

NEUROCRINE BIOSCIENCES INC

Form 10-K

February 08, 2013

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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, 2012

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 0-22705

**NEUROCRINE BIOSCIENCES, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**33-0525145**  
(I.R.S. Employer  
Identification Number)

**12780 El Camino Real, San Diego, CA**  
(Address of principal executive offices)

**92130**  
(Zip Code)

**Registrant's telephone number, including area code:**

**(858) 617-7600**

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

<b>Title of Each Class</b>	<b>Name of Each Exchange on Which Registered</b>
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, 2012 totaled approximately \$439,106,522 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, 2012. The identification of 10% or

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greater stockholders as of June 30, 2012 is based on Schedule 13G and amended Schedule 13G reports publicly filed before June 30, 2012. This calculation does not reflect a determination that such parties are affiliates for any other purposes.

As of January 31, 2013, there were 66,509,257 shares of the registrant's Common Stock outstanding.

### DOCUMENTS INCORPORATED BY REFERENCE

<b>Document Description</b>	<b>10-K Part</b>
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, 2012 are incorporated by reference into Part III of this report	III

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**PART I**

**FORWARD-LOOKING STATEMENTS**

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

Forward-looking statements can be identified by the use of forward-looking words such as believes, expects, hopes, may, will, plan, estimates, could, should, would, continue, seeks, pro forma, or anticipates, or other similar words (including their use in the 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, develop and intend to commercialize drugs for the treatment of neurological and endocrine-related diseases and disorders. Our product candidates address some of the largest pharmaceutical markets in the world, including endometriosis, tardive dyskinesia, uterine fibroids, stress-related disorders, pain, diabetes, insomnia, and other neurological and endocrine-related diseases and disorders. We currently have eleven programs in various stages of research and development, including six programs in clinical development. While we independently develop many of our product candidates, we have entered into collaborations for several of our programs. Our lead clinical development program, elagolix, is a drug candidate for the treatment of endometriosis and uterine fibroids that is partnered with AbbVie Inc. (AbbVie), a spinoff from Abbott Laboratories that was completed in January 2013.

**Table of Contents****Our Product Pipeline**

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

<b>Program</b>	<b>Target Indication(s)</b>	<b>Status</b>	<b>Rights</b>
<b>Product candidates in clinical development:</b>			
Elagolix	Endometriosis	Phase III	AbbVie
Vesicular Monoamine Transporter 2 Inhibitor (VMAT2)	Movement Disorders	Phase II	Neurocrine
CRF <sub>2</sub> Peptide Agonist urocortin 2	Cardiovascular	Phase II	Neurocrine
CRF <sub>1</sub> Antagonist (561679)	Stress-related Disorders	Phase II	Neurocrine
Elagolix	Uterine Fibroids	Phase II	AbbVie
<b>Research programs:</b>			
G Protein-Coupled Receptor 119 (GPR119)	Type II Diabetes	Research	Boehringer Ingelheim
VMAT2	Schizophrenia	Research	Neurocrine
GnRH Antagonists	Men's and Women's Health, Oncology	Research	AbbVie
Antiepileptic Drugs	Epilepsy, Essential Tremor, Pain	Research	Neurocrine
G Protein-Coupled Receptors	Other Conditions	Research	Neurocrine
<b>Product candidate subject to regulatory review:</b>			
Indiplon	Insomnia	FDA has deemed Approvable	Neurocrine/Dainippon Sumitomo Pharma Co. (Japan only)

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.

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.

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

CRF<sub>1</sub> and CRF<sub>2</sub> refer to two CRF receptor subtypes.

**Product Candidates In Clinical Development****Elagolix Gonadotropin-Releasing Hormone (GnRH) Antagonist**

GnRH is a peptide that stimulates the secretion of the pituitary hormones that are responsible for sex steroid production and normal reproductive function. Researchers have found that chronic administration of GnRH agonists, after initial stimulation, reversibly shuts down this transmitter pathway and is clinically useful in treating hormone-dependent diseases such as endometriosis and uterine fibroids. Several companies have developed peptide GnRH agonists on this principle, such as Lupron® and Zoladex®. However, since they are peptides, they must be injected via a depot formulation rather than the preferred oral route of administration. In addition, GnRH agonists can take up to several weeks to exert their

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desired effect once the initial stimulation has occurred, a factor not seen with the use of GnRH antagonists. Upon administration, GnRH agonists have shown a tendency to exacerbate the condition via a hormonal flare. More importantly, the profound suppression effect observed with GnRH agonists is similar to that seen after menopause and can be associated with hot flashes and the loss of bone mineral density.

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Orally active, nonpeptide GnRH antagonists potentially offer several advantages over injectable GnRH peptide drugs, including rapid onset of hormone suppression without a 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. Importantly, by using GnRH antagonists, it may be possible to alter the level of pituitary GnRH suppression thereby titrating circulating estrogen levels. Using this approach, an oral GnRH antagonist may provide patients relief from the painful symptoms of endometriosis while avoiding the need for the active management of bone loss.

*Endometriosis.* Endometriosis is associated with a multitude of symptoms, some of the most common of which include pain related both to menstruation (dysmenorrhea) and sexual intercourse (dyspareunia) as well as chronic pelvic pain throughout the menstrual cycle, infertility, and menorrhagia, among many others. The wide range of symptoms associated with endometriosis serves to complicate and delay diagnosis due to the significant overlap of symptoms with the disease profiles of other conditions. The World Endometriosis Research Foundation estimates that there are over 170 million women worldwide who suffer from endometriosis. Datamonitor (2009) estimates that there are approximately 7.5 million women in the United States who suffer from the symptoms of endometriosis. 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 a day, 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, with a mean time of return to ovulation of 24 days for elagolix subjects.

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

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



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The second additional Phase IIb trial (Tulip PETAL or 703 study) consisted of four arms, elagolix 150mg once daily, elagolix 250mg once daily, Prostag<sup>®</sup> 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 a 2.1 at baseline (0-3 scale) with a 1.13 reduction in the elagolix arm compared to a 0.37 reduction in the placebo arm at eight weeks. Daily non-menstrual pelvic pain scores were a 1.4 at baseline (0-3 scale) with a 0.47 reduction in the elagolix arm compared to a 0.19 reduction in the placebo arm at eight weeks. There were no treatment related serious adverse events in the 901 study and the two most common adverse events were headache and nausea, which were typically mild and transient and consistent with our previous studies.

In June 2010, we entered into a worldwide collaboration with Abbott Laboratories, now AbbVie Inc. (AbbVie) subsequent to a spinoff from Abbott Laboratories that was completed in January 2013, to develop and commercialize elagolix and all next-generation non-peptide GnRH antagonists for women's and men's health indications. We completed the final transfer of the Investigational New Drug (IND) application for elagolix to them during the fourth quarter of 2010. AbbVie now has primary responsibility for all regulatory interactions with the FDA related to elagolix and the next-generation GnRH antagonists covered by the collaboration.

We and AbbVie held an end of Phase II meeting with the FDA in March 2011, along with several Type C meetings with the FDA during 2011. These meetings led to a final protocol under which the Phase III program is being conducted. The Phase III program is assessing two separate doses of elagolix (150mg once-daily and another dose) over a 24-week treatment period. The initial randomized, parallel, double-blind, placebo-controlled pivotal trial (Violet PETAL) is expected to enroll 875 women in approximately 160 clinical sites throughout the United States, Canada and Puerto Rico. The co-primary endpoints are 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. Additional efficacy and safety endpoints include assessing persistence of pain reduction at month six and the impact on bone mineral density.

AbbVie initiated the elagolix endometriosis Phase III program during the second quarter of 2012, with a new drug application (NDA) filing expected in 2016.

*Uterine Fibroids.* Uterine fibroids are benign hormonally responsive tumors that form in the wall of the uterus. They are the most common solid tumor in women with a prevalence rate of at least 25% (American College of Obstetricians and Gynecologists). While many women do not have symptoms, depending on the size, location and number, uterine fibroids can cause pelvic pain, reproductive problems, and severe bleeding that can lead to anemia. Due to the severity of symptoms, treatment sometimes requires surgery, including the removal of the uterus. In fact, uterine fibroids is a leading indication for hysterectomy in the United States, with

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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 II 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 is an assessment of blood loss after three months of treatment with elagolix. The study is a dose ranging study designed to evaluate various doses of elagolix compared to placebo. Additional efficacy endpoints being evaluated are change in uterine volume, fibroid volume, and change in menstrual patterns. A Phase IIb study is expected to commence in 2013.

### ***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 re-packaging and transporting monoamines (dopamine, norepinephrine, serotonin, and histamine) among nerve cells. Specifically, dopamine enables neurotransmission among nerve cells that are involved in voluntary and involuntary motor control.

Tardive dyskinesia (TD) is defined by hyperkinetic involuntary movements which arise after months or years of treatment with dopamine receptor blocking agents (DRBA), 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 nearly 500,000 individuals are affected by TD in the United States alone (Kantar Health).

To address the unmet medical needs of patients suffering from TD, we are developing NBI-98854. NBI-98854 is a potent, highly selective, VMAT2 inhibitor that is effective in regulating pre-synaptic release of dopamine. This selectivity should reduce the likelihood of off target side effects. Additionally, we have designed this novel compound to provide low, sustained, plasma and brain concentrations of the active drug to minimize the potential side effects associated with excessive dopamine depletion, while at the same time having minimal impact on the other monoamines, e.g. norepinephrine and serotonin. With these features, NBI-98854 should be well tolerated in patients. NBI-98854 has been evaluated in several Phase I studies and two Phase II studies to assess its safety, tolerability and efficacy and to establish a treatment regimen to be used in future clinical trials. We believe that the potential efficacy and safety profile of NBI-98854 will address many of the shortcomings of current off-label treatments. Finally, NBI-98854 may well be useful in other disorders, such as Huntington's chorea, schizophrenia, Tourette syndrome and tardive dystonia.

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

During 2010, we completed a multiple, repeated 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

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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 IND 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).

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

The larger Phase IIb TD program began in 2012. The initial Phase IIb study (Kinect Study) is 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 120 subject study is assessing two doses of once-daily NBI-98854 over a six-week placebo-controlled dosing period. Half of the randomized subjects will receive placebo and half will receive one of two doses of NBI-98854. The two NBI-98854 dosing groups will consist of a 50mg group for six weeks and a group that will begin at 100mg for the initial two weeks and then convert to 50mg for the final four weeks of placebo-controlled dosing period. Subsequent to the placebo-controlled dosing, all subjects will enter a six-week open label safety extension, whereby 50mg of NBI-98854 will be administered once daily with additional AIMS assessments. The primary endpoint of the study is a comparison of placebo versus active scores utilizing the AIMS at the end of week six. Topline data from the Kinect Study is expected in the second quarter of 2013.

A second Phase IIb study (Kinect 2 Study) was launched in late 2012. The Kinect 2 Study is 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 90 subject study is assessing NBI-98854 over a six-week placebo-controlled dosing period where half of the randomized subjects will receive placebo and half will receive NBI-98854. The study will begin all subjects on once-daily 25mg of NBI-98854, or placebo. The treating physician is then permitted to escalate the dose at two-week intervals, end of week two and end of week four, to a maximum dose of once-daily 75mg. The dose escalation is determined by the treating physician based on week two and week four AIMS assessments coupled with safety and tolerability assessments at these same time points. The primary endpoint of the study is a comparison of placebo versus active scores utilizing the AIMS at the end of week six. Topline results from the Kinect 2 study are expected in mid-2013.

In light of the inconsistencies related to the AIMS scale that were experienced in the previous Phase IIa trial, we have designated a small panel of independent, blinded AIMS assessors to determine subject eligibility for the Kinect Study and Kinect 2 Study. Prior to the randomization of any subject, a video of each potential subject's initial screening AIMS evaluation will be reviewed by a member of this panel to determine whether the individual has moderate to severe TD. The independent panel is the sole determiner as to whether or not the subject meets the AIMS severity criteria to be eligible for either Study. Additionally, this central panel will continue to serve as independent quality control monitors of the AIMS assessments during the entire course of the trial. We have also enhanced the training and certification of the site specific, non-treating investigator to administer the AIMS assessments.

The data from the Kinect Study and Kinect 2 Study, along with the other Phase I and Phase II clinical studies, preclinical work, and drug manufacturing data will form the basis for an end of Phase II discussion with the FDA in late 2013.

### ***CRF<sub>2</sub> Receptor Peptide Agonist (Urocortin 2)***

Congestive heart failure (CHF) is a condition where the heart cannot pump enough blood to supply all of the body's organs. It is a result of narrowing of the arteries combined with high blood pressure, which results in increased respiration as well as edema from water retention. In the case of acute symptomology, CHF patients will eventually experience a rapid deterioration and require urgent treatment in the hospital. According to 2011 data from the American Heart Association, over 5 million people experience CHF and about 670,000 new cases are diagnosed each year in the United States. CHF becomes more prevalent with age and the number of cases is expected to grow as the overall age of the population increases. Current treatment options include a cocktail of

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drugs consisting of diuretics to remove excess water, beta blockers and digitalis to improve heart muscle contraction, and/or ACE inhibitors, Angiotensin Receptor Blockers, and vasodilators to expand blood vessels. According to the American Heart Association (2012), there are approximately one million hospital discharges each year in the United States for CHF.

Urocortin 2 is an endogenous peptide ligand of the CRF<sub>2</sub> receptor present in the cardiovascular system, notably the heart and cerebral arterial system. Urocortin 2 plays a role in the control of the hormonal, cardiovascular, gastrointestinal, and behavioral responses to stress, and has an array of effects on the cardiovascular system and metabolism. Based on preclinical efficacy and safety data, together with its known role in human physiology, we believe that urocortin 2 may have positive hemodynamic effects on cardiac output and blood pressure which may benefit patients with acute CHF.

