestones […***…] and any Milestone payment for such earlier Milestone will become due and payable to the extent it has not already been paid. Specifically, (i) should the Initiation of […***…] be achieved prior to or in the absence of the Acceptance of […***…], the Acceptance of […***…] shall be paid when the Initiation of […***…] is achieved and (ii) should a […***…] not be required or a previously conducted clinical study be accepted in place of such a study, the Initiation of […***…] will be paid upon the earlier of (A) receipt of […***…] or (B) first filing of […***…].

** Should another […***…] as the […***…] to advance through Development, the Milestone events enumerated in the […***…] stream above shall apply to that […***…] […***…] shall apply to […***…].

*** If Regulatory approval of a MAA […***…] is granted, such Milestone event shall be paid […***…]. If approved by […***…], without regard to order or combination.

b) Follow-On Compounds. On the first occurrence of the events set forth below for a Follow-on Compound, Abbott shall pay Neurocrine the following Milestones for Follow-on Compounds on […***…] (each Milestone stream would be payable one time only regardless of how many Products advance through development):

FOLLOW-ON EVENT*	[…***…]	[…***…]
Initiation of […***…]	[…***…]	[…***…]
Initiation of […***…]	[…***…]	[…***…]
Initiation of […***…]	[…***…]	[…***…]
Initiation of […***…]	[…***…]	[…***…]
Acceptance of […***…]	[…***…]	[…***…]
First Regulatory Approval of […***…]	[…***…]	[…***…]
First Regulatory Approval of […***…]	[…***…]	[…***…]
First Regulatory Approval of […***…]	[…***…]	[…***…]

Total Milestones payable under this Section 4.2(b) shall not exceed […***…].

In the event that a Product is discontinued in the course of development for […***…], only those Milestones that have not been paid at the time the Product has been discontinued would be payable for a future Product achieving the Milestone Event.

* Once a product achieves a Milestone for a […***…], it will be deemed to have achieved all earlier Milestones […***…] and any Milestone payment for such earlier Milestone will become due and payable to the extent it has not already been paid.

** In the event that Follow-on Compound […***…] is the same Follow-on Compound […***…], the […***…] Milestone shall be paid upon the achievement of the Initiation of […***…].

*** If Regulatory Approval of a MAA […***…] is granted, such Milestone event shall be paid […***…]. If approved by a […***…], without regard to order or combination.

4.3 **Royalties.** Subject to Section 4.4 (*Royalty Adjustments*) and Section 4.6 (*Royalty Term*), Abbott will pay to Neurocrine Royalties on Net Sales in an Abbott Year, of each Product […***…] containing *Elagolix* and the Follow-on Compounds, on a Product […***…] by Product […***…] and United States

Territory and Rest of World Territory basis (as the case may be), commencing upon the First Commercial Sale in the United States Territory or Rest of World Territory, as applicable, as follows:

For Products containing […***…]:

Abbott Year Net Sales	United States Territory Royalty (% Net Sales)	Rest of World Territory Royalty (% Net Sales)
Less than […***…]	[…***…]	[…***…]
Greater than or equal to […***…] and less than […***…]	[…***…]	[…***…]
Greater than or equal […***…]	[…***…]	[…***…]

For Products containing […***…]:

Abbott Year Net Sales	United States Territory Royalty (% Net Sales)	Rest of World Territory Royalty (% Net Sales)
Less than […***…]	[…***…]	[…***…]
Greater than or equal to […***…]	[…***…]	[…***…]

The Royalties set forth above are marginal rates and shall only apply to that portion of Net Sales opposite each applicable Royalty rate. For the purposes of Royalty payments, […***…] will be considered to be the same Product, regardless of the indications for which such Product […***…] may be used.

Notwithstanding anything to the contrary in this Agreement, the Parties shall, prior […***…] negotiate in good faith on commercially reasonable terms, and execute an amendment to this Agreement duly executed by authorized representatives of both Parties, setting forth […***…] of the applicable […***…] sold by Abbott or its Affiliates or Sublicensees. If the Parties are unable to agree […***…] after good faith negotiations, then the Parties shall submit the issue under Section 13.2 (*Dispute Resolution*).

4.4 **Royalty Adjustments.** Except as otherwise set forth in this Agreement, Royalties due hereunder are subject to adjustment on a Product by Product, […***…] basis as a result of the events set forth below (such adjustments to be prorated for the then-current […***…] in which the reduction becomes

applicable) provided, however, that the Royalties payable under Section 4.3 (*Royalties*) shall not be reduced by more than […***…] of the amounts set forth in Section 4.3 (*Royalties*) by reason of the adjustments set forth below.

a) Royalty Adjustment for Third Party License Payments. Neurocrine shall be responsible for and pay all amounts due under the […***…]. If Abbott, its Affiliates or Sublicensees, in their reasonable judgment, is required to pay any Third Party License Payments, then the amount of Royalties payable under Section 4.3 (*Royalties*) shall be reduced by […***…] of the amount of such Third Party License Payments paid to such Third Party.

b) Royalty Adjustment for Non-Patent Products. If the making, having made, using, offering for sale, sale, and/or importation of a Product would not infringe a Valid Claim within the […***…], Royalties payable to Neurocrine will be reduced by […***…] of the Royalty rate(s) set forth in Section 4.3 (*Royalties*).

c) Royalty Adjustment for Generic Competition. If there is Generic Competition, the Royalties payable to Neurocrine shall be reduced by […***…] of the Royalty rates set forth in Section 4.3 (*Royalties*).

4.5 **Sales Milestones.** Within […***…] days following the last day of the Abbott Year of the first achievement of each event of annual combined Net Sales of all Products as detailed below, Abbott shall make the following one-time payments:

Event	Sales Milestone
Abbott Year Net Sales of Product(s) exceeds [***]	[…***…]
Abbott Year Net Sales of Product(s) exceeds [***]	[…***…]
Abbott Year Net Sales of Product(s) exceeds [***]	[…***…]

4.6 **Term of Royalty.** Notwithstanding the foregoing, Abbott's Royalty obligations pursuant to Section 4.3 (*Royalties*) shall expire, on a Product by Product and country by country basis, following the later of: (i) the last to expire of all Valid Claims in the Neurocrine Patent Rights or Program Patent Rights covering the making, having made, using, offering to sell, selling, and importing of Product in such country or (ii) […***…] following the First Commercial Sale in such country. Notwithstanding the foregoing, if, after the aforementioned Royalty term, Neurocrine is required to make royalty payments […***…].

4.7 **Reports and Payments.**

a) Inter-Company Sales. Sales between or among Abbott, its Affiliates or Sublicensees shall not be subject to Royalties under this Section 4. Abbott shall be responsible for the payment of Royalties on Net Sales by its Affiliates or Sublicensees.

b) Cumulative Royalties. The obligation to pay Royalties under this Article 4 shall be imposed only once (i) with respect to any sale of the same unit of Product and (ii) with respect to a single unit of Product, in each case, regardless of how many Valid Claims in the Neurocrine Patent Rights or Program Patent Rights cover the Compound included in such Product.

c) Statements and Payments. Following commencement of Abbott's obligation to pay Royalties pursuant to Section 4.3, Abbott shall deliver to Neurocrine (a) within […***…] days after the end of each […***…] report setting forth […***…] and (b) within […***…] days after

the end of each […***…], a report certified by Abbott as accurate to the best of its ability based on information then available to Abbott, setting forth for such […***…] the following information on a Product by Product basis […***…]. The total Royalty due for the sale of Products during […***…] shall be remitted within […***…] days after the end of each […***…].

d) Taxes and Withholding.

1) VAT. It is understood and agreed between the Parties that any payments made by Abbott under this Agreement are inclusive of any value added or similar tax imposed upon such payments.

2) Tax Cooperation. Where any sum due to be paid to either Party hereunder is subject to any withholding or similar tax, the Parties shall use their commercially reasonable efforts to do all such acts and things and to sign all such documents as will enable them to take advantage of any applicable double taxation agreement or treaty. In the event there is no applicable double taxation agreement or treaty, or if an applicable double taxation agreement or treaty reduces but does not eliminate such withholding or similar tax, the payor shall pay such withholding or similar tax to the appropriate government authority, deduct the amount paid from the amount due to payee and secure and send to payee the best available evidence of such payment. On the Effective Date, each Party shall provide the other with a completed and signed Form W-8BEN.

3) Withholding Tax Matters. In addition, in the event any of the payments made by Abbott to Neurocrine under this Agreement become subject to withholding taxes under the Laws of any jurisdiction, Abbott shall deduct and withhold the amount of such taxes for the account of Neurocrine to the extent required by Law, such payment to Neurocrine shall be reduced by the amount of taxes deducted and withheld, and Abbott shall pay the amount of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Neurocrine an official tax certificate or other evidence of such tax obligations, together with proof of payment from the relevant Governmental Authority of all amounts deducted and withheld sufficient to enable Neurocrine to claim such payment of taxes. Any such withholding taxes required under applicable Law to be paid or withheld shall be an expense of, and borne solely by, Neurocrine. Abbott will provide Neurocrine with reasonable assistance, at Neurocrine's expense, to enable Neurocrine to recover such taxes as permitted by Law.

e) Currency. All amounts payable and calculations hereunder shall be in United States dollars. Conversion of sales recorded in local currencies to U.S. dollars will be at the monthly rate of exchange used by Abbott in its worldwide accounting system prevailing on the third to last business day of the month preceding the month in which such sales are recorded by Abbott. If governmental regulations prevent remittances from a foreign country with respect to sales made in that country, the Royalties shall continue to accrue but the obligation of Abbott to pay Royalties on sales in that country shall be delayed until such remittances are possible. Neurocrine shall have the right, upon giving written notice to Abbott, to receive payment in that country in local currency.

f) Late Payments. If Neurocrine does not receive payment of any sum due it hereunder on or before the due date set forth herein, simple interest thereon shall accrue on the sum from the due date until the date of payment at the rate equal to […***…]; provided, that with respect to any disputed payments, no interest payment shall be due until such dispute is resolved and

the interest which shall be payable thereon shall be based on the finally-resolved amount of such payment, calculated from the original date on which the disputed payment was due through the date on which payment is actually made.

g) Maintenance of Records; Audit. For a period […***…], Abbott shall maintain and shall cause its Affiliates and Sublicensees to maintain complete and accurate books and records in connection with the sale of Products hereunder, as necessary to allow the accurate calculation of Royalties due hereunder including any records required to calculate any Royalty adjustments hereunder. Once per calendar year, Neurocrine shall have the right to engage an registered public accounting firm of nationally recognized standing selected by Neurocrine and reasonably acceptable to Abbott, at Neurocrine's expense, which shall have the right to examine in confidence the relevant Abbott records as may be reasonably necessary to determine and/or verify the amount of Royalty payments due hereunder for any year ending not more than […***…] months prior to the date of such request. Such examination shall be conducted during Abbott's normal business hours, after at least […***…] days prior written notice to Abbott and shall take place at the Abbott facility(ies) where such records are maintained. In the event the report reflects an under-payment by Abbott hereunder, Abbott shall promptly (but in no event later than […***…] days after Abbott's receipt of the independent auditor's report) make payment to Neurocrine of any short-fall. In the event that there was an over-payment by Abbott hereunder, Neurocrine shall promptly (but in no event later than […***…] days after Neurocrine's receipt of the independent auditor's report so correctly concluding) refund to Abbott the excess amount. In the event any payment by Abbott shall prove to have been incorrect by more than […***…] to Neurocrine's detriment, Abbott will pay the reasonable fees and costs of Neurocrine's independent auditor for conducting the audit.

h) No Other Compensation. Each party hereby agrees that the terms of this Agreement, fully define all consideration, compensation and benefits, monetary or otherwise, to be paid, granted or delivered by one party to the other Party in connection with the transactions contemplated herein. Neither Party previously has paid or entered into any other commitment to pay, whether orally or in writing, any of the other Party's employees, directly or indirectly, any consideration, compensation or benefits, monetary or otherwise, in connection with the transaction contemplated herein.