We completed a Phase II placebo-controlled dose-escalation study in 2005 to evaluate the safety, pharmacokinetics and pharmacodynamics of two dose levels of urocortin 2 in patients with stable CHF. Results of this study demonstrated a dose-related increase in cardiac output of up to 50% with only a modest increase (6%) in heart rate. We completed an additional Phase II study evaluating urocortin 2 over four-hour infusions in patients with stable CHF in the first half of 2006. The treatments were generally well tolerated without serious adverse events, abnormalities in electrocardiograms or significant changes in renal function. Positive hemodynamic effects were noted in virtually all patients with increases in cardiac output ranging from 6% to 54%.

We have also completed the necessary preclinical work to allow for periods of infusion of urocortin 2 for up to 14 days. This substantially completes all of the preclinical toxicology work required by the FDA. Further development of urocortin 2 for CHF and other acute care cardiovascular diseases is highly dependent upon partnering of this program.

During 2009, The Christchurch Cardioendocrine Research Group at University of Otago, Christchurch School of Medicine and Health Sciences, New Zealand, began a pilot study of urocortin 2 in at least 50 patients with Acute Decompensated Heart Failure through a grant from the Health Research Council of New Zealand. In this blinded study, standard-of-care treatment (i.e., diuretics and vasodilators) are compared to standard of care treatment plus a four-hour infusion of urocortin 2. Infusion of urocortin 2 was generally well tolerated and there were no treatment-related serious adverse events. There was one heart failure related death, not related to drug, in the urocortin 2 arm of the study that occurred 48-hours post infusion.

The hemodynamic profile of urocortin 2 infusion was consistent with what had been established in earlier Phase I and Phase II clinical studies including improved cardiac output, reduction in peripheral vascular resistance and absence of sympathetic overstimulation. Mean arterial pressures were significantly reduced from 92 +/- 3 mmHg at baseline to 80 +/- 3 mmHg at the end of the urocortin 2 infusion (n=27) in contrast to placebo (n=26) where the mean arterial pressure was 92 +/- 3 mmHg at baseline and 89 +/- 4 mmHg at the end of the placebo infusion. Heart rates were slightly higher during urocortin 2 infusion than placebo, although these remained in normal range and comparable in both groups post infusion. In the subset of subjects undergoing right heart catheterization (n=20, 10 per arm), cardiac output increased markedly by over 50% in those randomized to urocortin 2 compared to unchanging values in the placebo group.

Clinical chemistry, hematology and urinalysis values were assessed and no statistically significant differences were reported between the subjects who received urocortin 2 or placebo, with the exception of an increase in plasma creatinine concentration during the four-hour infusion period. Adverse event reporting indicates that 55% of subjects randomized to urocortin 2 reported transient flushing (versus 23% in the placebo group). Four subjects had lowering of systolic blood pressure below pre-set stop values which, although asymptomatic, per protocol required a decrease or cessation of urocortin 2 infusion.

Additional urocortin 2 studies are being conducted by the Centre for Cardiovascular Sciences at The University of Edinburgh through a British Heart Foundation grant. A total of nine studies are to be conducted in

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both healthy volunteers and patients with stable CHF to determine the impact of urocortin 2 infusions on biomarkers of cardiovascular function and dysfunction. These studies began in 2010, and are expected to take several years to complete.

### ***Corticotropin-Releasing Factor (CRF) Receptor<sub>1</sub> Antagonist***

Researchers have identified what they believe to be the central mediator of the body's stress responses or stress-induced disorders. This mediator is a brain chemical known as CRF. CRF is overproduced in clinically depressed patients and may be dysregulated in individuals with anxiety disorders. Current research indicates that clinically depressed patients and patients with anxiety experience dysfunction of the hypothalamic-pituitary-adrenal axis, the system that manages the body's overall response to stress. This amplifies production of CRF, and induces the physical effects that are associated with stress that can lead to stress-related disorders such as post-traumatic stress disorder and acute stress disorder. According to National Institute of Mental Health there are approximately eight million post-traumatic stress disorder sufferers in the United States. We believe the novelty and specificity of the CRF mechanism of action and the prospect of improving upon selective serotonin reuptake inhibitor therapy represents a market opportunity both to better serve patients and expand the overall treatment of stress-related disorders.

We have a strategic position in the CRF field through our intellectual property portfolio and relationship with experts in the neuropsychiatric field. We have further characterized the CRF receptor system and have identified additional members of the CRF receptor family. We have patent rights on two receptor subtypes termed CRF<sub>1</sub> and CRF<sub>2</sub>, and we have pending patent applications on small molecule organic compounds modulating the CRF receptors.

In July 2001, we announced a worldwide collaboration with GlaxoSmithKline (GSK), to develop and commercialize CRF antagonists for psychiatric, neurological and gastrointestinal diseases. Under the terms of this agreement, GSK sponsored and we jointly conducted a research program and collaborated in the development of CRF antagonists identified through the collaborative research. The sponsored research portion of the collaboration was completed in 2005.

GSK advanced one of the lead CRF<sub>1</sub> receptor antagonist compounds, 561679, into a Phase II depression study during 2008. This multicenter randomized, double-blind, placebo-controlled trial was designed to assess the safety and efficacy of 561679 in approximately 150 women with Major Depressive Disorder over six weeks of treatment. The primary endpoint was a change from baseline in the Bech melancholia scale at Week 6 and a key secondary endpoint was a change from baseline in the HAMD-17 scale at Week 6. Results of the statistical analysis using the intent-to-treat population revealed no benefit of 561679 compared to placebo on either scale. During 2012, we and GSK agreed to terminate our collaboration to develop and commercialize CRF antagonists. As a result of this termination, we reacquired all worldwide rights to the CRF portfolio.

Emory University of Atlanta, Mt. Sinai Medical Center in New York, Baylor College of Medicine in Texas and University of California San Francisco, VA Medical Center through a grant from the National Institute of Mental Health, have been conducting a multi-site Phase II clinical trial evaluating 561679 in women with post-traumatic stress disorder. This randomized, double-blind, placebo-controlled trial is expected to enroll approximately 150 patients for a six-week treatment period. This study began in late 2009 and is expected to take several years to complete. Additionally, the National Institute on Alcohol Abuse and Alcoholism is currently enrolling subjects in a Phase II clinical trial evaluating 561679 in stress-induced craving in alcoholic women with high anxiety. This randomized, double-blind, placebo-controlled trial is expected to enroll 60 patients for a four-week treatment period. This study is also expected to take several years to complete.

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### **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 diabetes to stress-related disorders and neurodegenerative diseases. Central nervous system and endocrinology drug therapies are among the largest therapeutic categories, accounting for \$100 billion in worldwide drug sales according to MedAdNews (2011).

#### ***G Protein-Coupled Receptor 119 (GPR119)***

Type II diabetes is growing at epidemic proportions world-wide. This disease is characterized by reduced ability to secrete and respond to insulin. Drugs which can enhance the secretion of insulin in response to rising blood glucose levels can improve blood glucose control without increased risk of hypoglycemia. Nearly 26 million people suffer from diabetes in the United States alone with a worldwide prevalence in excess of 340 million. Recent estimates put the total direct and indirect costs of diabetes at \$174 billion.

GPR119 has been identified as a novel target for the treatment of Type II diabetes. GPR119 is expressed predominantly in the pancreas and gastrointestinal tract. The activation of GPR119 receptors located in the gastrointestinal tract stimulates incretins, resulting in increased insulin production, while activation of GPR119 receptors located on pancreatic islet beta cells can stimulate insulin secretion directly.

In June 2010, we entered into a worldwide collaboration with Boehringer Ingelheim International GmbH (Boehringer Ingelheim) to research and develop small molecule GPR119 agonists for the treatment of Type II diabetes and other indications. We worked jointly with Boehringer Ingelheim to identify and advance candidates into preclinical development during the collaborative research period which concluded in June 2012. Boehringer Ingelheim is now responsible for the global development and commercialization of potential GPR119 agonist products.

#### ***VMAT2***

VMAT2 inhibition results in the modulation of dopamine pathways which may also be useful for patients suffering from schizophrenia. Approximately 2.5 million people in the United States suffer from schizophrenia at an estimated annual cost of \$62 billion. Our discovery efforts around VMAT2 inhibitors also focuses on developing novel therapies for schizophrenia sufferers.

#### ***Antiepileptic Drugs***

Antiepileptic drugs are utilized in the treatment of epileptic seizures by suppressing the rapid firing of neurons that initiate a seizure. Antiepileptics also have additional effects within the central nervous system that have proven beneficial in bipolar disease, neuropathic pain and essential tremor. According to Datamonitor, in 2008, worldwide sales of anticonvulsants totaled approximately \$13 billion.

#### ***G Protein-Coupled Receptors (GPCR)***

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

Our GPCR research platform has met this requirement by integrating drug discovery research efforts with a suite of assays and assay systems and automated analytical techniques. This process provides a profile of GPCR pharmacological receptor/ligand interactions capable of predicting in vivo efficacy allowing for rapid discovery

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

### **Product Candidate Subject to Regulatory Review**

#### ***Indiplon***

Indiplon is a non-benzodiazepine GABA<sub>A</sub> receptor agonist for the treatment of insomnia which acts via the same mechanism as the currently marketed non-benzodiazepine therapeutics. We obtained the rights to indiplon through an exclusive worldwide sublicense agreement that we entered into with DOV Pharmaceutical, Inc. (DOV) in June 1998.

Based on the results of preclinical studies and Phase I, Phase II and Phase III clinical trials on indiplon, as well as a non-clinical data package related to indiplon manufacturing, formulation and commercial product development, we assembled and filed NDAs with the FDA for both indiplon capsules and indiplon tablets. On May 15, 2006, we received two complete responses from the FDA regarding our indiplon capsule and tablet NDAs. These responses indicated that indiplon 5mg and 10mg capsules were approvable (2006 FDA Approvable Letter) and that the 15mg tablets were not approvable.

We resubmitted our NDA for indiplon 5mg and 10mg capsules seeking clearance to market indiplon capsules for the treatment of insomnia. In December 2007, we received an action letter from the FDA stating the indiplon 5mg and 10mg capsules were approvable (2007 FDA Approvable Letter).

After receipt of the 2007 FDA Approvable Letter, we ceased all indiplon clinical development activities in the United States as well as all pre-commercialization activities. We continue to evaluate various alternatives for the indiplon program.

### **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 build our product pipeline, we can mitigate some of the clinical development risks associated with drug development. We currently have eleven programs in various stages of research and development, including six programs in clinical development. We take a portfolio approach to managing our pipeline that balances the size of the market opportunities with clear and defined clinical and regulatory paths to approval. We do this to ensure that we focus our internal development resources on innovative therapies with improved probabilities of technical and commercial success.

*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-injectible 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 \$37.2 million, \$31.0 million and \$31.2 million for the years ended December 31, 2012, 2011 and 2010, respectively.



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*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.

*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 Abbott Laboratories, now AbbVie subsequent to a spinoff from Abbott Laboratories that was completed in January 2013, to develop and commercialize elagolix and all next-generation gonadotropin-releasing hormone (GnRH) antagonists (collectively, GnRH Compounds) for women's and men's health. The goal of the agreement is to develop and commercialize GnRH Compounds. AbbVie made an upfront payment of \$75 million and has agreed to make additional development and regulatory event based payments of up to \$480 million and up to an additional \$50 million in commercial event based payments. 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.

*Boehringer Ingelheim International GmbH (Boehringer Ingelheim).* In June 2010, we announced a worldwide collaboration with Boehringer Ingelheim to research, develop and commercialize small molecule GPR119 agonists for the treatment of Type II diabetes and other indications. Under the terms of the agreement, we and Boehringer Ingelheim are working jointly to identify and advance GPR119 agonist candidates into preclinical development. Boehringer Ingelheim will then be responsible for the global development and commercialization of potential GPR119 agonist products. We received a \$10 million upfront payment and received research funding to support discovery efforts. We are eligible to receive up to approximately \$3 million in additional preclinical milestone payments and payments of up to approximately \$223 million in clinical development and commercial event based payments. We will be entitled to a percentage of any future worldwide sales of GPR119 agonists resulting from the collaboration. Under the terms of the agreement, the collaboration effort between the parties to identify and advance GPR119 agonist candidates into preclinical development is governed by a steering committee with representatives from both us and Boehringer Ingelheim; provided, however, that the final decision making authority rests with Boehringer Ingelheim. The collaborative research portion of the agreement concluded, as scheduled, on June 15, 2012. Boehringer Ingelheim may terminate the agreement at its discretion upon prior written notice to us. In such event, we may be entitled to specified

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payments and product rights would revert to us. Since the inception of the agreement, we have recorded revenues of \$10.0 million related to amortization of up-front license fees and \$3.0 million of sponsored research revenue.

*Dainippon Sumitomo Pharma Co. Ltd. (DSP)*. In October 2007, we announced an exclusive license agreement with DSP to develop and commercialize indiplon in Japan. Under the terms of the agreement, DSP made an up-front payment to us of \$20 million and is responsible for all future development, marketing and commercialization costs of indiplon in Japan. We will be eligible to receive additional event based payments upon specified future events related to the development and commercialization of indiplon in Japan. Should all event based payments be achieved, we may be entitled to additional payments totaling up to \$115 million. We are also entitled to royalties from DSP on future sales of indiplon in Japan. As of December 31, 2012, we had recorded revenues of \$15.1 million in license fees from DSP over the life of the agreement.

*GlaxoSmithKline (GSK)*. In July 2001, we announced a worldwide collaboration with GSK to develop and commercialize CRF antagonists for psychiatric, neurological and gastrointestinal diseases. Under the terms of this agreement, we and GSK conducted a collaborative research program and collaborated in the development of our then current lead CRF compounds, as well as novel back-up candidates and second generation compounds identified through the collaborative research.

In September 2012, we entered into a Termination Agreement with GSK, pursuant to which the parties mutually agreed to terminate the CRF antagonist collaboration agreement. Under the terms of the Termination Agreement GSK's license to our CRF assets terminated, reverting all rights to us and GSK assigned to us all patent rights created from the sponsored research portion of the collaboration agreement, including all related regulatory filings and approvals. GSK also assigned all other patent, regulatory and technology assets that were owned or controlled by GSK and its affiliates necessary for the development and commercialization of CRF antagonist compounds.

## **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 such as The Salk Institute, DOV, Research Development Foundation and others 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).

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Our highly selective VMAT2 inhibitor NBI-98854 is currently in clinical trials for the treatment of tardive dyskinesia and 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.

Urocortin 2 is an endogenous peptide ligand of the CRF<sub>2</sub> receptor which may be useful in the treatment of congestive heart failure based on preclinical efficacy and safety data. This peptide is covered by U.S. Patent Nos. 7,223,846 and 7,638,607, which are both due to expire in 2021 (not including potential patent term extensions of up to five years).

Our CRF antagonist 561679 is currently in clinical trials for the treatment of stress-related disorders and is covered by U.S. Patent No. 7,879,862 which expires in 2026 (not including potential patent term extensions of up to five years).

Indiplon is our non-benzodiazepine GABA<sub>A</sub> receptor agonist for the treatment of insomnia. The compound is covered by U.S. Patent No. 6,399,621 which is due to expire in 2020 (not including a potential patent term extension of up to five years).

## **Manufacturing and Distribution**

We currently rely on, and expect to continue to rely on, contract manufacturers to produce sufficient quantities of our product candidates for use in our preclinical and anticipated 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 and marketing 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. Various federal and state statutes and regulations also govern or influence testing, manufacturing, safety, labeling, storage and record-keeping related to such products and their marketing. 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.

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

**Phase I** Clinical trials are conducted with a small number of subjects to determine the early safety profile, maximum tolerated dose and pharmacological properties of the product in human volunteers.

**Phase II** Clinical trials are conducted with groups of patients afflicted with a specific disease in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety.

**Phase III** Large-scale, multi-center, comparative clinical trials are conducted with patients afflicted with a specific disease in order to determine safety and efficacy as primary support for regulatory approval by the FDA to market a product candidate for a specific disease.

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

Once Phase III trials are completed, drug developers submit the results of preclinical studies and clinical trials to the FDA in the form of an NDA or a biologics licensing application for approval to commence commercial sales. In response, the FDA may grant marketing approval, request additional information or deny the application if the FDA determines that the application does not meet regulatory approval criteria. FDA approvals may not be granted on a timely basis, or at all. Furthermore, the FDA may prevent a drug developer from marketing a product under a label for its desired indications, which may impair commercialization of the product.

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

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

## **Competition**

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



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Developments by others may render our product candidates or technologies obsolete or noncompetitive. We are performing research on or developing products for the treatment of several disorders including endometriosis, tardive dyskinesia, uterine fibroids, stress-related disorders, pain, diabetes, insomnia, and other neurological and endocrine-related diseases and disorders.

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

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

Our VMAT2 inhibitor is designed for the treatment of movement disorders, specifically TD. At present there are no approved drug therapies for TD; however, treatment regimens consist of utilizing various atypical antipsychotic medications (e.g., Clozapine), benzodiazepines (off-label) or botulinum toxin injections to treat the movements associated with TD. Other potential indications for our VMAT2 inhibitor are Tourette's syndrome, Huntington's disease, schizophrenia and tardive dystonia. Currently, Xenazine<sup>®</sup>, marketed by Lundbeck, is approved for the chorea associated with Huntington's disease. Generic neuroleptic medications (pimozide and haloperidol) are generally utilized to control the tics associated with Tourette's syndrome.

A potential indication currently being explored for our small molecule CRF antagonists is the area of post-traumatic stress disorders, for which there are no current approved drug therapies. However, clinicians utilize anxiolytics and anti-depressants such as Cymbalta<sup>®</sup>, marketed by Eli Lilly, Xanax<sup>®</sup>, marketed by Pfizer, Lexapro<sup>®</sup>, marketed by Forest Laboratories, Zoloft<sup>®</sup>, marketed by Pfizer, Paxil<sup>®</sup>, marketed by GSK and Pristiq<sup>®</sup>, marketed by Pfizer, among others, as well as any generic alternatives for each of these products.

In the area of insomnia, competitive products include Ambien<sup>®</sup>, Sonata<sup>®</sup>, Lunesta<sup>®</sup>, Intermezzo<sup>®</sup>, and Rozerem<sup>®</sup>, which are currently marketed by Sanofi-Aventis, Pfizer, Inc., Sunovion Pharmaceuticals, Inc., Transcept Pharmaceuticals, Inc. and Takeda Pharmaceutical Company, respectively.

If one or more of these 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

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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.

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### **Employees**

As of December 31, 2012, we had approximately 78 full-time employees, of which 19 hold Ph.D., M.D. or equivalent degrees, and 12 others hold an M.S., M.B.A., or equivalent degrees. Of these full-time employees, 60 were engaged in, or directly support, research and development activities, and 18 were in general and administrative positions. None of our employees are represented by a collective bargaining arrangement, and we believe our relationship with our employees is good. In addition, we rely on a number of consultants to assist us in formulating our research and development strategies.

### **Insurance**

We maintain product liability insurance for our clinical trials. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for products in development. However, insurance coverage is becoming increasingly expensive, and we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. In addition, we may not be able to obtain commercially reasonable product liability insurance for any products approved for marketing.

### **Available Information**

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

Additionally, copies of our annual report will be made available, free of charge, upon written request.



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

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Annual Report on Form 10-K and those we may make from time to time. If any of the following risks actually occur, our business, operating results, prospects or financial condition could be harmed. Additional risks not presently known to us, or that we currently deem immaterial, may also affect our business operations.

#### **Risks Related to Our Company**

*Our clinical trials may fail to demonstrate the safety and efficacy of our product candidates, which could prevent or significantly delay their regulatory approval.*

Before obtaining regulatory approval for the sale of any of our potential products, we must subject these product candidates to extensive preclinical and clinical testing to demonstrate their safety and efficacy for humans. Clinical trials are expensive, time-consuming and may take years to complete.

In connection with the clinical trials of our product candidates, we face the risks that:

the U.S. Food and Drug Administration (FDA) or similar foreign regulatory authority may not approve an Investigational New Drug (IND) or foreign equivalent filings required to initiate human clinical studies for our drug candidates or may require additional time consuming preclinical studies prior to such approval;

the product candidate may not prove to be effective or as effective as other competing product candidates;

we may discover that a product candidate may cause harmful side effects or results of toxicology studies required by the FDA may not be acceptable to the FDA;

the results may not replicate the results of earlier, smaller trials;

the FDA or similar foreign regulatory authorities may require use of new or experimental endpoints that may prove insensitive to treatment effects;

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

the results may not be statistically significant;

patient recruitment may be slower than expected;

patients may drop out of the trials; and

regulatory requirements may change.

These risks and uncertainties impact all of our clinical programs. Specifically, with respect to our gonadotropin-releasing hormone (GnRH) program with AbbVie Inc (AbbVie), a spinoff from Abbott Laboratories that was completed in January 2013, any of the clinical, regulatory or

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operational events described above could delay timelines for the completion of the Phase III endometriosis program or the Phase II uterine fibroids program, require suspension of these programs and/or obviate filings for regulatory approvals. Similarly, our VMAT2 inhibitor program will be impacted if any of the events above lead to delayed enrollment in, or completion of, the Phase II clinical trials of our lead candidate or the results of the ongoing Phase II clinical trials do not support advancing to later stage development.

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

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*We depend on continuing our current collaborations and developing additional collaborations to develop and commercialize our product candidates.*

Our strategy for fully developing and commercializing our products is dependent upon maintaining our current arrangements and establishing new arrangements with research collaborators, corporate collaborators and others. We have collaboration agreements with AbbVie, Boehringer Ingelheim International GmbH and Dainippon Sumitomo Pharma Co. Ltd. and previously have had collaborations with Pfizer, GlaxoSmithKline, Wyeth, Johnson & Johnson, Novartis, Taisho and Eli Lilly and Company. We historically have been dependent upon these corporate collaborators to provide adequate funding for a number of our programs, and our collaboration agreements with AbbVie and Boehringer Ingelheim provide for, among other things, significant future payments should certain development, regulatory and commercial milestones be achieved. Under these arrangements, our corporate collaborators are typically responsible for:

selecting compounds for subsequent development as drug candidates;

conducting preclinical studies and clinical trials and obtaining required regulatory approvals for these drug candidates; and

manufacturing and commercializing any resulting drugs.

Because we expect to continue to rely heavily on our current corporate collaborators and to enter into new collaborations in the future, the development and commercialization of our programs would be substantially delayed, and our ability to receive future funding would be substantially impaired if one or more of our current or future collaborators:

failed to select a compound that we have discovered for subsequent development into marketable products;

failed to gain the requisite regulatory approvals of these products;

did not successfully commercialize products that we originate;

did not conduct its collaborative activities in a timely manner;

did not devote sufficient time and resources to our partnered programs or potential products;

terminated its alliance with us;

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

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

merged with a third party that wants to terminate the collaboration.

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

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

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

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

fail to receive necessary regulatory approvals on a timely basis or at all;

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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.

***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 of our research and development programs;

progress with preclinical testing and clinical trials;

the time and costs involved in obtaining regulatory approvals;

the costs involved in filing and pursuing patent applications, enforcing patent claims, or engaging in interference proceedings or other patent litigation;

competing technological and market developments;

the establishment of additional strategic alliances;

the cost of commercialization activities and arrangements, including manufacturing of our product candidates; and

the cost of product in-licensing and any possible acquisitions.

We intend to seek additional funding through strategic alliances, and may seek additional funding through public or private sales of our securities, including equity securities. For example, we have effective shelf registration statements on file with the Securities and Exchange

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Commission (SEC) which allows us to issue shares of our common stock from time to time for an aggregate initial offering price of up to \$187 million. In addition, we have previously financed capital purchases and may continue to pursue opportunities to obtain additional debt financing in the future. In the past few years, the credit markets and the financial services industry have experienced a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the United States federal government. These events have generally made equity and debt financing more difficult to obtain. Accordingly, additional equity or debt financing might not be available on reasonable terms, if at all. Any additional equity financings will be dilutive to our stockholders and any additional debt financings may involve operating covenants that restrict our business.

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*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 \$719.7 million as of December 31, 2012. While we were profitable for the years ended December 31, 2012 and 2011, we did not generate positive cash flows from operations in either year. We do not expect to remain profitable, nor do we expect to become cash flow positive, for the foreseeable future.

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

seek regulatory approvals for our product candidates;

develop, formulate, manufacture and commercialize our product candidates;

in-license or acquire new product development opportunities;

implement additional internal systems and infrastructure; and

hire additional clinical, scientific and marketing personnel.

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

*The price of our common stock is volatile.*

The market prices for securities of biotechnology and pharmaceutical companies historically have been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Over the course of the last 12 months, the price of our common stock has ranged from approximately \$6.00 per share to approximately \$10.00 per share. The market price of our common stock may fluctuate in response to many factors, including:

the results of our clinical trials;

developments concerning new and existing collaboration agreements;

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

general economic and market conditions;

developments in patent or other proprietary rights;

developments related to the FDA;

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

comments by securities analysts;

fluctuations in our operating results;

government regulation;

health care reimbursement;



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

public concern as to the safety of our drugs.

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

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

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

We are dependent on licenses from third parties for some of our key technologies. These licenses typically subject us to various commercialization, reporting and other obligations. If we fail to comply with these obligations, we could lose important rights. For example, we have licensed indiplon from DOV Pharmaceuticals, Inc. In addition, we license some of the core technologies used in our research and development activities and collaborations from third parties, including the CRF receptor we license from The Salk Institute and use in our CRF<sub>1</sub> program, urocortin 2 which we license from Research Development Foundation, and the GnRH receptor we license from Mount Sinai School of Medicine and use in our elagolix program. If we were to default on our obligations under any of our licenses, we could lose some or all of our rights to develop, market and sell products covered by these licenses. Likewise, if we were to lose our rights under a license to use proprietary research tools, it could adversely affect our existing collaborations or adversely affect our ability to form new collaborations. We also face the risk that our licensors could, for a number of reasons, lose patent protection or lose their rights to the technologies we have licensed, thereby impairing or extinguishing our rights under our licenses with them.

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

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

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

We depend on independent clinical investigators and contract research organizations (CROs) to conduct our clinical trials under their agreements with us. The investigators are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If independent investigators fail to devote sufficient time and resources to our drug development programs, or if their performance is substandard, 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.

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

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

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

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

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

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

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

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

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

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

As is commonplace in the biotechnology industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have

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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 that could limit our product revenues and delay sustained profitability.***

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

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

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

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

the timing of receipt of marketing approvals;

the safety and efficacy of the products;

the success of existing products addressing our target markets or the emergence of equivalent or superior products; and

the cost-effectiveness of the products.

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

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

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, new SEC regulations and NASDAQ rules, are creating uncertainty for companies such as ours. These laws, regulations and standards are subject to varying interpretations in some cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, our efforts to comply with evolving laws, regulations and standards have resulted in, and are likely to continue to result in, increased general and administrative expenses and management time related to compliance activities. In particular, our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 and the related regulations regarding our required assessment of our internal controls over financial reporting requires, and we expect to continue to require, the commitment of significant financial and managerial resources. If we fail to comply with these laws, regulations and standards, our reputation may be harmed and we might be subject to sanctions or investigation by regulatory authorities, such as the SEC. Any such action could adversely affect our financial results and the market price of our common stock.

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*There is uncertainty regarding future development of our product candidate, indiplon, which may never receive regulatory approval or be commercialized.*

In December 2007, we received an action letter from the FDA stating that indiplon 5mg and 10mg capsules are approvable (2007 FDA Approvable Letter). After receipt of the 2007 FDA Approvable Letter, we ceased all indiplon clinical development activities in the United States as well as all pre-commercialization activities. We continue to evaluate various alternatives for the indiplon program.