ARTICLE FIVE - MANAGEMENT OF COLLABORATION

5.1 **Goal of the Collaboration.** The goals of the Collaboration are to conduct the Transition Program in accordance with the Transition Program Plan and conduct the Collaborative Development Program in accordance with the Collaborative Development Plan.

5.2 **Meetings of Senior Executives.** Upon agreement of the JDC for the necessity of a meeting(s) with senior executives, the Chief Executive Officer of Neurocrine and Senior Vice President, Pharmaceuticals Research & Development of Abbott shall meet and review the progress of the Collaboration and shall discuss any current issues of the Collaboration with the intent of proposing resolutions for such issues. Meetings may be in person or may be held telephonically or by videoconference.

5.3 **Joint Development Committee.**

a) Formation. Within thirty (30) days following the Effective Date, the Parties shall establish a joint development committee (the "***JDC***"). The JDC shall consist of senior representatives from each Party with decision making authority in such number as mutually agreed on by the Parties not to exceed […***…] from each Party. Each Party shall have the right at any time to substitute individuals, on a permanent or temporary basis, for any of its previously designated representatives to the JDC by giving written notice to the other Party. The JDC shall be chaired by a representative member from Abbott.

b) Responsibility. The JDC will be responsible for coordination and oversight of all activities conducted under the Transition Program and the Collaborative Development Program in accordance with this Agreement. The Parties shall cause their respective representatives on the JDC to use diligent efforts, acting in good faith, to resolve all matters presented to them as expeditiously as possible.

c) Decision Making and Dispute Resolution. All decisions of the JDC will be by consensus whereby each of Neurocrine and Abbott shall have one (1) vote on all matters before the JDC. If for any reason the JDC cannot resolve any matter properly before it, the matter shall be […***…].

d) Withdrawal; Disbandment. Subject to Neurocrine's other obligations herein, Neurocrine may irrevocably withdraw from participation in the JDC upon written notice to Abbott and subject to Abbott's consent, not to be unreasonably withheld, conditioned or delayed. The JDC shall disband upon completion of the Transition Program and Collaborative Development Program.

5.4 **JDC Meetings.** The JDC chairperson shall call meetings […***…], or as otherwise mutually agreed. Meetings may be held in person, by telephone, or by video conference call, and the location of each meeting shall be selected by the chairperson, unless otherwise agreed. In addition to the foregoing, either Party may call a special meeting of the JDC up to […***…] per year upon […***…] days notice to the other Party. Meetings will be minuted and signed by the chairperson and distributed the both Parties. Upon the other Party's consent, additional participants of a Party may be invited by any representative to attend meetings when and where appropriate. If feasible, prior to each JDC meeting, the Parties will distribute to each other written copies (or corresponding electronic files) of materials intended to be discussed at such meeting. In the event that after receipt of any such report, either Party shall request additional data or information, the Party to whom such request is made shall use reasonable efforts to promptly provide to the other Party such data or information.

5.5 **Alliance Managers.** In addition to the JDC set forth above, Neurocrine and Abbott each acknowledge and agree that it would be beneficial to the Collaboration for each to have a senior representative with a general understanding of the non-clinical and pharmaceutical development (API and drug product), clinical, regulatory, and manufacturing issues relating to Products to act as an alliance manager ("***Alliance Manager***"), and will appoint such a person to the extent each Party in its sole discretion determines it is practical. It is envisioned that the Alliance Managers will serve as a single point of contact within each Party with responsibility for facilitating communication and collaboration between the Parties. The Alliance Managers may attend JDC meetings as appropriate and will be provided access to decision making representatives of both Parties.

5.6 **Abbott Authority.** Subject to the oversight of the JDC as provided in Section 5.3 (*Joint Development Committee*) and except as provided elsewhere herein, Abbott shall have sole responsibility and authority with regard to (a) Development activities related to Products, including the timing and staging of Development work on the various Indications and the determination of which Indications to

pursue, (b) manufacturing and commercial supply of Products, including holding title to commercial inventory and responsibility for invoicing, credit and collection, and (c) Commercialization of Products, including pricing of Products, all pricing and reimbursement approvals and all other terms of sale.

5.7 **Reporting.** After the JDC has been disbanded, on […***…] basis until […***…], Abbott will provide to Neurocrine a written report setting forth […***…]; provided however, in the event of a Change of Control, Abbott will provide to Neurocrine, on […***…] basis, a written report setting forth […***…] only. If following receipt of […***…] report or […***…], Neurocrine shall reasonably request additional information about […***…], Neurocrine may make such request through the Alliance Managers of the Parties and Abbott will provide such information within a reasonable time after the request; provided however, in the event of a Change of Control, Abbott shall not be obligated to provide any such information.

ARTICLE SIX - TRANSITION PROGRAM

6.1 **Transition Program.**

a) Term. The activities under the Transition Program as outlined in the Transition Plan will terminate on the date set forth in the Transition Plan, provided that, prior to the end of the Transition Term, (i) all Regulatory Filings in existence on the Effective Date will have been assigned to, and accepted by, Abbott, (ii) all Assigned Third Party Development Contracts will have been assigned to, and accepted by Abbott, and (iii) all Assigned Third Party Manufacturing Contracts will have been assigned to, and accepted by, Abbott. The Parties shall use Commercially Reasonable Efforts to perform the activities set forth in the Transition Plan and complete the Transition Program, in accordance with the timelines set forth in the Transition Plan. The Parties currently agree that the Transition Program will be initiated on […***…] and will be substantially completed and will terminate on […***…], it being understood that such date is an estimate based on the current state of the Transition Program and may be changed by the JDC even if the Parties are exerting Commercially Reasonable Efforts to complete the Transition Program by such date.

b) Goal; Diligence. The goal of the Transition Program will be to (1) […***…] and (2) […***…]. Specifically, the Transition Program may include, but is not limited to, all activities under the Third Party Development Contracts and Third Party Manufacturing Contracts during the term of the Transition Program. Each Party shall use Commercially Reasonable Efforts in carrying out its activities under the Transition Program and Transition Plan and shall conduct the Transition Program in compliance with all applicable Laws.

c) Transition Plan. Subject to oversight of the JDC, Neurocrine shall (i) perform Product manufacturing, clinical, and regulatory activities set forth in the Transition Plan, in accordance with the terms of the Transition Plan, and (ii) transfer to Abbott the data and other assets set forth in the Transition Plan, in accordance with the terms of the Transition Plan. The Transition Plan will be updated by the JDC as needed and will specifically include detailed plans for staffing levels and activities, timelines and transition dates. In particular, the Transition Plan will address the timelines for the transfer of data and Technology to Abbott, and for the assignment to Abbott of Regulatory Filings, Third Party Manufacturing Contracts and Third Party Development Contracts, and the specific Development activities

(and corresponding timelines) to be performed by Neurocrine. Each amendment and update to the Transition Plan shall be prepared jointly by the Parties through the JDC in accordance with the limitations on total numbers of FTEs in any given period and allocation across functional areas set forth on Exhibit F. The Transition Plan may be amended by the JDC to accelerate, decelerate, add or remove activities thereunder including reducing or eliminating Neurocrine's responsibilities for an activity thereunder provided that, the number of Neurocrine FTEs funded and the allocation of Neurocrine FTEs across functional areas (e.g., CMC, pre-clinical, clinical) may not be reduced or increased or altered without Neurocrine's consent.

d) Transfer of Data, Information, Technology and Assets. From and after the Effective Date, all data, information, Technology and assets related to the Compounds and Products that are reasonably requested by Abbott shall be made available to Abbott through a secure electronic document sharing service. Additionally, hardcopy forms of data, information, Technology and assets related to the Compounds and Products that are reasonably requested by Abbott shall be transferred to a site selected by Abbott, and electronic forms of data, information, Technology and assets related to the Compounds that are reasonably requested by Abbott shall be transferred to an Abbott electronic system per Abbott's instructions. These transfers of data, information, Technology and assets shall occur at scheduled intervals as mutually agreed upon by the Parties and will be categorized as high priority, low priority and upon request to determine the expedience of such transfer. The Parties agree that the method of transfer of such data, information, Technology and assets will be of a secure nature, with an agreed upon applied data integrity method (such as a checksum utility), if applicable.

6.2 **Transition Budget.** Notwithstanding anything to the contrary in this Agreement, Abbott's total funding responsibility for the Transition Program shall not exceed […***…] without Abbott's prior written permission.

a) Internal Costs. Abbott will initially provide funding for Neurocrine FTEs devoted to the conduct of the Transition Program in accordance with the Transition Plan, at a rate of […***…] per FTE per year (such rate will be prorated for any partial year), and provided such funding shall not exceed […***…] without Abbott's prior written permission. The contemplated allocation of Neurocrine FTEs devoted to the conduct of the Transition Program in accordance with the Transition Plan, as of the Effective Date, is […***…]. Neurocrine FTEs in […***…] will be allocated by the JDC in accordance with the Transition Plan and Section 6.1(c) from time to time based on the progress of the activities under the Transition Plan. Within […***…] days after the end of each Abbott Quarter after the Effective Date, Neurocrine will provide to Abbott an invoice setting forth the amount of funding for Neurocrine FTEs allocated to Transition Plan activities in such preceding Abbott Quarter as well as a FTE report for the preceding Abbott Quarter, which FTE report details the FTEs committed to the Transition Program by department and/or functional area, and a brief summary of the work performed (which summary may be limited to references to the reports to the JDC). Invoices will be payable by Abbott within […***…] days of receipt of the invoice.

b) External and Third Party Costs.

1) Abbott agrees that Abbott will be responsible for all Third Party and external costs and expenses for the activities set forth on Exhibit F on or after […***…] and accrued and properly expensed under generally accepted accounting principles for activities undertaken on or after […***…], as set forth in the Transition Plan, or otherwise

approved by the JDC, *pr*ovided such amounts do not exceed the budget set forth in the Transition Plan by more than […***…] without Abbott's prior written permission. Within […***…] days after the end of each Abbott Quarter during the term of the Transition Program, Neurocrine will provide to Abbott a report and invoice setting forth the external and Third Party costs arising out of the Transition Program in such Abbott Quarter, including copies of original invoices for such Third Party costs. Neurocrine's quarterly invoice to Abbott will be payable by Abbott within […***…] days of receipt of the report.

2) All expenses under the Third Party Development Contracts and Third Party Manufacturing Contracts relating to activities conducted by Neurocrine pursuant to the Transition Plan on or after […***…] (including termination fees, if applicable, as contemplated by the Transition Plan) are included in the budget in the Transition Plan and will be reimbursed by Abbott as Third Party external costs and expenses hereunder.