The process of preparing and resubmitting the NDA for indiplon would require significant resources and could be time consuming and subject to unanticipated delays and cost. As a result, there is a significant amount of uncertainty regarding the future development of indiplon. Should the NDA be refiled, the FDA could again refuse to approve the NDA, or could still require additional data analysis or clinical trials, which would require substantial expenditures by us and would further delay the approval process. Even if our indiplon NDA is approved, the FDA may determine that our data do not support elements of the labeling we have requested. In such a case, the labeling actually granted by the FDA could limit the commercial success of the product. The FDA could require Phase IV, or post-marketing, trials to study the long-term effects of indiplon and could withdraw its approval based on the results of those trials. The FDA could also require a Risk Evaluation and Mitigation Strategy program for indiplon that could limit the commercial success of the product. We face the risk that for any of the reasons described above, as well as other reasons set forth herein, indiplon may never be approved by the FDA or commercialized anywhere in the world.

## **Risks Related to Our Industry**

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

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

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

*Health care reform measures could adversely affect our business.*

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payers to contain or reduce the costs of health care. In the United States, comprehensive health care reform legislation was enacted by the Federal government and we expect that there will continue to be a number of federal and state proposals to implement government control over the pricing of

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prescription pharmaceuticals. In addition, increasing emphasis on reducing the cost of health care in the United States will continue to put pressure on the rate of adoption and pricing of prescription pharmaceuticals. Moreover, in some foreign jurisdictions, pricing of prescription pharmaceuticals is already subject to government control. We are currently unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect the recently enacted Federal healthcare reform legislation or any such additional legislation or regulation would have on our business. The pendency or approval of such proposals or reforms could result in a decrease in our stock price or limit our ability to raise capital or to enter into collaboration agreements for the further development and commercialization of our programs and products.

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

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

Competition may also arise from, among other things:

other drug development technologies;

methods of preventing or reducing the incidence of disease, including vaccines; and

new small molecule or other classes of therapeutic agents.

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

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

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

capital resources;

research and development resources, including personnel and technology;

regulatory experience;

preclinical study and clinical testing experience;

manufacturing and marketing experience; and

production facilities.

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

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

obtain patent protection for our products;

preserve our trade secrets;

prevent third parties from infringing upon our proprietary rights; and

operate without infringing upon the proprietary rights of others, both in the United States and internationally.

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

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

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

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

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

***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

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suffer. Moreover, insurance coverage is becoming increasingly expensive, and we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, juries have awarded large judgments in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us would decrease our cash reserves and could cause our stock price to fall.

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

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



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**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

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

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

**ITEM 3. LEGAL PROCEEDINGS**

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

**ITEM 4. MINE SAFETY DISCLOSURES**

None.

**Table of Contents****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.

	<b>High</b>	<b>Low</b>
<b>Year Ended December 31, 2012</b>		
1st Quarter	\$ 9.98	\$ 7.33
2nd Quarter	8.09	6.25
3rd Quarter	8.38	6.75
4th Quarter	8.75	6.72
<b>Year Ended December 31, 2011</b>		
1st Quarter	\$ 8.40	\$ 6.41
2nd Quarter	8.60	6.77
3rd Quarter	8.44	5.49
4th Quarter	8.75	5.42

As of January 31, 2013, there were approximately 68 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 2012.

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**Stock Performance Graph and Cumulative Total Return**

The graph below shows the cumulative total stockholder return assuming the investment of \$100 on December 31, 2007 (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.

**\* \$100 INVESTED ON 12/31/07 IN STOCK OR INDEX INCLUDING REINVESTMENT OF DIVIDENDS AT FISCAL YEARS ENDING DECEMBER 31.**

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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.

	2012	2011	2010	2009	2008
	(In thousands, except for net income (loss) per share data)				
<b>STATEMENT OF COMPREHENSIVE INCOME (LOSS) DATA</b>					
Revenues:					
Sponsored research and development	\$ 18,897	\$ 10,462	\$ 10,938	\$ 34	\$ 47
Milestones and license fees	34,243	66,951	22,563	2,919	3,919
Grant income and other revenues					9
Total revenues	53,140	77,413	33,501	2,953	3,975
Operating expenses:					
Research and development	37,163	30,951	31,151	33,722	55,544
General and administrative	13,437	12,458	13,273	14,360	17,936
Cease-use expense	1,092	82	2,799	5,984	15,742
Restructuring expenses				2,557	2,051
Total operating expenses	51,692	43,491	47,223	56,623	91,273
Income (loss) from operations	1,448	33,922	(13,722)	(53,670)	(87,298)
Other income and (expense):					
Gain on sale/disposal of assets	3,074	3,195	3,161	3,626	3,570
Other income (expense), net	503	454	2,593	(994)	(4,885)
Total other income and (expense)	3,577	3,649	5,754	2,632	(1,315)
Net income (loss)	\$ 5,025	\$ 37,571	\$ (7,968)	\$ (51,038)	\$ (88,613)
Net income (loss) per common share:					
Basic	\$ 0.08	\$ 0.68	\$ (0.15)	\$ (1.30)	\$ (2.30)
Diluted	\$ 0.08	\$ 0.67	\$ (0.15)	\$ (1.30)	\$ (2.30)
Shares used in calculation of net income (loss) per common share:					
Basic	65,619	55,176	52,820	39,137	38,449
Diluted	66,946	56,347	52,820	39,137	38,449
<b>BALANCE SHEET DATA</b>					
Cash, cash equivalents and short-term investments	\$ 173,013	\$ 129,103	\$ 126,865	\$ 53,464	\$ 80,473
Working capital	173,618	85,366	80,274	35,426	55,329
Total assets	195,979	138,368	144,424	70,818	118,182
Long-term debt					
Accumulated deficit	(719,673)	(724,698)	(762,269)	(754,301)	(703,263)
Total stockholders' equity	154,372	60,081	19,345	3,954	36,774

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**ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

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

**Overview**

We discover, develop and intend to commercialize drugs for the treatment of neurological and endocrine-related diseases and disorders. Our product candidates address some of the largest pharmaceutical markets in the world, including endometriosis, tardive dyskinesia, uterine fibroids, stress-related disorders, pain, diabetes, insomnia, and other neurological and endocrine-related diseases and disorders. 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, 2012, we had an accumulated deficit of \$719.7 million and expect to incur operating cash flow losses for the foreseeable future, which may be greater than losses in prior years. We currently have eleven programs in various stages of research and development, including six programs in clinical development. Our lead clinical development program, elagolix, is a drug candidate for the treatment of endometriosis and uterine fibroids that is partnered with AbbVie Inc. (AbbVie), a spinoff of Abbott Laboratories that was completed in January 2013.

**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 revenues under collaborative research agreements, clinical trial accruals (research and development expense), share-based compensation, lease related activities, and fixed assets. Estimates are based on historical experience, information received from third parties and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. 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***

Revenues under collaborative research and development agreements are recognized as costs are incurred over the period specified in the related agreement or as the services are performed. These agreements are on a best-efforts basis, and do not require scientific achievement as a performance obligation, and provide for payment to be made when costs are incurred or the services are performed. All fees are nonrefundable to the collaborators. Prior to the revised multiple element guidance adopted by us on January 1, 2011, upfront,

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nonrefundable payments for license fees and advance payments for sponsored research revenues received in excess of amounts earned were classified as deferred revenue and recognized as income over the contract or development period. Estimating the duration of the development period includes continual assessment of development stages and regulatory requirements. If we enter into a new collaboration agreement or materially modify an existing collaboration agreement, we will be required to apply the revised multiple element guidance. Milestone payments are recognized as revenue upon achievement of pre-defined scientific events, which requires substantive effort, and for which achievement of the milestone was not readily assured at the inception of the agreement. In 2010, we entered into collaboration agreements for our gonadotropin-releasing hormone (GnRH) antagonist program and our GPR119 agonist program.

*AbbVie Inc. (AbbVie).* In June 2010, the Company announced an exclusive worldwide collaboration with Abbott Laboratories, now AbbVie subsequent to a spinoff of Abbott Laboratories that was completed in January 2013, to develop and commercialize elagolix and all next-generation GnRH antagonists (collectively, GnRH Compounds) for women's and men's health. The goal of the agreement is to develop and commercialize GnRH Compounds. AbbVie made an upfront payment of \$75 million and has agreed to make additional development and regulatory event based payments of up to \$480 million and up to an additional \$50 million in commercial event based payments. We have assessed event based payments under the revised authoritative guidance for research and development milestones and determined that event based payments prior to commencement of a Phase III clinical study, as defined in the agreement, meet the definition of a milestone in accordance with authoritative guidance as (1) they are events that can only be achieved in part on our past performance, (2) there is substantive uncertainty at the date the arrangement was entered into that the event will be achieved and (3) they result in additional payments being due to us. Development and regulatory event based payments subsequent to the commencement of a Phase III clinical study, however, currently do not meet these criteria as their achievement is based on the performance of AbbVie. As of December 31, 2012, there are no further event based payments that meet the definition of a milestone in accordance with authoritative 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 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 collaboration effort between the parties to advance GnRH Compounds towards commercialization was governed by a joint development committee with representatives from both us and AbbVie. The collaborative development portion of the agreement concluded, as scheduled, on December 31, 2012. 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. Our participation in the joint development committee was determined to be a substantive deliverable under the contract, and therefore, the upfront payment was deferred and recognized over the term of the joint development committee, which was completed in December 2012. For the years ended December 31, 2012, 2011 and 2010, we recorded revenues of \$29.1 million, \$29.0 million, and \$16.9 million in amortization of up-front license fees, respectively, and \$17.8 million, \$9.1 million and \$10.1 million of sponsored development revenue, respectively, under the AbbVie collaboration agreement. During 2012, we recorded \$13.1 million in revenue related to completion of the collaborative development period which is also included in sponsored development revenue. During 2011, we recorded \$30.0 million in milestone revenue, \$10.0 million of which was related to advancing elagolix into Phase II clinical trials for uterine fibroids and \$20.0 million of which was related to the outcome of an elagolix pre-Phase III meeting with the FDA for endometriosis.

*Boehringer Ingelheim International GmbH (Boehringer Ingelheim).* In June 2010, we announced a worldwide collaboration with Boehringer Ingelheim to research, develop and commercialize small molecule GPR119 agonists for the treatment of Type II diabetes and other indications. Under the terms of our agreement with Boehringer Ingelheim, we and Boehringer Ingelheim worked jointly, during a two year collaborative

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research period which ended in June 2012, to identify and advance GPR119 agonist candidates into preclinical development. Following the collaborative research period, Boehringer Ingelheim is responsible for the global development and commercialization of potential GPR119 agonist products, if any. We received a \$10 million upfront payment, and received research funding to support discovery efforts. Boehringer Ingelheim agreed to make payments of up to approximately \$3 million in additional preclinical milestone payments and payments of up to approximately \$223 million in clinical development and commercial event based payments. We have assessed milestones under the revised authoritative guidance for research and development milestones and determined that the preclinical milestone payments, as defined in the agreement, meet the definition of a milestone as (1) they are events that can only be achieved in part on our performance or upon the occurrence of a specific outcome resulting from our performance, (2) there is substantive uncertainty at the date the arrangement was entered into that the event will be achieved and (3) they result in additional payments being due to us. Clinical development and commercial milestone payments, however, currently do not meet these criteria as their achievement is solely based on the performance of Boehringer Ingelheim. No milestone payments were recognized during the periods presented. We will be entitled to a percentage of any future worldwide sales of GPR119 agonists. Under the terms of the agreement, the collaboration effort between the parties to identify and advance GPR119 agonist candidates into preclinical development was initially governed by a steering committee with representatives from both us and Boehringer Ingelheim; provided, however, that final decision making authority rests with Boehringer Ingelheim. The collaborative research portion of the agreement concluded, as scheduled, on June 15, 2012. Our participation in the steering committee was determined to be a substantive deliverable under the contract, and therefore, the upfront payment was deferred and recognized over the two-year term of the steering committee which was completed in June 2012. Boehringer Ingelheim may terminate the agreement at its discretion upon prior written notice to us. In such event, we may be entitled to specified payments and product rights would revert to us. For the years ended December 31, 2012, 2011 and 2010, we recorded revenues of \$2.2 million, \$5.0 million and \$2.7 million in amortization of up-front license fees, respectively, and \$1.0 million, \$1.3 million and \$0.8 million of sponsored research related to the Boehringer Ingelheim agreement, respectively.

***Research and Development Expense***

Research and development (R&D) expenses consists primarily of salaries, payroll taxes, employee benefits, and share-based compensation charges, for those individuals involved in ongoing research and development 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. 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 recognized in accordance with authoritative guidance for the years ended December 31, 2012, 2011 and 2010 was \$5.5 million, \$2.9 million and \$3.1 million, respectively.

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Stock option awards and restricted stock units generally vest over a three to four year period and expense is ratably recognized over those same time periods. However, due to certain retirement provisions in our 2003 Incentive Stock Plan, share-based compensation expense may be recognized over a shorter period of time, and in some cases the entire share-based compensation expense may be recognized upon grant of the share-based compensation award. Employees who are age 55 or older and have five or more years of service with us are entitled to accelerated vesting of certain unvested share-based compensation awards upon retirement. This retirement provision leads to variability in the quarterly expense amounts recognized in accordance with authoritative guidance, and therefore individual share-based compensation awards may impact earnings disproportionately in any individual fiscal quarter.

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.

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.

***Real Estate***

In December 2007, we closed the sale of our facility and associated real property for a purchase price of \$109 million. Concurrent with the sale we 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, we entered into a lease agreement (Lease) with DMH Campus Investors, LLC (DMH) whereby we leased back for an initial term of 12 years our 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. We entered into a series of lease amendments (Amendments), beginning in late 2008, through which we vacated the Front Building, but continue 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 in 2008. For the years ended 2012, 2011 and 2010, we recognized \$3.0 million, \$3.0 million and \$2.9 million, respectively, of the deferred gain and will recognize the remaining \$24.0 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, we pay 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 our behalf a letter of credit in the amount of \$4.2 million, which is secured by a deposit of equal amount with the same bank. We have the right to extend the Lease for two consecutive ten-year terms.