3) The budget included in the Transition Plan sets forth all the expenditures that will be incurred in the course of the Transition Program with respect to activities performed by Neurocrine and Third Parties. The Parties acknowledge and agree that, notwithstanding the Parties' efforts to fully budget all cost items of the Transition Program, costs may change over time and/or unbudgeted items may be identified. As such, the JDC will review the Transition Program budget on a quarterly basis and reforecast such budget based on the then current costs and expenses on the basis of whether such expenditure is reasonably necessary to maintain timelines and beyond the reasonable control of the Parties.

6.3 **Regulatory Filings.** In accordance with the Transition Plan, Neurocrine will assign to Abbott all Regulatory Filings and thereafter all Regulatory Filings shall be the property of Abbott and Abbott shall be responsible for, and pay all cost and expenses relating to, Regulatory Filings in the Territory. Each of the Parties shall take all reasonable steps to ensure an orderly transfer of the Regulatory Filings to Abbott as provided herein and in the Transition Plan, and in accordance with the timelines for transfer set forth in the Transition Plan.

6.4 **Adverse Events and Safety Information.** Within ninety (90) days after the date of this Agreement, the Parties shall enter into an agreement to initiate a process for the exchange of adverse event safety data in a mutually agreed format, including but not limited to, postmarketing spontaneous reports received by the Party or its Affiliates in order to monitor the safety of the product and to meet reporting requirements with any applicable regulatory authority.

6.5 **Assignment of Third Party Development Contracts.** If and to the extent applicable, Neurocrine will use Commercially Reasonable Efforts to obtain necessary consents from Third Parties to assign to Abbott all Third Party Development Contracts the JDC requests be assigned to Abbott. Neurocrine will assign to Abbott, and Abbott will accept assignment of, the assignable Third Party Development Contracts identified by the JDC prior to the end of the Transition Program (the "***Assigned Third Party Development Contracts***"). Upon assignment to Abbott of each Assigned Third Party Development Contract, Abbott will be responsible for all future performance under such Assigned Third Party Development Contract and will make all decisions regarding such Assigned Third Party Development Contract and any other future Development contracts Abbott elects. Subject to Section 6.2(b), Neurocrine remains responsible for all rights, duties and obligations of such Assigned Third Party Development Contracts prior to the date of assignment to Abbott. Any Third Party Development Contracts not included in the Assigned Third Party Development Contracts will not be assigned to Abbott and Abbott shall have no rights or obligations under such unassigned Third Party Development Contracts

(it being understood that Abbott has certain obligations to Neurocrine with respect to such unassigned Third Party Development Contracts pursuant to Section 6.2(b)).

6.6 **Assignment of Third Party Manufacturing Contracts.** If and to the extent applicable, Neurocrine will use Commercially Reasonable Efforts to obtain necessary consents from Third Parties to assign to Abbott all Third Party Manufacturing Contracts the JDC requests be assigned to Abbott. Neurocrine will assign to Abbott, and Abbott will accept assignment of, all assignable Third Party Manufacturing Contracts identified by the JDC prior to the end of the Transition Program (the "***Assigned Third Party Manufacturing Contracts***"). Upon assignment to Abbott of each Assigned Third Party Manufacturing Contract, Abbott will be responsible for all future performance under such Assigned Third Party Manufacturing Contract and will make all decisions regarding such Assigned Third Party Manufacturing Contract and any future manufacturing or Product supply contracts Abbott elects. Subject to Section 6.2(b), Neurocrine remains responsible for all rights, duties and obligations of such Assigned Third Party Development Contracts prior to the date of assignment to Abbott. Any Third Party Manufacturing Contracts not included in the Assigned Third Party Manufacturing Contracts will not be assigned to Abbott and Abbott shall have no rights or obligations under such unassigned Third Party Manufacturing Contracts (it being understood that Abbott has certain obligations to Neurocrine with respect to such unassigned Third Party Manufacturing Contracts pursuant to Section 6.2(b)).

6.7 **Use of Third Parties**. Neurocrine shall be entitled to utilize the services of Third Parties to perform its share of Transition Program activities, only upon Abbott's prior written consent, which […***…]. Notwithstanding the foregoing, Neurocrine shall remain at all times fully liable for its responsibilities under the Transition Program and this Agreement; provided, further, that Neurocrine shall not subcontract any such obligations unless the written agreement pursuant to which it engages any Third Party: (i) is consistent in all material respects with this Agreement, and (ii) contains terms obligating such Third Party to comply with the confidentiality, intellectual property, and all other relevant provisions no less stringent than those set forth in this Agreement.

ARTICLE SEVEN - COLLABORATIVE DEVELOPMENT PROGRAM

7.1 **Collaborative Development Program.**

a) Goal. The Parties will collaborate in a Collaborative Development Program to achieve […***…], as more expressly set forth in the Collaborative Development Plan.

b) Term. The term of the Collaborative Development Program will begin on […***…] and will end […***…], unless otherwise agreed by the Parties.

c) Efforts. The Parties will use Commercially Reasonable Efforts to perform the activities set forth in the Collaborative Development Plan in accordance with the timelines set forth in the Collaborative Development Plan. Both parties will participate in […***…] and, as appropriate, […***…] as Transition Program or Collaborative Development Program activities, as the case may be.

7.2 **Collaborative Development Plan and Budget.**

a) Activities. The Collaborative Development Program, subject to JDC approval and oversight, may include any of the types of activities contemplated in the Collaborative Development Plan set forth as Exhibit G. The Parties understand and agree that Exhibit G is not intended

to represent a final Collaborative Development Plan. In addition, while Exhibit G includes estimated numbers of Neurocrine FTEs that will be required to conduct development activities, it is understood that these numbers are estimates only and may change depending on timing of the activities and final study designs for selected activities. Within […***…] days following the Effective Date, the JDC will finalize a Collaborative Development Plan for the term of the Collaborative Development Program. The Collaborative Development Plan will allocate to Neurocrine activities equivalent to the Neurocrine FTE Funding Commitment (as defined in Section 7.3(a) in accordance with the limitations on total numbers of FTEs in any given period and allocation across functional areas set forth on Exhibit G. The initial Collaborative Development Plan will focus on the activities to be conducted in the […***…]. Thereafter the Collaborative Development Plan will be updated by the JDC quarterly as needed and will specifically include detailed plans for staffing levels and activities, timelines and transition dates and outline all Neurocrine FTE funding and external costs and expenses. The Parties acknowledge and agree that, notwithstanding the Parties' efforts to fully budget all cost items of the Collaborative Development Program, costs may change over time and/or unbudgeted items may be identified. As such, the JDC will review the budget set forth in the Collaborative Development Plan on a quarterly basis and reforecast such budget based on the then current costs and expenses on the basis of whether such expenditure is reasonably necessary to maintain timelines and beyond the reasonable control of the Parties.

b) Amendments. The Collaborative Development Plan and each amendment and update thereto shall be prepared jointly by the Parties through the JDC. The JDC shall have the authority to amend the Collaborative Development Plan with […***…] days prior written notice to Neurocrine, including accelerating, decelerating, extending, adding or removing activities thereunder; provided that, (i) the amendment is consistent with the goals of the Collaborative Development Program and (ii) the number of Neurocrine FTEs funded pursuant to Section 7.3(a), the limitations on total numbers of FTEs in any given period and the allocation of Neurocrine FTEs across functional areas (e.g., CMC, pre-clinical, clinical) may not be decreased or extended or activities added that result in an increase, in either case except as set forth in Section 7.3(a) or with Neurocrine's written approval, (iii) the Third Party activities set forth in the Third Party Development Contracts and Third Party Manufacturing Contracts will not be terminated except in accordance with their terms (and any associated expenses being payable pursuant to Section 7.3(b)).

7.3 **Collaborative Development Program Funding.**

a) Internal Costs. Abbott will provide funding for Neurocrine FTEs devoted to the conduct of the Collaborative Development Program in accordance with the Collaborative Development Plan at a rate of […***…] per year (such rate will be prorated for any partial year), in an amount equal to […***…] over the term of the Collaborative Development Program (the "***Neurocrine FTE Funding Commitment***"). The Neurocrine FTE Funding Commitment will not exceed […***…] without Abbott's prior written permission.

b) External and Third Party Costs. Abbott will be responsible for all Third Party and external costs and expenses approved in advance by Abbott for the Collaborative Development Program activities.

c) Invoices. During the term of the Collaborative Development Program, within […***…] days after the end of each Abbott Quarter, Neurocrine will provide to Abbott an invoice

setting forth the amount of funding for Neurocrine FTEs allocated to Collaborative Development Plan activities and Third Party external costs and expenses incurred by Neurocrine pursuant to the Collaborative Development Plan for such preceding Abbott Quarter, as well as a FTE report for the preceding Abbott Quarter, which FTE report details the FTEs committed to the Collaborative Development Program by department and/or functional area, and a brief summary of the work performed (which summary may be limited to references to the reports to the JDC). Invoices will be payable by Abbott within […***…] days of receipt of the invoice.

7.4 **Use of Third Parties**. The provisions set forth in Section 6.7 (*Use of Third Parties*) apply *mutatis mutandis* for the Collaborative Development Program.

ARTICLE EIGHT – MANUFACTURING

8.1 **Manufacturing Responsibility.** Product manufacturing shall be the responsibility of Abbott and Abbott, at its sole discretion, may (1) modify or terminate Assigned Third Party Manufacturing Agreements, subject to the terms of such agreements; (2) negotiate with Neurocrine or its designee an agreement for the manufacture and supply Compound or Product to Abbott, its Affiliates or Sublicensees which agreement will contain standard manufacturing commercial terms, conditions and payments mutually acceptable to Neurocrine and Abbott (for avoidance of doubt Neurocrine will not be obligated to enter into such a manufacturing agreement if it mutually acceptable terms cannot be negotiated); (3) transfer some or all of the manufacture of the Product to locations selected by Abbott, (4) modify the manufacturing process for Products, (5) modify the quality assurance process for the manufacture or release of Product, and (5) take such other actions related to the manufacture of Products that Abbott deems appropriate.

8.2 **Clinical Supply.** Neurocrine will arrange for the transfer to Abbott of all *Elagolix* clinical trial material owned by Neurocrine on the Effective Date. Neurocrine will invoice Abbott for all costs incurred by Neurocrine in the manufacture, testing, formulation, packaging, storage, and release of the *Elagolix* clinical trial material as well as shipment costs to Abbott, provided however such cost shall not exceed […***…] without Abbott's prior written consent. Abbott shall only be responsible to pay for such clinical trial material that conforms to the applicable Product specifications in effect on the Effective Date, and (b) which has been manufactured in compliance with cGMP and all applicable laws and regulations; and (c) which is not adulterated or misbranded within the meaning of the U.S. Food, Drug & Cosmetics Act or other applicable law. Abbott may request that Neurocrine assume responsibility for *Elagolix* clinical supply production after the Effective Date as a Collaborative Development Program activity.

8.3 **Inspections.** Abbott shall be responsible for the management of any governmental or regulatory review, audit or inspection of facilities or processes relating to the manufacture of Products and all communications to governmental or regulatory authorities on such matters shall be made by Abbott.

8.4 **Manufacturing Technology Transfer.** All manufacturing Neurocrine Technology transfer activities will be Transition Program or Collaborative Development Program activities, as the case may be. Upon receipt of written notice from Abbott, Neurocrine shall use Commercially Reasonable Efforts to make available or to cause to be made available to Abbott or its designee, all manufacturing Neurocrine Technology, including, product manufacturing, packaging and sterilization specifications, utilities and process equipment information, and other technical information, relating to the manufacture of the

Products, then within Neurocrine's possession or Control, and shall thereafter render such assistance to Abbott or its designee as would allow Abbott or its designee to manufacture the Products (such transfer, the "***Manufacturing Technology Transfer***"). If any manufacturing Neurocrine Technology is within the control or possession of a Third Party pursuant to a Third Party Manufacturing Contract, Neurocrine shall use Commercially Reasonable Efforts to obtain the cooperation and assistance of such Third Party in such Manufacturing Technology Transfer. The Manufacturing Technology Transfer shall include the successful completion of installation qualification, operational qualification, performance qualification and process validation of the manufacturing process at the facility designated by Abbott. In connection with the Manufacturing Technology Transfer, Neurocrine and/or its Third Party manufacturer shall (i) deliver a comprehensive manual in English setting forth in detail the techniques, processes, documentation and know-how that are reasonably necessary or directly useful in the manufacture of Products then within either Neurocrine's possession or control and (ii) make available to Abbott at a site designated by Abbott the services of such personnel of Neurocrine's as Abbott may reasonably request in order to assist Abbott in establishing the manufacturing facility.

ARTICLE NINE - CONFIDENTIAL INFORMATION

9.1 **Treatment of Confidential Information.** During the Term and for a period of […***…] years thereafter, each Party shall maintain Confidential Information of the other Party in confidence, and shall not disclose, divulge or otherwise communicate such Confidential Information to any Third Party, or use it for any purpose other than as permitted under this Agreement or in connection with the development, manufacture, marketing, promotion, distribution or sale of the Products pursuant to this Agreement, and each Party agrees to exercise its reasonable efforts to prevent and restrain the unauthorized disclosure of such Confidential Information by any of its directors, officers, employees, or permitted Third Parties.

If, in the opinion of the receiving Party's counsel, any of the disclosing Party's Confidential Information is required to be disclosed pursuant to law, regulation, or court order, the receiving Party shall give the disclosing Party prompt, written notice and, to the extent practical and consistent with the receiving Party's legal obligations (as determined in good faith by counsel to the receiving Party) withhold disclosure to allow the disclosing Party to take whatever action it reasonably deems necessary to protect its Confidential Information. In the event that (i) no protective order or other remedy is obtained, or (ii) the disclosing Party waives compliance with the terms of this Article 9 (*Confidential Information*), or (iii) in the good faith opinion of counsel to the receiving Party, disclosure of the disclosing Party's Confidential information can or should not be withheld to allow (i) or (ii) above, then in each case the receiving Party will furnish only that portion of the Confidential Information which receiving Party is advised by counsel is legally required.

Notwithstanding the foregoing, the receiving Party may disclose the disclosing Party's Confidential Information to the extent that such:

a) is disclosed to governmental or other regulatory agencies in order to obtain and/or maintain patents pursuant to and in accordance with Article 12 (*Intellectual Property*) or to gain or maintain Regulatory Approvals in accordance with a Party's rights to do so under this Agreement, but such disclosure, in each case, may only be to the extent reasonably necessary to obtain and/or maintain patents or Regulatory Approvals and reasonable measures shall be taken to assure confidential treatment of such information;

b) is deemed reasonably necessary by a Party to be disclosed to agents, consultants, Sublicensees and/or other Third Parties for the research, development, manufacturing and/or marketing of

Products (or for such entities to determine their interest in entering into applicable agreements to perform such activities with or for such Party) in accordance with this Agreement provided such Third Parties agree to be bound by confidentiality and non-use provisions no less stringent that those contained in this Agreement for terms of not less than […***…] years; or

c) is deemed necessary by counsel to the receiving Party to be disclosed to (1) such Party's directors, attorneys, auditors and advisors for the sole purpose of enabling such parties to provide advice to the receiving Party, or (2) to […***…], provided such Third Parties agree to be bound by confidentiality and non-use provisions no less stringent that those contained in this Agreement for terms of not less than […***…] years; or

d) is required to be disclosed by the receiving Party defend or prosecute litigation pursuant to and in accordance with Article 12 (*Intellectual Property*), provided that the receiving Party provides prior notice of such disclosure to the other Party and takes reasonable and lawful actions to avoid and/or minimize the degree of such disclosure; or

e) is required to be disclosed by the receiving Party to comply with applicable Laws including disclosure required by the U.S. Securities and Exchange Commission, subject to the second paragraph above and Section 9.3.

9.2 **Publications.** The Parties, through the JDC, will develop a publication plan for the Collaboration, as well as a Joint Publication Practices, Processes, and Policies document that is consistent with the Parties' respective policies and procedures for publication and disclosure of results of clinical trials. During the term of the Transition Program and Collaborative Development Program, each Party will submit to the other Party through the JDC for review and approval all peer-reviewed academic, scientific and medical publications relating to the Development of Compounds or Products. The submitting Party will also provide all data (eg, final protocol, statistical analysis plan, relevant statistical tables generated from the plan, figures, and reports) needed to prepare the publication. Neurocrine agrees that it will, and will cause its Affiliates to, not publish any such publications without the prior written consent of Abbott. The non-publishing Party shall have at least […***…] days to review each proposed publication. The review period may be extended for up to […***…] days in the event the non-publishing Party can demonstrate to the JDC a reasonable need for such extension including, but not limited to, the preparation and filing of patent applications. Such period may be further extended by the JDC. In the event that the two Parties differ in their opinion or interpretation of data in the publication, the parties shall resolve such differences in good faith through appropriate scientific debate. The Parties agree to, and will cause their respective Affiliates to, comply with the ICMJE criteria for authorship of scientific publications and acknowledgement of contributions of other Parties in any publications relating to research or Development of Products. Notwithstanding the foregoing, the Parties shall endeavor as far as possible, for ease and convenience, to agree on a universal basis joint authorship in respect of such publications. After the expiration of the Transition Program and Collaborative Development Program, Neurocrine agrees that it will, and will cause its Affiliates to, not publish any such publications relating to the Compounds or Products without the prior written consent of Abbott.

9.3 **Public Announcements.**

a) Coordination. The Parties agree on the importance of coordinating their public announcements respecting this Agreement and the subject matter thereof (other than academic, scientific or medical publications that are subject to the publication provision set forth above). Neurocrine and Abbott will, from time to time, and at the request of the other Party discuss and agree on the general information content relating to this Agreement and/or Products which may be publicly disclosed.

b) Announcements. The Parties agree that the public announcement of the execution of this Agreement shall be in the form of the press release attached as Exhibit I. Any other publication, news release or other public announcement relating to this Agreement or to the performance hereunder, may only be made by Neurocrine or Abbott with the review and prior written approval of the other Party, […***…]. The party wishing to make a publication, news release or other public announcement hereunder shall provide written notice to the other Party regarding the same. If a publication, news release or other public announcement is agreed upon by both Parties, the other Party shall be allowed to review and comment on the publication, news release or other public announcement. The aforementioned approval procedure and review period in total shall not exceed […***…] days. In no event shall such statements or disclosures disclose, if previously undisclosed, the stage of development of Products and/or the financial terms of the transaction; provided, however, that any disclosure which is required by applicable law, including disclosures required by the U.S. Securities and Exchange Commission or made pursuant to the requirements of the national securities exchange or other recognized stock market on which such Party's securities are traded, as advised by the disclosing Party's counsel, may be made without the prior consent of the other Party, although, to the extent practicable and in opinion of counsel to the disclosing Party consistent with such Party's disclosure obligations, the other Party shall, as far in advance as reasonably practicable but in no event less than […***…] days provide advance notice of any such legally required disclosure to comment and reasonably consider such comments provided by such Party on the proposed disclosure. Notwithstanding the foregoing, with respect to […***…], and is thus […***…], the Parties agree: […***…].

c) Notwithstanding anything to the contrary in this Agreement, but subject to the provisions of Article 9 (*Confidential Information*) and Section 13.19 (*Use Of Names, Logos Or Symbols*), Abbott shall have the right to publicly disclose research, development and commercial information regarding the Compound(s) and Product(s).

ARTICLE TEN – INDEMNIFICATION AND INSURANCE

10.1 **Indemnification by Abbott.** Abbott will indemnify, defend and hold harmless Neurocrine, its licensees, sublicensees and Affiliates, and each of its and their respective employees, officers, directors and agents (each, a "***Neurocrine Indemnified Party***") from and against any and all liability, loss, damage, expense (including reasonable attorneys' fees and expenses) and cost (collectively, a "***Liability***") which the Neurocrine Indemnified Party may be required to pay to one or more Third Parties resulting from or arising out of: (i) any claims of any nature arising out of (y) the conduct of the Product Development or Commercialization by, on behalf of or under authority of, Abbott (other than by a Neurocrine Indemnified Party) or (z) research, Development and/or Commercialization of Products by, on behalf of or under authority of, Abbott (other than by Neurocrine Indemnified Party) and/or (ii) any Abbott representation or warranty set forth herein being untrue in any material respect when made; except in each case, to the extent caused by the negligence or willful misconduct of Neurocrine or any Neurocrine Indemnified Party. Notwithstanding the foregoing, Abbott shall have no obligation to defend, indemnify or hold harmless any Neurocrine Indemnified Party from and against any Liability arising out of or resulting from the infringement of a Third Party Patent Right provided such indemnify does fall within the foregoing indemnification requirements.

10.2 **Indemnification by Neurocrine.** Neurocrine will indemnify, defend and hold harmless Abbott, its licensees, Sublicensees and Affiliates, and each of its and their respective employees, officers, directors and agents (each, a "***Abbott Indemnified Party***") from and against and all Liability which the

Abbott Indemnified Party may be required to pay to one or more Third Parties arising out of (i) any claims of any nature arising out of (x) the conduct of Product Development or Commercialization of by, on behalf of or under authority of, Neurocrine (other than by an Abbott Indemnified Party) or (y) research, Development and/or Commercialization of Products by, on behalf of or under authority of, Neurocrine (other than by an Abbott Indemnified Party) and/or (ii) any Neurocrine representation or warranty set forth herein being untrue in any material respect when made; except in each case, to the extent caused by the negligence or willful misconduct of Abbott or any Abbott Indemnified Party. Notwithstanding the foregoing, Neurocrine shall have no obligation to defend, indemnify or hold harmless any Abbott Indemnified Party from and against any Liability arising out of or resulting from the infringement of a Third Party Patent Right provided such indemnify does fall within the foregoing indemnification requirements.