In December 2010, we entered into a sublease agreement (Sublease) for approximately 16,000 square feet of the Rear Building. The Sublease is expected to result in approximately \$0.6 million of rental income per year over the three year term of the Sublease and is recorded as an offset to rent expense. The Sublease provides the subtenant with an option to extend the term for two one-year renewal periods. The income generated under the



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Sublease is lower than our financial obligation under our Lease for the Rear Building as determined on a per square foot basis. Consequently, at December 31, 2010, we were required to record a cease-use liability for the net present value estimated difference between the expected income to be generated under the Sublease and future subleases and the Lease obligation over the remaining term of the Lease for the space that is occupied by the subtenant. This transaction resulted in \$2.5 million of gross cease use expense, and a reversal of associated deferred rent of \$173,000. In August 2012, we extended the term of the Sublease and increased the leased square footage to approximately 17,000 square feet. This transaction resulted in an additional \$150,000 of gross cease-use expense, and a reversal of associated deferred rent of \$15,000, being recorded in September 2012.

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

In November 2012, we entered into a third sublease agreement (Third Sublease) for approximately 14,000 square feet of space in the Rear Building. The Third Sublease is expected to result in approximately \$0.5 million in rental income per year over the three and a half year term and is recorded as an offset to rent expense. The Third Sublease provides the subtenant with an option to extend the term for a two one-year renewal periods. Similar to the previous subleases, the Third Sublease resulted in \$1.2 million of gross cease use expense, and a reversal of associated deferred rent of \$249,000, being recorded in December 2012.

At December 31, 2012 and 2011, we had recorded in our consolidated balance sheet a cease-use liability related to the multiple sublease agreements of \$3.7 million and \$2.6 million, respectively.

**Asset Impairment**

In accordance with authoritative accounting guidance, if indicators of impairment exist, we assess 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 impairment is indicated, we measure the amount of such impairment by comparing the carrying value of the asset to the estimated fair value of the related asset, which is generally determined based on the present value of the expected future cash flows.

**Results of Operations for Years Ended December 31, 2012, 2011 and 2010****Revenue**

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

	2012	Year Ended December 31, 2011	2010
	(In millions)		
Revenues under collaboration agreements:			
AbbVie Inc. (AbbVie)	\$ 46.9	\$ 68.1	\$ 27.0
GlaxoSmithKline (GSK)	0.1	0.1	0.1
Dainippon Sumitomo Pharma Co. Ltd. (DSP)	2.9	2.9	2.9
Boehringer Ingelheim International GmbH (Boehringer Ingelheim)	3.2	6.3	3.5
Total revenues	\$ 53.1	\$ 77.4	\$ 33.5

The decrease in revenues from the year ended December 31, 2011 to the year ended December 31, 2012 was primarily due to two milestones, totaling \$30.0 million, recognized under the AbbVie collaboration agreement in

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2011. Sponsored research and development revenue has also decreased year over year as both the AbbVie and Boehringer Ingelheim collaborative development and research portions of the collaborations were completed, as planned, during 2012. During 2012, we recognized \$13.1 million in sponsored research and development revenue related to the completion of the collaborative development period with AbbVie.

The increase in revenues from the year ended December 31, 2010 to the year ended December 31, 2011 was primarily due to two milestones recognized under the AbbVie collaboration agreement. During 2011, we recorded an aggregate of \$30.0 million in milestone revenue, \$10.0 million of which was related to advancing elagolix into Phase II clinical trials for uterine fibroids and \$20.0 million of which was related to the outcome of an elagolix pre-Phase III meeting with the FDA for endometriosis. Additionally, 2011 represented the first full year under the AbbVie and Boehringer Ingelheim collaboration agreements and revenue recognized from the amortization of up-front license fees increased from \$19.6 million in 2010 to \$34.0 million in 2011.

During each of the three years ended December 31, 2012, 2011 and 2010, we recognized \$2.9 million in revenue under our collaboration agreement with DSP from amortization of up-front licensing fees.

We expect revenue to decrease significantly during 2013, primarily due to lower revenue under our collaboration agreements. We do not expect to recognize any milestone revenue in 2013.

**Operating Expenses***Research and Development*

Our research and development expenditures include costs related to preclinical and clinical trials, scientific personnel, equipment, consultants, sponsored research, share-based compensation and allocated facility costs. We do not track fully burdened research and development costs separately for each of our drug candidates. We review our research and development expenses by focusing on four categories: external development, personnel, facility and depreciation, and other. External development expenses consist of costs associated with our external preclinical and clinical trials, including pharmaceutical development and manufacturing. Personnel expenses include salaries and wages, share-based compensation, payroll taxes and benefits for those individuals involved in ongoing research and development efforts. Other research and development expenses mainly represent lab supply expenses, scientific consulting expenses and other expenses. We currently have eleven programs in various stages of research and development, including six programs in clinical development.

The following table presents our total research and development expenses by category during the periods presented:

	Years Ended December 31,		
	2012	2011	2010
	(In millions)		
External development expense:			
Elagolix	\$ 2.2	\$ 4.0	\$ 7.9
VMAT2	7.9	4.4	1.8
Other	1.5	0.1	
Total external development expense	11.6	8.5	9.7
R&D personnel expense	14.5	11.6	11.3
R&D facility and depreciation expense	5.9	6.2	7.0
Other R&D expense	5.2	4.7	3.2
Total research and development expense	\$ 37.2	\$ 31.0	\$ 31.2

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R&D expense increased from \$31.0 million in 2011 to \$37.2 million in 2012. The increase is primarily due to an increase in external development expense as our VMAT2 program continues in Phase II development, partially offset by a decrease in elagolix related expenses as work transitioned to AbbVie. Personnel related research and development costs increased due to higher research and development headcount, coupled with a \$1.6 million increase in share-based compensation expense due primarily to the timing of stock option grants. Additionally, increased laboratory related costs for basic research accounted for approximately \$0.6 million of the increase in other R&D expense year over year.

R&D expense decreased from \$31.2 million in 2010 to \$31.0 million in 2011. The increase in VMAT2 external development expense, due to Phase II clinical trial activity, was offset by a decrease in elagolix external development expenses as responsibility for that program has shifted to AbbVie. Other R&D expense increased from 2010 to 2011, primarily attributable to outside consultants who advise us on research and clinical projects. The \$2.5 million decrease in research and development expense from 2009 to 2010 was primarily due to our restructuring program in 2009 coupled with lower depreciation expense which decreased by \$1.5 million due to fixed asset sales and fixed assets reaching the end of their depreciable lives.

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

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

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

We expect research and development expenses to increase from 2012 levels primarily due to increased clinical efforts related to our VMAT2 program.

*General and Administrative*

General and administrative expenses increased to \$13.4 million in 2012 compared to \$12.5 million in 2011 and \$13.3 million during 2010. The \$0.9 million increase in expenses from 2011 to 2012 resulted primarily from a \$1.0 million increase in share-based compensation expense, due primarily to the timing of stock option grants. The \$0.8 million decrease in expenses from 2010 to 2011 resulted primarily from company-wide cost containment efforts.

We expect our general and administrative expenses in 2013 to increase from 2012 expense levels primarily due to higher share-based compensation expense.

*Cease-use Expense*

During 2012, 2011 and 2010, we recognized \$1.1 million, \$0.1 million and \$2.8 million, respectively, in net cease-use expense, related to our corporate headquarters, under the amendment of the Lease and the three subleases discussed above.

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### ***Other Income***

Other income was \$3.6 million in 2012, \$3.6 million in 2011 and \$5.8 million during 2010. The decrease in other income from 2010 to 2011 resulted primarily from a one-time realized gain of \$1.3 million on the disposal of auction rate securities in 2010 and \$1.0 million in Qualified Therapeutic Discovery Project Program funding received in 2010.

### ***Net Income***

Our net income for 2012 was \$5.0 million or \$0.08 income per fully diluted share, net income for 2011 was \$37.6 million or \$0.67 income per fully diluted share, our net loss for 2010 was \$8.0 million, or \$0.15 loss per share.

The decrease in net income from 2011 to 2012 was primarily a result of lower revenue recognized under our collaboration agreements with AbbVie and Boehringer Ingelheim, coupled with an increase in research and development expense primarily related to our VMAT2 program and increased overall share-based compensation expense.

The change to net income in 2011 from a net loss position in 2010 was primarily the result of revenue recognized under our AbbVie collaboration agreement. During 2011, we recorded an aggregate of \$30.0 million in milestone revenue under our AbbVie collaboration agreement, \$10.0 million of which was related to advancing elagolix into Phase II clinical trials for uterine fibroids and \$20.0 million of which was related to the outcome of an elagolix pre-Phase III meeting with the FDA for endometriosis. Additionally, 2011 represented the first full year under the AbbVie and Boehringer Ingelheim collaboration agreements and the amortization of up-front license fees increased from \$19.6 million in 2010 to \$34.0 million in 2011.

We expect to have a net loss in 2013, primarily due to lower revenue related to the amortization of up-front fees under our collaboration agreements coupled with higher research and development expenses resulting from the progress of our VMAT2 inhibitor.

### **Liquidity and Capital Resources**

At December 31, 2012, our cash, cash equivalents, and investments totaled \$173.5 million compared with \$129.1 million at December 31, 2011.

Net cash used in operating activities during 2012 was \$35.3 million compared to net cash used of \$0.7 million in 2011. The change in cash flows from operating activities is primarily related to \$30.0 million in milestones achieved under the AbbVie collaboration agreement during 2011, plus an increase in research and development expenses of \$6.2 million as a result of expanded work in basic research and on our VMAT2 program.

Net cash used in operating activities during 2011 was \$0.7 million compared to net cash provided of \$49.9 million during 2010. The \$50.6 million change in cash provided by operating activities was primarily due to upfront payments from AbbVie and Boehringer Ingelheim of \$75 million and \$10 million received in 2010 related to our partnering of our GnRH and GPR119 programs, respectively, offset by milestone payments of \$30.0 million in 2011 under the AbbVie collaboration agreement.

Net cash used in investing activities was \$34.8 million, \$3.5 million and \$54.7 million in 2012, 2011 and 2010, respectively. The fluctuation in net cash used in investing activities resulted primarily from the timing differences in investment purchases, sales and maturities, and the fluctuation of our portfolio mix between cash equivalents and short-term investment holdings. The average term to maturity in our investment portfolio is less than one year.

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Net cash provided by financing activities during 2012 was \$83.7 million compared to \$0.3 million and \$21.5 million in 2011 and 2010, respectively. The increase of \$83.4 million in cash provided by financing activities was primarily due to the net proceeds of \$83.0 million received from our public offering of shares of common stock in January 2012. During 2010, we sold common stock for net cash proceeds of approximately \$21.4 million. We had no outstanding debt at December 31, 2012.

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

In March 2010, we completed a public offering of common stock in which we sold approximately 10.5 million shares of our common stock at an offering price of \$2.20 per share. The shares were sold pursuant to an effective shelf registration statement with the SEC. The net proceeds generated from this transaction, after underwriting discounts and commissions and offering costs, were approximately \$21.4 million.

*Shelf Registration Statements.* In December 2012, the SEC declared effective a shelf registration statement filed by us in November 2012. The shelf registration statement allows us to issue shares of our common stock from time to time for an aggregate initial offering price of up to \$150 million. The specific terms of offerings, if any, under the shelf registration statement would be established at the time of such offerings. As of January 31, 2013, we had not sold any shares under this shelf registration statement.

In December 2010, the SEC declared effective a shelf registration statement filed by us earlier that month. The shelf registration statement allows us to issue shares of our common stock from time to time for an aggregate initial offering price of up to \$125 million. The specific terms of offerings, if any, under the shelf registration statement would be established at the time of such offerings. As of January 31, 2013, we had approximately \$37 million still available under this shelf registration statement. This shelf registration statement expires in the fourth quarter of 2013.

## **Factors That May Affect Future Financial Condition and Liquidity**

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

Our inlicensed, research and clinical development agreements are generally cancelable with written notice within 180 days or less. In addition to the minimum payments due under inlicense and research agreements, we may be required to pay approximately \$13 million in milestone payments, plus sales royalties, in the event that all scientific research under these agreements is successful.

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

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

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As of December 31, 2012, the total estimated future annual minimum lease payments under our non-cancelable operating lease obligations are as follows (*in thousands*):

	<b>Payment Amount</b>
Year ending:	
2013	\$ 6,961
2014	7,169
2015	7,385
2016	7,606
2017	7,834
Thereafter	16,381
Total future minimum lease payments	\$ 53,336

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

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

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

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

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

we may discover that a product candidate may cause harmful side effects;

patient recruitment may be slower than expected; and

patients may drop out of the trials.

For each of our programs, we periodically assess the scientific progress and merits of the programs to determine if continued research and development is economically viable. Certain of our programs have been terminated due to the lack of scientific progress and lack of prospects for ultimate commercialization. Because of



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

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

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

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

continued scientific progress in our research and development programs;

the magnitude of our research and development programs;

progress with preclinical testing and clinical trials;

the time and costs involved in obtaining regulatory approvals;

the costs involved in filing and pursuing patent applications and enforcing patent claims;

competing technological and market developments;

the establishment of additional collaborations and strategic alliances;

the cost of manufacturing facilities and of commercialization activities and arrangements; and

the cost of product in-licensing and any possible acquisitions.

We believe that our existing capital resources, together with investment income and future payments due under our strategic alliances, will be sufficient to satisfy our current and projected funding requirements for at least the next 12 months. However, we cannot guarantee that our existing capital resources and anticipated revenues will be sufficient to conduct and complete all of our research and development programs as planned.



## Edgar Filing: NEUROCRINE BIOSCIENCES INC - Form 10-K

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 effective shelf registration statements on file with the SEC which allows us to issue shares of our common stock from time to time for an aggregate initial offering price up to approximately \$187 million. 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

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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, 2012, 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 December 2011, the Financial Accounting Standards Board (FASB) issued accounting guidance requiring an entity to disclose information about offsetting arrangements and the impact of these arrangements on our financial position. This guidance is effective for interim and annual periods beginning on or after January 1, 2013. We do not expect the adoption of this guidance will have a material impact on our consolidated financial statements.

In May 2011, the FASB issued updated accounting guidance that clarifies existing fair value measurements and disclosures, and eliminates differences between accounting principles generally accepted in the United States and International Financial Reporting Standards to make convergence guidance more understandable. This guidance is effective for interim and annual periods beginning after December 15, 2011. The adoption of this guidance did not have a material impact on our condensed consolidated financial statements.

Effective January 1, 2012, we adopted guidance issued by the FASB concerning presentation and disclosure only for the presentation of comprehensive (loss) income. The adoption of this guidance did not have a material impact on our condensed consolidated financial position or results of operations, other than its impact on the presentation of comprehensive income (loss).

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

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

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**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA  
NEUROCRINE BIOSCIENCES, INC.**

**INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS**

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<u>Consolidated Balance Sheets as of December 31, 2012 and 2011</u>	49
<u>Consolidated Statements of Comprehensive Income (Loss) for the years ended December 31, 2012, 2011 and 2010</u>	50
<u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2012, 2011 and 2010</u>	51
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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, 2012 and 2011, and the related consolidated statements of comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2012. 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, 2012 and 2011, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, 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, 2012, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 8, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, CA

February 8, 2013

**Table of Contents****NEUROCRINE BIOSCIENCES, INC.****Consolidated Balance Sheets****(In thousands, except for par value and share totals)**

	December 31,	
	2012	2011
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 63,754	\$ 50,107
Short-term investments, available-for-sale	109,259	78,996
Receivables under collaborative agreements	14,089	1,903
Other current assets	2,162	1,470
<b>Total current assets</b>	<b>189,264</b>	<b>132,476</b>
Property and equipment, net	1,900	1,586
Long-term investments	480	
Restricted cash	4,335	4,306
<b>Total assets</b>	<b>\$ 195,979</b>	<b>\$ 138,368</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 911	\$ 1,111
Accrued liabilities	8,094	8,451
Current portion of deferred revenues	2,919	34,242
Current portion of cease-use liability	589	264
Current portion of deferred gain on sale of real estate	3,133	3,042
<b>Total current liabilities</b>	<b>15,646</b>	<b>47,110</b>
Deferred revenues	2,919	2,919
Deferred gain on sale of real estate	20,872	24,005
Deferred rent	1,840	1,800
Cease-use liability	3,097	2,328
Other liabilities	152	125
<b>Total liabilities</b>	<b>41,607</b>	<b>78,287</b>
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 66,446,888 and 55,262,734 at December 31, 2012 and 2011, respectively	66	55
Additional paid-in capital	873,981	784,811
Accumulated other comprehensive loss	(2)	(87)
Accumulated deficit	(719,673)	(724,698)
<b>Total stockholders' equity</b>	<b>154,372</b>	<b>60,081</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 195,979</b>	<b>\$ 138,368</b>

See accompanying notes.



**Table of Contents****NEUROCRINE BIOSCIENCES, INC.****Consolidated Statements of Comprehensive Income (Loss)****(In thousands, except net income (loss) per share data)**

	Year Ended December 31,		
	2012	2011	2010
<b>Revenues:</b>			
Sponsored research and development	\$ 18,897	\$ 10,462	\$ 10,938
Milestones and license fees	34,243	66,951	22,563
<b>Total revenues</b>	<b>53,140</b>	<b>77,413</b>	<b>33,501</b>
<b>Operating expenses:</b>			
Research and development	37,163	30,951	31,151
General and administrative	13,437	12,458	13,273
Cease-use expense	1,092	82	2,799
<b>Total operating expenses</b>	<b>51,692</b>	<b>43,491</b>	<b>47,223</b>
<b>Income (loss) from operations</b>	<b>1,448</b>	<b>33,922</b>	<b>(13,722)</b>
<b>Other income:</b>			
Gain on sale/disposal of assets	32	242	294
Deferred gain on real estate	3,042	2,953	2,867
Investment income, net	489	418	1,538
Other income, net	14	36	1,055
<b>Total other income</b>	<b>3,577</b>	<b>3,649</b>	<b>5,754</b>
<b>Net income (loss)</b>	<b>\$ 5,025</b>	<b>\$ 37,571</b>	<b>\$ (7,968)</b>
<b>Net income (loss) per common share:</b>			
Basic	\$ 0.08	\$ 0.68	\$ (0.15)
Diluted	\$ 0.08	\$ 0.67	\$ (0.15)
<b>Shares used in the calculation of net income (loss) per common share:</b>			
Basic	65,619	55,176	52,820
Diluted	66,946	56,347	52,820
<b>Other comprehensive income (loss):</b>			
Net income (loss)	\$ 5,025	\$ 37,571	\$ (7,968)
Net unrealized gains (losses) on available-for-sale securities	85	(39)	(1,257)
<b>Comprehensive income (loss)</b>	<b>\$ 5,110</b>	<b>\$ 37,532</b>	<b>\$ (9,225)</b>

See accompanying notes.

**Table of Contents****NEUROCRINE BIOSCIENCES, INC.****Consolidated Statements of Stockholders' Equity**

(In thousands)

	Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders Equity
	Shares	Amount				
BALANCE AT DECEMBER 31, 2009	43,992	\$ 44	\$ 757,002	\$ 1,209	\$ (754,301)	\$ 3,954
Net loss					(7,968)	(7,968)
Unrealized loss on investments				(1,257)		(1,257)
Share-based compensation			3,133			3,133
Issuance of common stock for restricted share units vested	383	1				1
Issuance of common stock for option exercises	42		124			124
Issuance of common stock, net of offering costs	10,465	10	21,348			21,358
BALANCE AT DECEMBER 31, 2010	54,882	55	781,607	(48)	(762,269)	19,345
Net income					37,571	37,571
Unrealized loss on investments				(39)		(39)
Share-based compensation			2,918			2,918
Issuance of common stock for restricted share units vested	287					
Issuance of common stock for option exercises	94		286			286
BALANCE AT DECEMBER 31, 2011	55,263	\$ 55	\$ 784,811	\$ (87)	\$ (724,698)	\$ 60,081
Net income					5,025	5,025
Unrealized gain on investments				85		85
Share-based compensation			5,479			5,479
Issuance of common stock for restricted share units vested	50					
Issuance of common stock for option exercises	209		731			731
Issuance of common stock, net of offering costs	10,925	11	82,960			82,971
BALANCE AT DECEMBER 31, 2012	66,447	\$ 66	\$ 873,981	\$ (2)	\$ (719,673)	\$ 154,372

See accompanying notes.



**Table of Contents****NEUROCRINE BIOSCIENCES, INC.****Consolidated Statements of Cash Flows****(In thousands)**

	Years Ended December 31,		
	2012	2011	2010
<b>CASH FLOW FROM OPERATING ACTIVITIES</b>			
Net income (loss)	\$ 5,025	\$ 37,571	\$ (7,968)
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:			
Depreciation and amortization	657	694	1,436
Gain on sale of assets	(3,074)	(3,195)	(3,161)
Loss on sale of investments		17	186
Realized gain on sale of auction rate securities			(1,320)
Cease-use expense	1,092	82	2,799
Deferred revenues	(34,242)	(37,027)	62,490
Deferred rent	305	434	680
Amortization of premiums on investments	3,135	2,341	833
Non-cash share-based compensation expense	5,479	2,918	3,133
Change in operating assets and liabilities:			
Accounts receivable and other assets	(12,878)	2,813	(4,278)
Cease-use liability	(263)	(7,502)	(4,537)
Other liabilities	27	24	(1,335)
Accounts payable and accrued liabilities	(557)	149	985
Net cash (used in) provided by operating activities	(35,294)	(681)	49,943
<b>CASH FLOW FROM INVESTING ACTIVITIES</b>			
Purchases of investments	(166,313)	(139,099)	(89,787)
Sales/maturities of investments	132,520	134,259	34,839
Deposits and restricted cash	(29)	1,796	223
Proceeds from sales of property and equipment	32	245	336
Purchases of property and equipment	(971)	(750)	(315)
Net cash used in investing activities	(34,761)	(3,549)	(54,704)
<b>CASH FLOW FROM FINANCING ACTIVITIES</b>			
Issuance of common stock	83,702	286	21,483
Net cash provided by financing activities	83,702	286	21,483
Net change in cash and cash equivalents	13,647	(3,944)	16,722
Cash and cash equivalents at beginning of the year	50,107	54,051	37,329
Cash and cash equivalents at end of the year	\$ 63,754	\$ 50,107	\$ 54,051
<b>SUPPLEMENTAL DISCLOSURES</b>			
Taxes paid	\$	\$	\$

See accompanying notes.

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**NEUROCRINE BIOSCIENCES, INC.**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**December 31, 2012**

**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, develops and intends to commercialize drugs for the treatment of neurological and endocrine-related diseases and disorders. The Company's product candidates address some of the largest pharmaceutical markets in the world, including endometriosis, tardive dyskinesia, uterine fibroids, stress-related disorders, pain, diabetes, insomnia, and other neurological and endocrine-related diseases and disorders. While the Company independently develops many of its product candidates, it has entered into collaborations for several of its programs. The Company's lead clinical development program, elagolix, is a drug candidate for the treatment of endometriosis and uterine fibroids that is partnered with AbbVie Inc. (AbbVie), a spinoff of Abbott Laboratories that was completed in January 2013.

Neurocrine Continental, Inc. (formerly Neurocrine Commercial Operations, Inc.), is a Delaware corporation and a wholly owned subsidiary of the Company which is inactive.

**Principles of Consolidation.** The consolidated financial statements include the accounts of Neurocrine as well as its wholly owned subsidiary. 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 Investments Available-for-Sale.** Certain short-term 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 income (loss). The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in investment income. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income or expense. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in investment income.

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

**Collaboration Agreements.** During the years ended December 31, 2012, 2011, and 2010, collaborative research and development agreements accounted for all of the Company's revenue.

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

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**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-related 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.** Research and development (R&D) expenses consists primarily of salaries, payroll taxes, employee benefits, and share-based compensation charges, for those individuals involved in ongoing research and development 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 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.

**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 and (expense) (in thousands):

	Years Ended December 31,		
	2012	2011	2010
Interest income	489	435	397
Dividends			7
Realized gains/(losses), net		(17)	1,134
Total	\$ 489	\$ 418	\$ 1,538

**Net Income (Loss) Per Share.** The computation of basic earnings per share is based upon the weighted-average number of common shares outstanding. The computation of diluted earnings per share is based upon the weighted-average number of common shares and dilutive potential common shares outstanding. Dilutive

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potential common shares outstanding, determined using the treasury stock method, principally include shares that may be issued under the Company's stock option agreements. At December 31, 2012, the Company had approximately 1.3 million additional dilutive potential common shares as computed under the treasury method, yielding a total of 66.9 million diluted common shares outstanding. For the years ended December 31, 2012, 2011 and 2010, there were employee stock options, calculated on a weighted average basis, to purchase 2.2 million, 1.3 million and 0.5 million shares of our common stock for these periods that are not included in the computation of diluted EPS as their impact would have been anti-dilutive.

**Impact of Recently Issued Accounting Standards.** In December 2011, the Financial Accounting Standards Board (FASB) issued accounting guidance requiring an entity to disclose information about offsetting arrangements and the impact of these arrangements on the Company's financial position. This guidance is effective for interim and annual periods beginning on or after January 1, 2013. The Company does not expect the adoption of this guidance to have a material impact on its consolidated financial statements.

In May 2011, the FASB issued updated accounting guidance that clarifies existing fair value measurements and disclosures, and eliminates differences between GAAP and International Financial Reporting Standards to make convergence guidance more understandable. This guidance is effective for interim and annual periods beginning after December 15, 2011. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

Effective January 1, 2012, the Company adopted guidance issued by the FASB concerning presentation and disclosure only for the presentation of comprehensive (loss) income. The adoption of this guidance did not have a material impact on the Company's consolidated financial position or results of operations, other than its impact on the presentation of comprehensive (loss) income.

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

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

**AbbVie Inc. (AbbVie)** In June 2010, the Company announced an exclusive worldwide collaboration with Abbott Laboratories, now AbbVie subsequent to a spinoff of Abbott Laboratories that was completed in January 2013, to develop and commercialize elagolix and all next-generation gonadotropin-releasing hormone (GnRH) antagonists (collectively, GnRH Compounds) for women's and men's health. The goal of the agreement is to develop and commercialize GnRH Compounds. AbbVie made an upfront payment of \$75 million and has agreed to make additional development and regulatory event based payments of up to \$480 million and up to an additional \$50 million in commercial event based payments. 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

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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. During the year ended December 31, 2011, the Company recognized \$30.0 million in milestone revenue under the AbbVie collaboration, \$10.0 million of which was related to advancing elagolix into Phase II clinical trials for uterine fibroids and \$20.0 million of which was related to the outcome of an elagolix pre- Phase III meeting with the U.S. Food and Drug Administration (FDA) for endometriosis. As of December 31, 2012, there are no further event based payments that meet the definition of a milestone in accordance with authoritative guidance.

Under the terms of the agreement, AbbVie is responsible for all third-party development, marketing and commercialization costs. The Company received funding for certain internal collaboration expenses which included reimbursement from AbbVie for internal and external expenses related to the GnRH Compounds through the end of 2012. The Company will be entitled to a percentage of worldwide sales of GnRH Compounds for the longer of ten years or the life of the related patent rights. Under the terms of the Company's agreement with AbbVie, the collaboration effort between the parties to advance GnRH Compounds towards commercialization was governed by a joint development committee with representatives from both the Company and AbbVie. AbbVie may terminate the collaboration at its discretion upon 180 days written notice to the Company. In such event, the Company would be entitled to specified payments for ongoing clinical development and related activities and all GnRH Compound product rights would revert to the Company. The Company's participation in the joint development committee was determined to be a substantive deliverable under the contract, and therefore, the upfront payment was deferred and recognized over the term of the joint development committee, which was completed in December 2012. During 2012, the Company recorded \$13.1 million in revenue related to completion of the collaborative development period which is included in sponsored research and development revenue.