10.3 **Procedure.** Each Party will provide prompt written notice to the other in the event it becomes aware of a claim for which indemnification may be sought hereunder. In case any proceeding (including any governmental investigation) shall be instituted involving any Party in respect of which indemnity may be sought pursuant to this Article 10, such Party (the "***Indemnified Party***") shall promptly notify the other Party (the "***Indemnifying Party***") in writing. Within […***…] days after delivery of such notification, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such Third Party claim with counsel reasonably satisfactory to the Indemnified Party and control the disposition or settlement thereof (including all decisions relative to litigation, appeal, and settlement subject to this Article). The Indemnified Party shall cooperate fully with the Indemnifying Party in such defense. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense. The Party not controlling such defense may participate therein at its own expense; provided the Indemnified Party shall bear the expense if the named parties to any such proceeding (including any impleaded parties) include both the Indemnifying Party and the Indemnified Party and representation of both parties by the same counsel would be inappropriate due to actual or potential differing interests between them. All such fees and expenses shall be reimbursed as they are incurred, and provided reasonable documentation along with an invoice is provided. The Indemnifying Party shall not be liable for any settlement of any proceeding effected without its prior written consent, but if settled with such prior written consent or if there be a final judgment for the plaintiff, the Indemnifying Party agrees to indemnify the Indemnified Party from and against any Liability by reason of such settlement or judgment. The Indemnifying Party shall not, without the prior written consent of the Indemnified Party, effect any settlement of any pending or threatened proceeding in respect of which the Indemnified Party is, or arising out of the same set of facts could have been, a party and indemnity could have been sought hereunder by the Indemnified Party, unless […***…].

10.4 **Insurance.** Each Party acknowledges that they each maintain and shall, maintain adequate insurance for liability insurance adequately covering such Party's obligations under this Agreement. During the Term Abbott shall maintain comprehensive general liability insurance, including products liability insurance, with reputable and financially secure insurance carriers, or shall provide an explanation of self insurance, in a minimum amount of $[…***…] per occurrence and $[…***…] aggregate prior to first commercial sale and $[…***…] aggregate on and after first commercial sale (exclusive of deductible amounts) as respects personal injury, bodily injury and property damage arising out of a Abbott's Development and Commercialization of Products. Abbott shall provide Neurocrine with evidence of such insurance, upon request. Such insurance shall include Neurocrine as a named insured and shall require prior notice to the Neurocrine before cancellation. Notwithstanding the foregoing, either Party may self-insure in whole or in part the insurance requirements described above, provided such Party continues to be investment grade determined by reputable and accepted financial rating agencies. This Section shall apply *mutatis mutandis* to Neurocrine, in the event Neurocrine obtains a license to Compounds and Products pursuant to Section 11.2(b), 11.3, 11.4, 11.5 and 11.7.

10.5 **Survival**. All obligations of indemnification and insurance imposed under this Article 10 (*Indemnification and Insurance*) shall expire […***…] years following the longer of termination or expiration of this Agreement or, with respect to a particular Party, last sale of a Product sold under this Agreement by a Party.

ARTICLE ELEVEN - TERM AND TERMINATION

11.1 **Term; Effect of Expiration**.

a) Unless earlier terminated by mutual agreement of the Parties, or pursuant to the provisions of this Article 11, this Agreement shall commence on the Effective Date and will continue in full force and effect, on a country by country and Product by Product basis, until the final obligation to pay Royalties with respect to the sale of such Product in a country expires as provided in Article 4 and Abbott's obligations […***…] expire, at which time this Agreement shall expire in its entirety in such country for such Product ("***Term***").

b) On a country by country and Product by Product basis, upon expiration of this Agreement with respect to a Product in a country pursuant to this Section 11.1(a) (*Term*), the license set forth in Section 3.1 (*License*) shall be deemed to be irrevocable, unrestricted, perpetual and fully paid-up with respect to such Product in such country.

11.2 **Termination for Convenience; Effects.**

a) Termination for Convenience. Notwithstanding anything contained herein to the contrary, Abbott shall have the right to terminate this Agreement at any time in its sole discretion by giving Neurocrine one hundred eighty (180) days prior written notice.

b) Effects of Termination. If Abbott terminates this Agreement pursuant to Section 11.2(a), (i) Abbott will pay all amounts due and owing to Neurocrine as of the termination effective date; and (ii) Abbott shall continue to be obligated during the termination notice period to perform all of its obligations under this Agreement, including its obligation to pay all expenses associated with the Transition Program and Collaborative Development Program. In addition, if Abbott terminates this Agreement pursuant to Section 11.2(a):

1) All of Abbott's licenses and rights to the Neurocrine Technology and Neurocrine Patent Rights will terminate;

2) All Neurocrine Confidential Information provided to Abbott in tangible form and all substances or compositions provided by Neurocrine to Abbott will be returned to Neurocrine or destroyed, except that Abbott may retain one copy of the Neurocrine Confidential Information solely for legal archive purposes;

3) All Abbott Confidential Information provided to Neurocrine in tangible form and all substances or compositions delivered or provided to Neurocrine by Abbott shall be returned to Abbott or destroyed, except that Neurocrine may retain one copy of the Abbott Confidential Information solely for legal archive purposes;

4) Abbott will transfer to Neurocrine such […***…] and information reasonably necessary to allow Neurocrine to […***…], including, at Neurocrine's option, exercisable within […***…] days following the effective date of such termination, transfer to Neurocrine of any […***…];

5) Abbott will transfer to Neurocrine any […***…];

6) Abbott will transfer and assign ownership to Neurocrine of all […***…] as well as (1) a copy of the […***…], (2) copies of […***…], and access to the […***…], (3) copies of all documents […***…], (4) access to […***…] (5) copies of correspondence with […***…] and (6) access to information Abbott determines is relevant to […***…];

7) At Abbott's option, Abbott will either […***…], provided, if Abbott […***…]; and

8) Abbott will grant to Neurocrine an […***…] license under the Abbott Technology, Abbott Patent Rights, […***…] and […***…] to make, have made, use, import, offer for sale and sell Compounds and Products.

9) The […***…] pursuant to subsections 7 and 8 above, shall be […***…]. Subject to […***…], if there is a termination […***…] pursuant to […***…], then the parties shall negotiate in good faith […***…], whereby the Parties shall take into consideration: […***…].

11.3 **Termination if Abbott** […***…]. In the event Abbott, Abbott's Affiliates or Sublicensees […***…], Neurocrine shall have the right to terminate this Agreement upon […***…] days written notice to Abbott. Any such termination shall only become effective if Abbott or its Affiliate or Sublicensees, as applicable, has not […***…] before the end of the above notice period and the provisions of Section 11.2(b) shall apply *mutatis mutandis* to termination pursuant to this Section.

11.4 **Termination for Cause.**

a) Termination for Cause. If either Party (the "***Notifying Party***") believes that the other Party (the "***Other Party***") is in Default of this Agreement, then the Notifying Party may deliver notice of such breach to the Other Party.

1) If the Other Party disputes that it is in Default of this Agreement, the matter shall be handled pursuant to Section 13.2 (*Dispute Resolution*). If the neutral renders a ruling that the Other Party is in Default of this Agreement (the "***Adverse Ruling***"), such ruling shall also specify the actions to be taken by the Other Party to cure such Default, which actions must be completed within […***…] days after such ruling (or […***…] days if such Default relates […***…]). If the Other Party has failed to comply with the terms of the Adverse Ruling within such […***…] or […***…] day period, as applicable, or if such compliance cannot be fully achieved within such […***…] day or […***…] day period, the Other Party has failed to commence compliance and/or has failed to use diligent efforts to achieve full compliance as soon thereafter as is reasonably possible, then the Notifying Party shall have the following rights:

a) where […***…] is the Other Party and where the basis for such Default is […***…] failure to abide by a material obligation under this Agreement with respect to […***…] may terminate this Agreement with respect […***…] by delivering written notice to […***…] of such termination; and

b) notwithstanding (A) above, where […***…] is the Other Party and where the basis for such breach is […***…] may terminate this Agreement by delivering written notice to […***…] of such termination; and

c) where […***…] is the Other Party, […***…] may terminate this Agreement by delivering written notice to […***…] of such termination.

2) If the Other Party does not dispute that it has committed a material breach of this Agreement, then if the Other Party fails to cure such breach, or take steps as would be considered reasonable to effectively cure such breach, within […***…] (or […***…] days if such Default relates to […***…]), after receipt of notice as provided above, the the provisions of Section 11.4(1)(a)(b) or (c) shall apply.

b) Effect of Termination for Cause. If a Party terminates this Agreement pursuant to Section 11.4(a), the Parties shall have the rights set forth below, each measured from the date written notice of such termination is given to the Other Party.

(i) Neurocrine. Where Neurocrine is the Other Party and Abbott terminated […***…] pursuant to 11.4(a), Abbott may in its sole discretion: (i) […***…] and (ii) […***…]. Except as set forth in this clause (a): all rights and obligations under this Agreement shall survive such termination and continue unaffected , subject to […***…], as determined in accordance with Section 13.2 (*Dispute Resolution*).

(ii) Abbott. Where Abbott is the Other Party and Neurocrine terminated […***…] pursuant to 11.4(a), the provisions of Section 11.2(b) shall apply provided however, that if this Agreement is terminated only with respect to […***…], the provisions of Section 11.2(b) shall apply *mutatis mutandis* to termination by Neurocrine pursuant to this Section but only with respect to […***…].

11.5 **Bankruptcy.** Each Party may, in addition to any other remedies available to it by Law or in equity, exercise the rights set forth below by written notice to the other Party (the "***Insolvent Party***"), in the event the Insolvent Party shall have become insolvent or bankrupt, or shall cease conducting business in the ordinary course, or shall have made an assignment for the benefit of its creditors, or there shall have been appointed a trustee or receiver of the Insolvent Party or for all or a substantial part of its property, or any case or proceeding shall have been commenced or other action taken by or against the Insolvent Party in bankruptcy or seeking reorganization, liquidation, dissolution, winding-up arrangement, composition or readjustment of its debts or any other relief under any bankruptcy, insolvency, reorganization or other similar act or Law of any jurisdiction now or hereafter in effect, or there shall have been issued a warrant of attachment, execution, distraint or similar process against any substantial part of the property of the Insolvent Party, and any such event shall have continued for sixty (60) days undismissed, unbonded and undischarged.

All rights and licenses granted under or pursuant to this Agreement by Neurocrine and Abbott are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code or its foreign equivalent, licenses of rights to "intellectual property" as defined under Section 101

of the Bankruptcy Code or its foreign equivalent. The Parties agree that the Parties as licensees of such rights under this Agreement shall retain and may fully exercise all of their rights and elections under the Bankruptcy Code or its foreign equivalent. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the Bankruptcy Code or its foreign equivalent, the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and the same, if not already in the other Party's possession, shall be promptly delivered to other Party (i) upon any such commencement of a bankruptcy proceeding upon its written request therefore, unless the Party subject to such proceeding elects to continue to perform all of their obligations under this Agreement or (ii) if not delivered under (i) above, upon the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefore by the other Party.

a) Neurocrine. In the event Neurocrine is the Insolvent Party, in addition to any other remedies available to Abbott at Law or in equity, Abbott may in its sole discretion (i) […***…]. Except as set forth in this clause (a), all rights and obligations under this Agreement shall survive such termination and continue unaffected upon Neurocrine becoming an Insolvent Party, unless this Agreement is terminated by Abbott pursuant to Section 11.2(a).

b) Abbott. In the event Abbott is the Insolvent Party, in addition to any other remedies available to Neurocrine at Law or in equity, Neurocrine may terminate this Agreement and the provisions of Section 11.2(b) shall apply to termination by Neurocrine pursuant to this Section.

11.6 **Change of Control.** In the event of a Change of Control of Neurocrine, Abbott may in its discretion within […***…] days following the Change of Control elect some or all of the following:

a) with no less than […***…] prior written notice […***…] and thereafter […***…];

b) with no less than […***…] prior written notice, terminate […***…];

c) Abbott may elect to require Neurocrine and the Change of Control party to adopt […***…];

d) Abbott may elect to terminate the […***…];

e) All other rights and obligations under this Agreement shall continue unaffected upon a Change of Control, unless this Agreement is terminated pursuant to this Agreement.

11.7 **Divestiture by** […***…]**.** If in connection with any proposed acquisition, merger, or agreement, […***…] determines that in order to […***…], it would be advisable, in […***…] business judgment, […***…] shall notify […***…] thereof […***…].

If […***…] in good faith believes, based on a determination made by […***…], that it is capable of […***…] shall have […***…] days from […***…] to (i) […***…] and (ii) […***…]. Upon receipt of […***…] notice hereunder, […***…] shall […***…]. […***…] shall be free at any and all times to […***…]; provided however, […***…] shall provide to […***…] notice of […***…] and […***…] shall have […***…] days following receipt of such notice to […***…].

11.8 **Debarment and Exclusion**.

a) Neurocrine represents and warrants that prior to the Effective Date neither it, nor any of its employees, nor […***…] each of its consultants, or independent contractors or any other person working on its behalf that provided services in connection with an NDA for a Product, were at the time the services were performed a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual, or after the services were performed, […***…] became a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual due to actions related to the services in connection with an NDA for a Product.

b) Neurocrine covenants that with respect to work conducted pursuant to the Transition Plan and Collaborative Development Plan neither it, nor any of its employees, nor […***…] each of its consultants, or independent contractors and any other person working on its behalf that provide services in connection with an NDA for a Product (i) will be at the time services are performed a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual or (ii) […***…] are currently the subject of a proceeding that could lead to it or such employees, consultants, independent contractors, becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual.

c) Abbott covenants that neither it, nor any of its employees, nor […***…] each of its consultants, or independent contractors or any other person working on its behalf that provide services in connection with an NDA for a Product, (i) will be at the time services are performed a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual or (ii) […***…] are currently the subject of a proceeding that could lead to it or such employees, consultants, independent contractors, becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual.

d) Each Party covenants, represents and warrants that if, during the Term, it, or any of its employees, consultants, independent contractors, or any other person working on its behalf that provided services or are providing services in connection with an NDA for a Product becomes, as applicable, a Debarred Entity, or Debarred Individual, an Excluded Entity or Excluded Individual, a Convicted Entity, or Convicted Individual, it shall immediately notify the other Party. The parties shall serve said written notice in accordance with Section 13.4 (*Notices*).

e) Upon breach of this Section 11.7, the […***…].

For purposes of this provision, the following definitions shall apply

a) A “Debarred Individual” is an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from providing services in any capacity to a person that has an approved or pending drug or biological product application.

b) A “Debarred Entity” is a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of a Debarred Entity.

c) An “Excluded Individual” or “Excluded Entity” is (i) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services, or (ii) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA).

d) A “Convicted Individual” or “Convicted Entity” is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §335a (a) or 42 U.S.C. §1320a - 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

11.9 **Liabilities.** Termination of this Agreement shall not release either Party from any obligation or liability which shall have accrued at the time of termination, or preclude either Party from pursuing all rights at Law and in equity with respect to any Default under this Agreement.

11.10 **LIMITATION ON LIABILITY**. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT OR OTHERWISE, EXCEPT FOR THE WILLFUL MISCONDUCT OF A PARTY OR ITS AFFILIATES, OR A MATERIAL BREACH OF THE CONFIDENTIALITY AND INTELLECTUAL PROPERTY PROVISIONS, NEITHER PARTY SHALL BE LIABLE TO THE OTHER WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT, WHETHER UNDER CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY FOR ANY INCIDENTAL, INDIRECT, SPECIAL, EXEMPLARY, PUNITIVE, MULTIPLE OR CONSEQUENTIAL DAMAGES EXCEPT SUCH DAMAGES OWED TO THIRD PARTIES EXPRESSLY PROVIDED IN THIS AGREEMENT.

11.11 **Survival**. Upon expiration or termination of this Agreement the following provisions shall expressly survive any such expiration or termination: Articles 1, 12, and 13 and Sections 2.6, 3.5, 3.6, 11.1(c), 11.2(b), 11.4(b), 11.5(a) and 11.5(b), 11.8, 11.9, 11.10, and this 11.11 and the following provisions shall expressly survive any such expiration or termination for the period stated therein: Articles 9, 10, and Section 4.7(g).

ARTICLE TWELVE - INTELLECTUAL PROPERTY

12.1 **Ownership, Filing, Prosecution and Maintenance.**

a) Abbott Patent Rights. Abbott shall solely own and shall, at its expense, be solely responsible for the preparation, filing, all prosecution matters, including all inter parte and ex parte patent office submissions, procedural decisions and patent office adversarial proceedings, for example, requests for, or filing or declaration of, interference or opposition, or reexamination (collectively, “Prosecution”) and maintenance of Abbott Patent Rights. Abbott shall have no obligation to continue the Prosecution and/or maintenance of any Abbott Patent Right in any country and shall be free to abandon such Abbott Patent Rights at its sole discretion.

b) Program Patent Rights. Abbott shall solely own and shall, at its expense, be solely responsible for the preparation, filing, Prosecution and maintenance of Program Patent Rights. Neurocrine agrees that it will, and will cause its Affiliates to, (i) execute and file those notices and other filings as Abbott shall request be made, from time to time, with the United States Patent and Trademark Office (or any successor agency) or any analogous patent office in the Territory with respect to the rights granted under this Agreement, and (ii) execute and deliver to Abbott all assignments and other instruments as Abbott shall request to effect the ownership, filing, Prosecution and maintenance of Program Patent Rights. Abbott will keep Neurocrine reasonably informed of the status of the Program Patent Rights and will provide Neurocrine with copies of all substantive documentation submitted to, or received from, the patent offices in connection therewith. With respect to any substantive submissions that Abbott is required to or otherwise intends to submit to a patent office, Abbott shall provide a draft of such submission to Neurocrine at least […***…] days prior to the deadline or intended filing date, whichever is earlier, for submission of such documentation. Neurocrine shall have the right to review and comment upon any such submission by Abbott to a patent office, and will provide such comments, if any, no later than […***…] days prior to the applicable deadline or intended filing date provided that Abbott shall not be obligated to incorporate comments provided by Neurocrine. Abbott shall have the right to cease the Prosecution and/or maintenance of, or not to pursue, or cease to pay the expenses of Prosecution or maintenance of, any Program Patent Right in any country in which such Program Patent Right has been filed. In all cases, Abbott shall have final decision-making authority with respect to the filing, Prosecution, and maintenance of Program Patent Rights.

c) Neurocrine Patents.

(i) Neurocrine shall solely own the Neurocrine Patent Rights and shall be responsible for, through […***…] counsel reasonably acceptable to Abbott, the preparation, filing, Prosecution (except as provided in Article 12.1(c)(ii)) and maintenance of Neurocrine Patent Rights. […***…]. Neurocrine will keep Abbott fully informed of all significant steps to be taken in the preparation and Prosecution of all patent applications and any subsequent actions to be taken with respect to issued patents within the Neurocrine Patents and Neurocrine shall furnish Abbott with copies of any such applications, amendments thereto and other related […***…] correspondence to and from patent offices and patent associates to allow for review by and consultation with Abbott reasonably in advance of any submission to a patent office which could […***…] affect the scope or validity of the patent coverage that may result. Copies of all such applications filed prior to the Effective Date shall be provided to Abbott promptly after the Effective Date. With respect to any substantive submissions that Neurocrine is required to or otherwise intends to submit to a patent office, Neurocrine shall provide a draft of such submission to Abbott at least […***…] days prior to the deadline or intended filing date, whichever is earlier, for submission of such documentation. Abbott shall have the right to review and comment upon any such submission by Neurocrine to a patent office, and will provide such comments, if any, no later than […***…] days prior to the applicable deadline or intended filing date. Neurocrine shall also act on recommendations Abbott may make with respect to issued patents within the Neurocrine Patent Rights.

(ii) Notwithstanding the foregoing, Neurocrine shall promptly inform Abbott of any adversarial patent office proceeding, including, but not limited to a request for, or filing or declaration of, any interference, opposition, or reexamination relating to Neurocrine Patent Rights. Abbott and Neurocrine shall thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding and Neurocrine shall incorporate all comments provided by Abbott. Neurocrine shall not initiate any reexamination, interference

or reissue proceeding relating to Neurocrine Patent Rights without the prior written consent of Abbott.

(iii) In the event that Neurocrine disagrees with any comment or suggestion provided by Abbott under Section 12.1(i) or Section 12.1(ii), Neurocrine shall provide Abbott with a written explanation detailing the basis for such disagreement. If Abbott does not accept Neurocrine's explanation, Abbott shall have final decision-making authority with respect to the matter in dispute.

d) Abandonment of Patent Rights. Abbott may elect to discontinue payment for the costs and expenses of preparation, filing, Prosecution, validation or maintenance of any Program Patent Right pursuant to Section 12.1(b) or Neurocrine Patent Right pursuant to Section 12.1(c) on a country-by-country and application-by-application or patent-by-patent basis, at any time and in its sole discretion. If Neurocrine thereafter chooses to resume the preparation, filing, Prosecution, validation or maintenance of any Program Patent Rights […***…] or Neurocrine Patent Right, the licenses to Abbott hereunder with respect to such applications or patents shall terminate and Neurocrine will own sole right, title and interest in and to such applications or patents.

e) Trademarks. Abbott shall solely own and shall, at its expense, be solely responsible for the development, selection, filing prosecution, enforcement, and maintenance of the Trademarks. Abbott shall have no obligation to continue the prosecution and/or maintenance of any Trademark in any country and shall be free to abandon such Trademark at its sole discretion. Neurocrine agrees, at its own expense, to cooperate with Abbott in the protection of the Trademarks by executing documents, and by taking any other action reasonably requested by Abbott to effectuate the intent of this Section 12.1(e). Neurocrine also agrees not to take any action detrimental to Abbott's interest in the Trademarks. Neurocrine agrees to notify Abbott immediately if Neurocrine becomes aware of any infringement of the Trademarks. Abbott shall have the sole right but no obligation to initiate any legal proceedings alleging infringement of the Trademarks.

12.2 **Extension of Patent Rights.** At the time of the granting of approval of an NDA or equivalent in any country in respect of a Product, Abbott shall have the exclusive right, but not the obligation, to seek, in Neurocrine's name if so required, patent term extensions or supplemental patent protection in any country in the Territory in respect of a Neurocrine Patent Right, Program Patent Right or Abbott Patent Right. Abbott shall use Commercially Reasonable Efforts to obtain such patent term extensions or supplement protection, where applicable. Neurocrine and Abbott shall cooperate in connection with all such activities, and Abbott, its agents and attorneys will give due consideration to all suggestions and comments of Neurocrine regarding any such activities, but in the event of a disagreement between the parties, Abbott will have the final decision-making authority. In the case where Abbott determines to seek such patent term extensions or supplement patent protection in respect of a Neurocrine Patent Right, Neurocrine shall appoint Abbott or its designee as Neurocrine's agent for the sole purpose of submitting an application to extend the term of such patent, an application for a Supplementary Protection Certificate, or an equivalent thereof. Neurocrine shall co-operate with Abbott or its designee in connection with any such application.