During the years ended December 31, 2012, 2011 and 2010, revenues recognized under the collaboration agreement with AbbVie were as follows (*in millions*):

	Year Ended December 31,		
	2012	2011	2010
Milestones and amortization of up-front license fees	\$ 29.1	\$ 59.0	\$ 16.9
Sponsored research and development	17.8	9.1	10.1
Revenues recognized under the AbbVie collaboration agreement	\$ 46.9	\$ 68.1	\$ 27.0

**Boehringer Ingelheim International GmbH** (*Boehringer Ingelheim*). In June 2010, the Company announced a worldwide collaboration with Boehringer Ingelheim to research, develop and commercialize small molecule GPR119 agonists for the treatment of Type II diabetes and other indications. Under the terms of the Company's agreement with Boehringer Ingelheim, the Company and Boehringer Ingelheim are working jointly, during a two year collaborative research period which ended in June 2012, to identify and advance GPR119 agonist candidates into preclinical development. Following the collaborative research period, Boehringer Ingelheim is responsible for the global development and commercialization of potential GPR119 agonist products, if any. The Company received a \$10 million upfront payment, and received research funding to support discovery efforts. Boehringer Ingelheim agreed to make payments of up to approximately \$3 million in additional preclinical milestone payments and payments of up to approximately \$223 million in clinical development and commercial event based payments. The Company has assessed milestones under the revised authoritative guidance for research and development milestones and determined that the preclinical milestone payments, as defined in the agreement, meet the definition of a milestone as they are (1) events that can only be achieved in part on the Company's performance or upon the occurrence of a specific outcome resulting from the Company's performance, (2) there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (3) they result in additional payments being due to the Company. Clinical

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development and commercial milestone payments, however, currently do not meet these criteria as their achievement is solely based on the performance of Boehringer Ingelheim. No milestone payments were recognized during the periods presented. The Company will be entitled to a percentage of any future worldwide sales of GPR119 agonists. Under the terms of the agreement, the collaboration effort between the parties to identify and advance GPR119 agonist candidates into preclinical development was initially governed by a steering committee with representatives from both the Company and Boehringer Ingelheim; provided, however, that final decision making authority rests with Boehringer Ingelheim. The Company's participation in the steering committee was determined to be a substantive deliverable under the contract, and therefore, the upfront payment was deferred and recognized over the two-year term of the steering committee which was completed in June 2012. Boehringer Ingelheim may terminate the agreement at its discretion upon prior written notice to the Company. In such event, the Company may be entitled to specified payments and product rights would revert to the Company.

During the years ended December 31, 2012, 2011 and 2010, revenues recognized under the collaboration agreement with Boehringer Ingelheim were as follows (*in millions*):

	Year Ended December 31,		
	2012	2011	2010
Amortization of up-front license fees	\$ 2.2	\$ 5.0	\$ 2.7
Sponsored research and development	1.0	1.3	0.8
Revenues recognized under the Boehringer Ingelheim collaboration agreement	\$ 3.2	\$ 6.3	\$ 3.5

**Dainippon Sumitomo Pharma Co., Ltd. (DSP).** On October 31, 2007, the Company entered into an exclusive license agreement with DSP, under which the Company licensed rights to indiplon to DSP and agreed to collaborate with DSP on the development and commercialization of indiplon in Japan. Pursuant to the license agreement, among other things, the Company received an up-front license fee of \$20 million. The Company is also eligible to receive additional event based payments upon specified future events related to the development and commercialization of indiplon in Japan. Should all event based payments be achieved, the Company may be entitled to payments totaling an additional \$115 million. Event based payments under the DSP agreement do not meet the criteria of a milestone in accordance with the authoritative guidance as they are based on the performance of DSP. Additionally, the Company is entitled to royalties from DSP on future sales of indiplon in Japan. For each of the years ending December 31, 2012, 2011 and 2010, the Company amortized annually into revenue \$2.9 million of the upfront license fee under the DSP agreement.

**GlaxoSmithKline (GSK).** In July 2001, the Company announced a worldwide collaboration with GSK to develop and commercialize CRF antagonists for psychiatric, neurological and gastrointestinal diseases. Under the terms of this agreement, the Company and GSK conducted a collaborative research program and collaborated in the development of Neurocrine's current lead CRF compounds, as well as novel back-up candidates and second generation compounds identified through the collaborative research. The Company recognized \$0.1 million in revenue under the GSK agreement in each of the years ended December 31, 2012, 2011 and 2010. The sponsored research portion of this collaboration agreement ended in 2005.

In September 2012, the Company and GSK entered into a Termination Agreement, pursuant to which the parties mutually agreed to terminate the collaboration agreement. Pursuant to the terms of the Termination Agreement, GSK's license to the Company's CRF assets terminated, reverting all rights to the Company and GSK assigned to the Company all patent rights created from the sponsored research portion of the collaboration agreement, including all related regulatory filings and approvals. GSK also assigned to the Company all other patents, regulator and technology assets that were owned or controlled by GSK and its affiliates necessary for the development and commercialization of CRF antagonist compounds.

**Table of Contents****NOTE 3. INVESTMENTS**

Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in comprehensive income (loss). The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in 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, 2012 and 2011 consist of the following (in thousands):

	Years Ended December 31,	
	2012	2011
Certificates of deposit	\$ 12,434	\$ 4,552
Commercial paper	19,695	12,467
Corporate debt securities	77,610	61,977
Total investments	\$ 109,739	\$ 78,996

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
<b>December 31, 2012:</b>					
Classified as current assets:					
Certificates of deposit	Less than 1	\$ 11,960	\$	\$ (6)	\$ 11,954
Commercial paper	Less than 1	19,713		(18)	19,695
Corporate debt securities	Less than 1	77,588	33	(11)	77,610
Total short-term available-for-sale securities		\$ 109,261	\$ 33	\$ (35)	\$ 109,259
Classified as non-current assets:					
Certificates of deposit	1 to 2	\$ 480	\$	\$	\$ 480
Total long-term available-for-sale securities		\$ 480	\$	\$	\$ 480
<b>December 31, 2011:</b>					
Classified as current assets:					
Certificates of deposit	Less than 1	\$ 4,560	\$	\$ (8)	\$ 4,552
Commercial paper	Less than 1	12,476	2	(11)	12,467
Corporate debt securities	Less than 1	62,047	6	(76)	61,977
Total short-term available-for-sale securities		\$ 79,083	\$ 8	\$ (95)	\$ 78,996

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





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

	Year Ended December 31,		
	2012	2011	2010
Proceeds from sales/maturities of available-for-sale securities	\$ 132,520	\$ 134,259	\$ 22,064
Gross realized gains on sales of available-for-sale securities			1,320
Gross realized losses on sales of available-for-sale securities		17	
Gains reclassified out of accumulated other comprehensive income (loss) into earnings			1,289

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

	Less Than 12 Months		12 Months or Greater		Total	
	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses
<b>December 31, 2012:</b>						
Certificates of deposit	\$ 10,273	\$ (6)	\$	\$	\$ 10,273	\$ (6)
Commercial paper	19,695	(18)			19,695	(18)
Corporate debt securities	37,524	(11)			37,524	(11)
<b>Total</b>	<b>\$ 67,492</b>	<b>\$ (35)</b>	<b>\$</b>	<b>\$</b>	<b>\$ 67,492</b>	<b>\$ (35)</b>
<b>December 31, 2011:</b>						
Certificates of deposit	\$ 4,312	\$ (8)	\$	\$	\$ 4,312	\$ (8)
Commercial paper	5,980	(11)			5,980	(11)
Corporate debt securities	54,974	(76)			54,974	(76)
<b>Total</b>	<b>\$ 65,266</b>	<b>\$ (95)</b>	<b>\$</b>	<b>\$</b>	<b>\$ 65,266</b>	<b>\$ (95)</b>

**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, 2012 and 2011.

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The Company's assets which are measured at fair value on a recurring basis as of December 31, 2012 and 2011 were determined using the inputs described above (in millions):

	Carrying Value	Fair Value Measurements Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>December 31, 2012:</b>				
Classified as current assets:				
Cash and money market funds	\$ 53.2	\$ 53.2	\$	\$
Certificates of deposit	16.2	16.2		
Commercial paper	25.7		25.7	
Corporate bonds	82.2		82.2	
Subtotal	177.3	69.4	107.9	
Classified as long-term assets:				
Certificates of deposit	0.5	0.5		
Total	177.8	69.9	107.9	
Less cash, cash equivalents and restricted cash	(68.1)	(57.5)	(10.6)	
Total investments	\$ 109.7	\$ 12.4	\$ 97.3	\$
<b>December 31, 2011:</b>				
Classified as current assets:				
Cash and money market funds	\$ 50.5	\$ 50.5	\$	\$
Certificates of deposit	5.2	5.2		
Commercial paper	12.5		12.5	
Corporate bonds	65.2		65.2	
Total	133.4	55.7	77.7	
Less cash, cash equivalents and restricted cash	(54.4)	(51.1)	(3.3)	
Total investments	\$ 79.0	\$ 4.6	\$ 74.4	\$

**NOTE 5. PROPERTY AND EQUIPMENT**

Property and equipment, net, at December 31, 2012 and 2011 consisted of the following (in thousands):

	2012	2011
Tenant improvements	1,195	1,118
Furniture and fixtures	819	966
Equipment	34,209	34,389
	36,223	36,473
Less accumulated depreciation	(34,323)	(34,887)
Property and equipment, net	\$ 1,900	\$ 1,586

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For the years ended December 31, 2012, 2011 and 2010, depreciation expense was \$0.7 million, \$0.7 million and \$1.4 million, respectively. During 2012, 2011 and 2010, the Company recognized a gain of approximately \$32,000, \$242,000 and \$294,000, respectively, related to disposal of capital equipment.

**Table of Contents****NOTE 6. ACCRUED LIABILITIES**

Accrued liabilities at December 31, 2012 and 2011 consist of the following (in thousands):

	2012	2011
Accrued employee related costs	\$ 3,811	\$ 3,842
Accrued development costs	1,231	1,475
Other accrued liabilities	3,052	3,134
	\$ 8,094	\$ 8,451

**NOTE 7. COMMITMENTS AND CONTINGENCIES**

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

Upon the closing of the sale of the facility and associated real property, the Company entered into a lease agreement (Lease) with DMH Campus Investors, LLC (DMH) whereby it leased back for an initial term of 12 years its corporate headquarters comprised of two buildings located at 12790 El Camino Real (Front Building) and 12780 El Camino Real (Rear Building) in San Diego, California. The Company also entered into a series of lease amendments (Amendments), beginning in late 2008, through which it vacated the Front Building, but continues to occupy the Rear Building. The ultimate result of this real estate sale was a net gain of \$39.1 million which was deferred in accordance with authoritative guidance. For the years ended December 31, 2012, 2011 and 2010, the Company recognized \$3.0 million, \$3.0 million and \$2.9 million, respectively, of the deferred gain and will recognize the remaining \$24.0 million of the deferred gain over the initial Lease term which will expire at the end of 2019.

Under the terms of the Lease and the Amendments, the Company pays base annual rent (subject to an annual fixed percentage increase), plus a 3.5% annual management fee, property taxes and other normal and necessary expenses associated with the Lease such as utilities, repairs and maintenance. In lieu of a cash security deposit under the Lease, Wells Fargo Bank, N.A. issued on the Company's behalf a letter of credit in the amount of \$4.2 million, which is secured by a deposit of equal amount with the same bank. The Company also has the right to extend the Lease for two consecutive ten-year terms.

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

In September 2011, the Company entered into a second sublease agreement (Second Sublease) for approximately 3,300 square feet of space in the Rear Building. The Second Sublease is expected to result in approximately \$0.1 million in rental income per year over the three year term and is recorded as an offset to rent

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expense. The Second Sublease provides an option to extend for a one-year renewal period. Similar to the Sublease, the Second Sublease resulted in \$0.3 million of gross cease-use expense, and a reversal of \$47,000 in associated deferred rent, being recorded in September 2011.

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

At December 31, 2012 and 2011, the Company had recorded in its consolidated balance sheet an aggregate cease-use liability related to the Sublease (as amended), the Second Sublease and the Third Sublease of \$3.7 million and \$2.6 million, respectively. At December 31, 2010, the Company also had a liability of \$7.5 million to the landlord related to the Amendments which permitted the Company to vacate the Front Building. This liability was retired in its entirety during 2011.

The following table sets forth changes to the accrued cease-use liability during 2012 and 2011 (in thousands):

	Years Ended December 31,	
	2012	2011
Beginning balance	\$ 2,592	\$ 9,965
Accreted cease use costs		277
Impact of Sublease cease-use charges(1)	1,360	324
Change in estimate	(3)	(472)
Payments	(263)	(7,502)
Ending balance	\$ 3,686	\$ 2,592

(1) Total sublease cease-use expense was offset by a related adjustment to deferred rent of approximately \$265,000 during 2012 and \$47,000 during 2011.

**Rent Expense.** Rent expense was \$5.9 million, \$6.2 million and \$6.4 million for the years ended December 31, 2012, 2011 and 2010, respectively. For financial reporting purposes, the Company recognizes rent expense on a straight-line basis over the term of the lease. Accordingly, rent expense recognized in excess of rent paid is reflected as a liability in the accompanying consolidated balance sheets.

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

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As of December 31, 2012, the total estimated future annual minimum lease payments under the Company's non-cancelable building lease for the years ending after December 31, 2012 are as follows (in thousands):

	<b>Payment Amount</b>
2013	\$ 6,961
2014	7,169
2015	7,385
2016	7,606
2017	7,834
Thereafter	16,381
<b>Total future minimum lease payments</b>	<b>\$ 53,336</b>

**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 \$13 million over the lives of these agreements, in addition to royalties on sales of the affected products at rates ranging up to 5%. Due to the uncertainties of the development process, the timing and probability of the milestone and royalty payments cannot be accurately estimated.

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

**NOTE 8. SHARE-BASED COMPENSATION**

**Share-Based Compensation Plans.** In May 2011, the Company adopted the Neurocrine Biosciences, Inc. 2011 Equity Incentive Plan (the 2011 Plan) pursuant to which 5,500,000 shares of Company common stock were reserved for future issuance. The 2011 Plan is the successor to the Company's 2003 Incentive Stock Plan (the 2003 Plan), 2001 Stock Option Plan (the 2001 Plan), 1997 Incentive Stock Plan, 1996 Director Stock Option Plan and 1992 Incentive Stock Plan (the 1992 Plan) (together, the Prior Plans). Although the Company no longer grants equity awards under the Prior Plans, all outstanding stock awards granted under the Prior Plans will continue to be subject to the terms and conditions as set forth in the agreements evidencing such stock awards and the terms of the Prior Plans, as applicable.