12.3 **Enforcement and Defense of Patent Rights.**

a) Notification. Each Party shall promptly notify each other of any infringement, alleged infringement or non-patent office adverserial proceeding challenging the validity or enforceability of the Neurocrine Patent Rights or Program Patent Rights. In the event of a

notification under 21 U.S.C. §355(b)(2)(A)(iv) or 355(j)(2)(A)(vii) (IV) concerning Neurocrine Patent Rights or Program Patent Rights, then the Party receiving the notice shall provide a copy of such notice to the other Party within […***…] days after its receipt thereof.

b) Abbott shall have the sole right, but not the obligation, in its own name, to (i) enforce Neurocrine Patent Rights and Program Patent Rights against any Third Party suspected of infringing a claim of such a Patent Right in the Territory, and (ii) defend Neurocrine Patent Rights and Program Patent Rights against any Third Party asserting that a claim of such a Patent Right is invalid or unenforceable. Neurocrine, upon request of Abbott, shall reasonably cooperate with Abbott in any such litigation, or file such action in Neurocrine's name, if required, at Abbott's expense and shall join in any such litigation at Abbott's request and expense. Abbott shall have exclusive control over the conduct of any such proceedings, including the right to not bring an action, settle or compromise such proceedings. Any award or recovery paid to Abbott by a Third Party as a result of such patent infringement or defense proceedings (whether by way of settlement or otherwise) shall first be applied toward reimbursement of legal fees, costs and expenses incurred by Abbott, and from the remainder, if any, […***…]. Any excess shall be […***…].

c) In the event Abbott shall not elect to enforce or defend any such Patent Right in the Territory pursuant to 12.3(b), it may grant, in its sole discretion, such right to Neurocrine and Neurocrine shall have the sole right, but not the obligation, in its own name, to (i) enforce Neurocrine Patent Rights and Program Patent Rights against any Third Party suspected of infringing a claim of such a Patent Right in the Territory, and (ii) defend Neurocrine Patent Rights and Program Patent Rights against any Third Party asserting that a claim of such a Patent Right is invalid or unenforceable. Abbott, upon request of Neurocrine, shall reasonably cooperate with Neurocrine in any such litigation, or file such action in Abbott's name, if required, at Neurocrine's expense and shall join in any such litigation at Neurocrine's request and expense. Neurocrine shall have exclusive control over the conduct of any such proceedings, including the right to not bring an action, settle or compromise such proceedings. Any award or recovery paid to Neurocrine by a Third Party as a result of such patent infringement proceedings (whether by way of settlement or otherwise) shall first be applied toward reimbursement of legal fees, costs and expenses incurred by Neurocrine, and the excess, if any shall be […***…].

12.4 **Infringement Defense.** Abbott will be responsible for defending and controlling any suit against any of Abbott, Abbott's Affiliates or Sublicensees, alleging infringement of any patent or other intellectual property right of a Third Party arising out of the manufacture, use, sale, offer to sell or importation of a Product by Abbott, Abbott's Affiliates or Sublicensees in the Territory. Abbott shall be responsible for the costs and expenses, including legal fees and costs, associated with any suit or action. Upon Abbott's request, Neurocrine will consult with Abbott and co-operate in the defense of any such action. If Abbott finds it necessary or desirable to join Neurocrine as a party to any such action, Neurocrine will execute all papers and perform such acts as shall be reasonably required, at Abbott expense.

12.5 **Inventorship.** Inventorship with respect to all Patent Rights under this Agreement shall be determined according to United States Law.

12.6 **Hold Harmless.** The Parties hereby agree to hold each other harmless in respect of their good faith activities hereunder to file, prosecute, maintain, enforce and defend Patent Rights under this Article 12.6.13.

ARTICLE THIRTEEN – MISCELLANEOUS

13.1 **Governing Law.** This Agreement (and any claims or disputes arising out of or related thereto or to the transactions contemplated thereby or to the inducement of a Party to enter therein, whether for breach of contract, tortious conduct, or otherwise and whether predicated on common law, statute or otherwise) shall be governed by and interpreted in accordance with the internal laws of […***…], including all matters of construction, validity and performance, and in each case without regard to its conflicts of laws rules that might lead to the application of the laws of any other jurisdiction. Notwithstanding the foregoing, questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent shall have been granted.

13.2 **ADR**. If a dispute arises between the Parties, the Parties will follow the procedures set forth in Exhibit H.

13.3 **Waiver.** Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party or Parties waiving such term or condition. Neither the waiver by any Party of any term or condition of this Agreement nor the failure on the part of any Party, on one or more instances, to enforce any of the provisions of this Agreement or to exercise any right or privilege, shall be deemed or construed to be a waiver of such term or condition for any similar instance in the future or of any subsequent breach hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be a limitation of any other remedy, right, undertaking, obligation or agreement.

13.4 **Notices.** All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address below and shall be: (a) delivered personally; (b) sent by registered or certified mail, return receipt requested, postage prepaid; (c) sent via a reputable nationwide overnight courier service; or (d) sent by facsimile transmission. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if

delivered by hand, three (3) business days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) business day after it is sent via a reputable nationwide overnight courier service, or when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is on a business day; otherwise, on the next business day following such transmission).

Notices to Abbott shall be addressed to:

Abbott International Luxembourg S.à r.l.
26, Boulevard Royal
L-2449 Luxembourg
Luxembourg
Attention: Treasurer, Logistics

With a copy to:
Abbott International Luxembourg S.à r.l
c/o Abbott Laboratories
Pharmaceutical Products Group
100 Abbott Park Road
Abbott Park, IL 60064-3500
Attention: Executive Vice President
Facsimile No.: […***…]

Abbott Laboratories
Pharmaceutical Products Group Legal Operations
Bldg. AP6A-2
100 Abbott Park Road
Abbott Park, IL 60064-3500
Attention: DVP & Associate General Counsel
Fax: […***…]

Notices to Neurocrine shall be addressed to:

Neurocrine Biosciences, Inc.
12780 El Camino Real
San Diego, California 92130

Attention: Chief Executive Officer and President
Fax: […***…]
with a copy to: General Counsel
Fax: […***…]

Either Party may change its address by giving notice to the other Party in the manner provided above.

13.5 **Entire Agreement.** This Agreement (including Exhibits and Schedules), contains the complete understanding of the Parties with respect to the subject matter hereof and supersedes all prior agreements or understandings between the Parties with respect to the subject matter hereof, including the Confidential Disclosure Agreement between the Parties, dated […***…]. None of the terms of this Agreement shall be amended, supplemented or modified except in writing signed by duly authorized representatives of the Parties hereto.

13.6 **Headings; References.** Headings in this Agreement are for convenience of reference only and shall not be considered in construing this Agreement. References to Articles, Sections, Exhibits and Schedules are to Articles, Sections, Exhibits and Schedules of this Agreement unless otherwise specified.

13.7 **Severability.** If and solely to the extent that any provision of this Agreement shall be invalid or unenforceable, or shall render this entire Agreement to be unenforceable or invalid, such offending provision shall be of no effect and shall not effect the validity of the remainder of this Agreement or any of its provisions; provided, however, the Parties shall use their respective reasonable efforts to renegotiate the offending provisions to best accomplish the original intentions of the Parties.

13.8 **Registration and Filing of the Agreement.** To the extent, if any, that counsel of a Party concludes in good faith that it is required under applicable Laws to file or register this Agreement or a notification thereof with any Governmental Authority, including without limitation the US Securities and Exchange Commission, or the US Federal Trade Commission, in accordance with applicable Laws, such Party may do so and shall provide the other Party to this Agreement with a written copy of all proposed filings or registrations to allow for a reasonably sufficient time for review and comment by the other Party. The other Party shall cooperate in such filing or notification and shall execute all documents reasonably required in connection therewith. If confidential treatment of sensitive provisions of the Agreement is available, the Parties will request such treatment and file a redacted copy of this Agreement mutually agreed to promptly following the Effective Date. The Parties shall promptly inform each other as to the activities or inquiries of any such Governmental Authority relating to this Agreement, and shall cooperate to respond to any request for further information therefrom.

13.9 **Assignment.** Except as expressly set forth herein, this Agreement may not be assigned or transferred, nor may any right or obligation hereunder be assigned or transferred without the prior written consent of the other Party.

a) Abbott may assign this Agreement, in whole or in part, to an Affiliate of Abbott or in whole to a Third Party in connection with the transfer or sale of all or substantially all of business unit which relates to this Agreement, or to a Third Party in the event of its merger, consolidation, change in control or similar transaction.

b) Neurocrine may assign this Agreement to the surviving entity in a merger, consolidation, reorganization or similar transaction of Neurocrine with another person that does not constitute a Change of Control, provided the management and Board of Directors of the surviving entity are predominantly comprised of the Neurocrine management and Board of Directors immediately preceding the transaction.

c) Subject to Section 11.6 (*Change of Control*), Neurocrine may assign this Agreement to a Change of Control party.

Any attempted assignment not in accordance with this Section 13.9 shall be void.

13.10 **Successors and Assigns.** This Agreement will be binding on and inure to the benefit of successors and permitted assigns.

13.11 **Counterparts.** This Agreement may be executed in any number of counterparts, each of which, when executed, shall be deemed an original and all of which together shall constitute one and the same instrument. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail shall be deemed to be original signatures.

13.12 **Force Majeure.** The Parties agree that, if either of them find themselves wholly or partially unable to fulfill their respective obligations in this Agreement by reasons of Force Majeure, the Party affected will advise the other Party in writing of its inability to perform giving a detailed explanation of the occurrence of the event which excuses performance as soon as possible after the cause or event has occurred. If said notice is given, the performance of the Party giving the notification, except for the payment of funds and except as otherwise expressly provided in this Agreement, shall be abated, and any time deadlines shall be extended, for so long as performance may be prevented by such event of Force Majeure. Except as otherwise expressly provided in this Agreement and except for the payment of funds that are due and payable, neither Party shall be required to make up any performance that was prevented by Force Majeure.

13.13 **Non-Solicitation of Employees.** Commencing on the Effective Date and for a period of […***…] thereafter, neither Party shall, directly or indirectly, actively recruit, or solicit any employee of the other Party with whom such Party has come into contact or interacted for the purposes of performing this Agreement, without the prior consent of the other Party For purposes of this Section, "solicit" shall be deemed not to include: (a) circumstances where an employee of one Party or any of its Affiliates initially contacts the other Party, or any of such Party's Affiliates, seeking employment or (b) general solicitations of employment not specifically targeted at such employees.

13.14 **Third Party Beneficiaries.** Except as provided in Article 10 (*Indemnification and Insurance*), None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including, any creditor of either Party hereto. Except as provided in Article 10 (*Indemnification and Insurance*), no such Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against either Party hereto.

13.15 **Relationship of the Parties.** Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other except as expressly provided in this Agreement. Neither Party shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, each Party's legal relationship under this Agreement to the other Party shall be that of independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint venturers between the Parties.

13.16 **Further Assurances.** Following the date hereof, Neurocrine and Abbott shall, and shall cause each of their respective Affiliates to, from time to time, execute and deliver such additional instruments, documents, conveyances or assurances and take such other actions as shall be

necessary or otherwise reasonably requested by Abbott or Neurocrine, to confirm and assure the rights and obligations provided for in this Agreement, and render effective the consummation of the transactions contemplated thereby provided however that neither Party will be required under this Section 13.16 to deliver instruments, documents, conveyances or assurances of any third Party.

13.17 **Waiver of Rule of Construction.** Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

13.18 **Cumulative Remedies.** No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Law.

13.19 **Use Of Names, Logos Or Symbols**. No Party shall use the name, trademarks, logos, physical likeness, employee names or owner symbol of the other Party for any promotional or publicity purpose without the other Party's prior written consent. The restrictions imposed by this Section 13.19 shall not prohibit either Party from making any disclosure identifying the other Party that is required by Law or the requirements of a national securities exchange or similar regulatory body, provided the procedures set forth in Section 9.3(b) (*Announcements*) are followed. Nothing contained in this Agreement shall be construed as granting either Party any rights or license to use any of the other Party's trademarks or trade names without separate, express written permission of the owner of such trademark or trade name or name.

13.20 **Exhibits; Schedules**. In the event of inconsistencies between this Agreement and any exhibits, schedules or attachments hereto, the terms of this Agreement shall control.

[The remainder of this page is intentionally blank]

IN WITNESS WHEREOF, the Parties have signed this Agreement as of the date first written above.

ABBOTT INTERNATIONAL LUXEMBOURG S.À R.L

/s/ William J. Chase

By: William J. Chase
Title: Vice President, Corporate Licensing and Acquisitions

NEUROCRINE BIOSCIENCES, INC.

/s/ Kevin C. Gorman

By: Kevin C. Gorman
Title: President and Chief Executive Officer

Exhibit A

Elagolix

[…***…]

***** Confidential Treatment Requested**

Exhibit B

Follow-On Compounds

[…***…]

***** Confidential Treatment Requested**

Exhibit C

Neurocrine Patent Rights

[…***…]

***** Confidential Treatment Requested**

Exhibit D
Third Party Development Contracts

[…***…]

***** Confidential Treatment Requested**

Exhibit E
Third Party Manufacturing Contracts

[…***…]

***** Confidential Treatment Requested**

Exhibit F
Transition Plan

[…***…]

***** Confidential Treatment Requested**

Exhibit G
Collaborative Development Plan

[…***…]

***** Confidential Treatment Requested**

Exhibit H
ALTERNATIVE DISPUTE RESOLUTION

[…***…]

***** Confidential Treatment Requested**

Exhibit I
PRESS RELEASE

ABBOTT PARK, Ill. and SAN DIEGO, June 16 /PRNewswire-FirstCall/ — Abbott (NYSE: ABT) and Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced that they have entered into a collaboration agreement to develop and commercialize elagolix for the treatment of endometriosis-related pain. Elagolix is a novel, first-in-class oral gonadotropin-releasing hormone (GnRH) antagonist, which has recently completed a phase IIb study in endometriosis. In addition to endometriosis, elagolix will be evaluated for the treatment of uterine fibroids.

“Extensive preclinical and clinical experience with elagolix suggests this drug could be an important advance for women with endometriosis and uterine fibroids, highly prevalent conditions where there is a need for new treatments,” said John Leonard, M.D., senior vice president, pharmaceuticals, research and development, Abbott. “This agreement enhances Abbott’s late stage pipeline, with the potential for additional compounds in earlier stage development.”

Under the terms of the agreement, Abbott will receive worldwide exclusive rights to develop and commercialize elagolix and all next-generation GnRH antagonists for women’s and men’s health. Abbott will make an upfront payment of $75 million and will fund all ongoing development activities. Neurocrine is eligible to receive additional milestone payments of approximately $500 million from Abbott for the achievement of certain development, regulatory and commercial milestones; funding for certain internal collaboration expenses; plus royalty payments on any future product sales.

“We are pleased to have one of the world’s most admired companies as our partner in developing our entire GnRH portfolio for both women’s and men’s health indications,” said Kevin Gorman, president and chief executive officer, Neurocrine Biosciences. “Abbott shares our long-term vision for elagolix, and, together, we look forward to bringing this important new treatment option to endometriosis and uterine fibroid sufferers.”

About GnRH and Elagolix

Elagolix inhibits gonadatropin releasing hormone (GnRH) receptors in the pituitary gland and ultimately reduces circulating sex hormone levels. Elagolix has a unique profile that allows partial estrogen suppression. It maintains estradiol in the low-normal range, providing symptom reduction while avoiding significant bone loss or other adverse effects that can sometimes be associated with excessive suppression of estrogen. In Phase II studies, elagolix has been found to be effective in reducing the pain associated with endometriosis. To date, elagolix has been studied in 18 clinical trials totaling more than 1,000 subjects.

About Endometriosis and Uterine Fibroids

Endometriosis is associated with a multitude of symptoms, some of the most common of which include pain related both to menstruation (dysmenorrhea) as well as chronic pelvic pain

throughout the menstrual cycle, and infertility. The World Endometriosis Research Foundation estimates that there are approximately 100 million women worldwide who suffer from endometriosis. With annual healthcare costs and endometriosis-related productivity losses of approximately $4,000 per patient, the annual direct and indirect costs of endometriosis are estimated to exceed $20 billion in the United States alone.

Uterine fibroids are benign tumors that form on the wall of the uterus. They are the most common type of growth found in a woman's pelvis and are most common in women aged 30-40 years. While many women do not have symptoms, depending on the size, location and number, uterine fibroids can cause heavy menstrual bleeding, can put pressure on the bladder and rectum, and can cause pain and nausea. Symptoms can also include miscarriages and infertility. Depending on the symptoms, treatment sometimes requires surgery.

About Neurocrine Biosciences

Neurocrine Biosciences is a biopharmaceutical company focused on neurological and endocrine diseases and disorders. Our product candidates address some of the largest pharmaceutical markets in the world including endometriosis, anxiety, depression, pain, diabetes, irritable bowel syndrome, insomnia, and other neurological and endocrine related diseases and disorders. Neurocrine Biosciences news releases are available through the Company's website at http://www.neurocrine.com.

About Abbott Laboratories

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs approximately 83,000 people and markets its products in more than 130 countries. Abbott's news releases and other information are available on the company's website at www.abbott.com

Neurocrine Biosciences Forward Looking Statement

In addition to historical facts, this press release may contain forward-looking statements that involve a number of risks and uncertainties. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties associated with Neurocrine's business and finances in general, as well as risks and uncertainties associated with the Company's GnRH program and Company overall. Specifically, the risks and uncertainties the Company faces with respect to the Company's GnRH program include, but are not limited to, risk that the elagolix clinical trials will fail to demonstrate that elagolix is safe and effective; risk that elagolix will not proceed to Phase III clinical trials; risk associated with the Company's dependence on Abbott for Phase III development, commercial manufacturing and marketing and sales activities. With respect to its pipeline overall, the Company faces risk that it will be unable to raise additional funding required to complete development of all of its product candidates; risk relating to the Company's dependence on contract manufacturers for clinical drug supply; risks associated with the Company's dependence on corporate collaborators for commercial manufacturing and marketing and sales

activities; uncertainties relating to patent protection and intellectual property rights of third parties; risks and uncertainties relating to competitive products and technological changes that may limit demand for the Company's products; and the other risks described in the Company's report on Form 10-K for the year ended December 31, 2009 and reports on Form 10-Q for the quarter ended March 31, 2010. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

Abbott Forward Looking Statement

Some statements in this news release may be forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. Abbott cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Economic, competitive, governmental, technological and other factors that may affect Abbott's operations are discussed in Item 1A, "Risk Factors," to our Annual Report on Securities and Exchange Commission Form 10-K for the year ended Dec. 31, 2009, and in Item 1A, "Risk Factors," to our Quarterly Report on Securities and Exchange Commission Form 10-Q for the period ended March 31, 2010, and are incorporated by reference. Abbott undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments.

EXHIBIT 21.1

NEUROCRINE BIOSCIENCES INC. SUBSIDIARIES

NAME OF SUBSIDIARY	JURISDICTION
Neurocrine Continental, Inc.	Delaware, USA
Neurocrine Europe, Ltd.	Ireland
Neurocrine Therapeutics, Ltd.	Ireland

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-194123) of Neurocrine Biosciences, Inc.,

(2) Registration Statements (Form S-8 Nos. 333-105907, 333-135909, 333-147120, 333-152689, and 333-160934) pertaining to the 2003 Incentive Stock Plan, as amended, of Neurocrine Biosciences, Inc.,

(3) Registration Statement (Form S-8 No. 333-127214) pertaining to the Employment Commencement Nonstatutory Stock Option with Richard Ranieri and 2003 Incentive Stock Plan, as amended, of Neurocrine Biosciences, Inc.,

(4) Registration Statement (Form S-8 No. 333-118773) pertaining to the Employment Commencement Nonstatutory Stock Option and 2003 Incentive Stock Plan, as amended May 25, 2004 and August 2, 2004, of Neurocrine Biosciences, Inc.,

(5) Registration Statements (Form S-8 Nos. 333-175889, 333-190178, and 333-197916) pertaining to the 2011 Equity Incentive Plan of Neurocrine Biosciences, Inc.,

(6) Registration Statement (Form S-8 Nos. 333-199837) pertaining to the Inducement Plan of Neurocrine Biosciences, Inc., and

(7) Registration Statement (Form S-8 No. 333-205933) pertaining to the 2011 Equity Incentive Plan and Inducement Plan of Neurocrine Biosciences, Inc.;

of our reports dated February 11, 2016, with respect to the consolidated financial statements of Neurocrine Biosciences, Inc., and the effectiveness of internal control over financial reporting of Neurocrine Biosciences, Inc., included in this Annual Report (Form 10-K) of Neurocrine Biosciences, Inc. for the year ended December 31, 2015.

/s/ Ernst & Young LLP

San Diego, California
February 11, 2016

EXHIBIT 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT
TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kevin C. Gorman, President and Chief Executive Officer of Neurocrine Biosciences, Inc., certify that:

1. I have reviewed this annual report on Form 10-K of Neurocrine Biosciences, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this annual report based on such evaluation; and

   d) Disclosed in this annual report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of the internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Dated: February 11, 2016

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

EXHIBIT 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT
TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Timothy P. Coughlin, Chief Financial Officer of Neurocrine Biosciences, Inc., certify that:

1. I have reviewed this annual report on Form 10-K of Neurocrine Biosciences, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this annual report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of the internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Dated: February 11, 2016

/s/ Timothy P. Coughlin
Timothy P. Coughlin
Chief Financial Officer

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

In connection with the Annual Report on Form 10-K of Neurocrine Biosciences, Inc. (the "Company") for the year ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kevin C. Gorman, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), of the Securities Exchange Act of 1934; and

(2) That information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

February 11, 2016

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

In connection with the Annual Report on Form 10-K of Neurocrine Biosciences, Inc. (the "Company") for the year ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Timothy P. Coughlin, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), of the Securities Exchange Act of 1934; and

(2) That information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

February 11, 2016

By: /s/ Timothy P. Coughlin
Name: Timothy P. Coughlin
Title: Chief Financial Officer