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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, stock appreciation rights, performance stock awards and other forms of equity compensation, as well as performance cash awards.

Since 1992, the Company has authorized approximately 20.7 million shares of common stock for issuance pursuant to the Prior Plans, several Employment Commencement Nonstatutory Stock Option Agreements and the 2011 Plan, (collectively, the Option Plans). The Option Plans provide for the grant of stock options, restricted stock awards, restricted stock unit awards, and stock bonuses to officers, directors, employees, and consultants of the Company. Currently, all new grants of stock options are made from the 2011 Plan or through Employment Commencement Nonstatutory Stock Option Agreements. As of December 31, 2012, of the 20.7 million shares originally reserved for issuance under the Option Plans, 3.9 million of these shares were originally reserved for issuance pursuant to the terms of the Prior Plans and would currently be available for issuance but for the Company's determination not to make further grants under these plans; 8.0 million were issued upon exercise of stock options previously granted or pursuant to restricted stock or stock bonus awards; 6.2 million were subject to outstanding options; and 2.6 million remained available for future grant under the 2011 Plan. 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 restricted stock units, and has 8.7 million shares of common stock reserved for such issuance as of December 31, 2012.

**Vesting Provisions of Share-Based Compensation.** Stock options granted under the Option Plans have terms from seven to ten years from the date of grant, and generally vest over a three to four-year period. Restricted stock units granted under the Option Plans generally have vesting periods of three years. However, certain retirement provisions in the 2003 Option Plan provide that employees who are age 55 or older, and have five or more years of service with the Company, will be entitled to accelerated vesting of all of the unvested stock option awards upon retirement from the Company. In these cases, share-based compensation expense may be recognized over a shorter period of time, and in some cases the entire share-based compensation expense may be recognized upon grant of the share-based compensation award. The maximum contractual term for all options granted from the 2011 Plan is ten years.

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

	Years Ended December 31,		
	2012	2011	2010
General and administrative expense	\$ 2,746	\$ 1,760	\$ 1,573
Research and development expense	2,733	1,158	1,560
Share-based compensation expense	\$ 5,479	\$ 2,918	\$ 3,133

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.

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**Stock Options.** The exercise price of all options granted during the years ended December 31, 2012, 2011 and 2010 was equal to the market value 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, 2012:

	Years Ended December 31,		
	2012	2011	2010
Risk-free interest rate	1.3%	1.4%	2.2%
Expected volatility of common stock	79%	82%	90%
Dividend yield	0.0%	0.0%	0.0%
Expected option term	6.8 years	6.2 years	4.6 years

The Company estimates the fair value of stock options using a Black-Scholes option-pricing model on the date of grant. The fair value of equity instruments that are ultimately expected to vest, net of estimated forfeitures, are recognized and amortized on a straight-line basis over the requisite service period. The Black-Scholes option-pricing model incorporates various and highly sensitive assumptions including expected volatility, expected term and interest rates. The expected volatility is based on the historical volatility of the Company's common stock over the most recent period commensurate with the estimated expected term of the Company's stock options. The expected option term is estimated based on historical experience as well as the status of the employee. For example, Directors and Officers have a longer expected option term than all other employees. Additionally, recent grants of stock options have a contractual life of ten years, versus seven years for older option grants, and the vesting period for recent option grants has been extended to four years, which together have resulted in an increase in the expected option term. The risk-free rate for periods within the contractual life of the option is based upon observed interest rates appropriate for the expected term of the Company's employee stock options. The Company has never declared or paid dividends and has no plans to do so in the foreseeable future.

Authoritative guidance requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Pre-vesting forfeitures for awards with monthly vesting terms were estimated to be 0% in 2012 based on historical experience. The effect of pre-vesting forfeitures for awards with monthly vesting terms has historically been negligible on the Company's recorded expense. Pre-vesting forfeitures for awards with annual vesting terms were also estimated at 0% in 2012 based on historical employee turnover experience. The effect of past restructurings has been excluded from the historical review of employee turnover. 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, 2012, 2011 and 2010, estimated as of the grant date using the Black-Scholes option valuation model, were \$6.05, \$4.14 and \$1.80, respectively.

A summary of the status of the Company's stock options as of December 31, 2012, 2011 and 2010 and of changes in options outstanding under the plans during the three years ended December 31, 2012 is as follows (in thousands, except for weighted average exercise price data):

	2012		2011		2010	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding at January 1	5,315	\$ 8.82	4,047	\$ 11.22	2,809	\$ 21.50
Granted/amended	1,446	8.50	1,605	5.90	2,019	2.65
Exercised	(209)	3.49	(94)	3.05	(42)	2.93
Canceled	(386)	29.66	(243)	31.73	(739)	27.34
Outstanding at December 31	6,166	\$ 7.62	5,315	\$ 8.82	4,047	\$ 11.22



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Options outstanding at December 31, 2012 have a weighted average remaining contractual term of 5.8 years.

For the year ended December 31, 2012, share-based compensation expense related to stock options was \$5.5 million. As of December 31, 2012, there was approximately \$9.8 million of unamortized compensation cost related to stock options, which is expected to be recognized over a weighted average vesting period of approximately 2.5 years. As of December 31, 2012, there were approximately 4.0 million options exercisable with a weighted average exercise price of \$8.02 and a weighted-average remaining contractual term of 4.5 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, 2012, 2011, and 2010 was \$943,000, \$423,000 and \$187,000, respectively. As of December 31, 2012, the total intrinsic value of options outstanding and exercisable was \$9.9 million. Cash received from stock option exercises for the years ended December 31, 2012, 2011 and 2010 was \$731,000, \$286,000 and \$124,000, respectively.

On September 10, 2010, the Company entered into Stock Option Cancellation Agreements with certain of its executive officers and directors, pursuant to which certain stock options previously granted to each such executive officer or director, were cancelled in exchange for a nominal payment by the Company of \$100 in the aggregate. The Stock Option Cancellation Agreements indicated that other than such nominal payment, the applicable executive officer or director had not received, and would not receive, any additional consideration in exchange for the cancellation of such options. Accordingly, while each such executive officer or director will be eligible to receive future equity grants in connection with the Company's regular grant practices, no such executive officer or director will receive any future equity award in exchange for the cancellation of such options. The Company recognized no compensation expense in conjunction with the cancellations other than the \$100 paid to each optionee because the cancelled options were all fully vested at the time of cancellation.

On January 10, 2013 the Company granted its employees approximately 0.6 million options that vest monthly over a four year period with a strike price of \$8.65.

**Restricted Stock Units.** Beginning in January 2006, certain employees received restricted stock units under the 2003 and 2011 Plans. The fair value of restricted stock units is based on the closing sale price of the Company's common stock on the NASDAQ Global Select Market on the date of issuance. The total number of restricted stock awards expected to vest is adjusted by estimated forfeiture rates, which has been based on historical experience of restricted stock awards. As of December 31, 2011, all compensation cost related to outstanding restricted stock units had been recognized. For the year ended December 31, 2011, share-based compensation expense related to restricted stock units was \$0.5 million. The total intrinsic value of restricted stock units converted into common shares during the years ended December 31, 2012, 2011 and 2010 was \$0.4 million, \$1.9 million and \$1.0, respectively. There were no restricted stock units outstanding as of December 31, 2012. The total intrinsic value of restricted stock units outstanding at December 31, 2011 was \$0.4 million based on the Company's closing stock price on that date.

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A summary of the status of the Company's restricted stock units as of December 31, 2012, 2011 and 2010 and of changes in restricted stock units outstanding under the plans for the three years ended December 31, 2012 is as follows (in thousands, except for weighted average grant date fair value per unit):

	2012		2011		2010	
	Number of	Weighted Average	Number of	Weighted Average	Number of	Weighted Average
	Units	Grant Date	Units	Grant Date	Units	Grant Date
		Fair		Fair		Fair
		Value per		Value per		Value per
		Unit		Unit		Unit
Restricted stock units outstanding at January 1	50	\$ 5.88	287	\$ 5.08	681	\$ 5.88
Restricted stock units granted			50	5.88		
Restricted stock units cancelled					(11)	5.62
Restricted stock units converted into common shares	(50)	5.88	(287)	5.08	(383)	6.49
Restricted stock units outstanding at December 31		\$	50	\$ 5.88	287	\$ 5.08

On January 10, 2013 the Company granted its employees approximately 0.4 million restricted stock units that vest annually over a four year period.

**NOTE 9. STOCKHOLDERS' EQUITY*****Equity Financing***

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

In March 2010, the Company completed a public offering of common stock in which it sold approximately 10.5 million shares of its common stock at an offering price of \$2.20 per share. The shares were sold pursuant to the Company's effective shelf registration statement with the SEC. The net proceeds generated from this transaction, after underwriting discounts and commissions and offering costs, were approximately \$21.4 million.

***Shelf Registration Statements***

In December 2012, the SEC declared effective a shelf registration statement filed by the Company in November 2012. The shelf registration statement allows the Company to issue shares of its common stock from time to time for an aggregate initial offering price of up to \$150 million. The specific terms of future offerings, if any, under the shelf registration statement would be established at the time of such offerings.

In December 2010, the SEC declared effective a shelf registration statement filed by the Company earlier in that month. The shelf registration statement allows the Company to issue shares of its common stock from time to time for an aggregate initial offering price of up to \$125 million. As December 31, 2012, the Company had approximately \$37 million still available under this shelf registration statement. The specific terms of future offerings, if any, under the shelf registration statement would be established at the time of such offerings.

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**NOTE 10. INCOME TAXES**

On January 1, 2007, the Company adopted the provisions of the FASB's authoritative accounting guidance, which, among other things, related to uncertain tax positions. Under the accounting guidance, 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.

There were no unrecognized tax benefits as of the date of adoption. As a result of the implementation of the guidance, the Company did not recognize an increase in the liability for unrecognized tax benefits and did not have any unrecognized tax benefits included in the balance sheet that would, if recognized, affect the effective tax rate. The adoption of the guidance did not impact the Company's financial condition, results of operations or cash flows.

The Company's practice 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, 2012 or December 31, 2011, and has not recognized interest and/or penalties in the statement of comprehensive income (loss) for the year ended December 31, 2012.

The Company is subject to taxation in the United States and various state jurisdictions. The Company's tax years for 1995 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, 2012, the Company had deferred tax assets of \$321.2 million. Due to uncertainties surrounding the Company's ability to generate future taxable income to realize these assets, a full valuation has been established to offset the net deferred tax asset. Additionally, the future utilization of the Company's net operating loss and research and development credit carry forwards to offset future taxable income may be subject to an annual limitation, pursuant to Internal Revenue Code Sections 382 and 383, as a result of ownership changes that could occur in the future. The Company has determined that no ownership changes have occurred through December 31, 2012.

At December 31, 2012, the Company had Federal and California income tax net operating loss carry forwards of approximately \$601.6 million and \$576.7 million, respectively. The Federal and California tax loss carry forwards will begin to expire in 2021 and 2015, respectively, unless previously utilized. In addition, the Company has Federal and California research and development tax credit carry forwards of \$29.9 million and \$21.5 million, respectively. The Federal research and development tax credit carry forwards began expiring in 2007 and will continue to expire unless utilized. There were \$1.2 million of Federal research and development tax credit carryforwards that have expired through 2012. The California research and development tax credit carryforwards carry forward indefinitely. The Company also has Federal Alternative Minimum Tax credit carryforwards of approximately \$257,000, which will carry forward indefinitely. At December 31, 2012, approximately \$17.6 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.

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Significant components of the Company's deferred tax assets as of December 31, 2012 and 2011 are listed below. A valuation allowance of \$321.2 million and \$325.3 million at December 31, 2012 and 2011, 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):

	2012	2011
Deferred tax assets:		
Net operating losses	\$ 236,500	\$ 238,000
Research and development credits	25,600	26,300
Capitalized research and development	21,000	6,000
Share-based compensation expense	4,900	4,500
Deferred revenue	2,000	16,000
Deferred gain on sales leaseback	9,800	11,000
Intangibles	15,800	18,400
Cease-use expense	1,500	1,100
Fixed assets	200	200
Other	3,900	3,800
Total deferred tax assets	321,200	325,300
Valuation allowance	(321,200)	(325,300)
Net deferred tax assets	\$	\$

The provision for income taxes on earnings subject to income taxes differs from the statutory Federal rate at December 31, 2012, 2011 and 2010, due to the following (in thousands):

	2012	2011	2010
Federal income taxes at 35%	\$ 1,759	\$ 13,150	\$ (2,789)
State income tax, net of Federal benefit	406	2,230	(177)
Tax effect on non-deductible expenses	9	43	(3)
Stock compensation	1,154	385	5,215
Expired tax attributes	327	159	132
Research credits	(428)	(3,395)	(508)
(Re-established)/removal of net operating losses and R&D credits		(278,778)	(16,429)
Change in valuation allowance	(4,061)	248,803	14,521
Uncertain tax positions	876	17,432	
Other	(42)	(29)	38
	\$	\$	\$

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

	2012	2011
Balance as of the beginning of the year	\$ 20,237	\$
Increases related to prior year tax positions	1,434	19,922
Increases related to current year tax positions	165	395
Expiration of the statute of limitations for the assessment of taxes	(164)	(80)
Balance as of the end of the year	\$ 21,672	\$ 20,237

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During the current year, the Company concluded that an ownership change did not occur in the current or prior years. However, 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 total \$1.4 million and \$0.2 million for prior year tax positions and current year tax positions, respectively, as reflected in the tabular rollforward above. The American Taxpayer Relief Act of 2012, which reinstated the United States federal research and development tax credit retroactively from January 1, 2012

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through December 31, 2013, was not enacted into law until the first quarter of 2013. Therefore, the expected tax benefit resulting from such reinstatement for 2012 will not be reflected in the Company's estimated annual effective tax rate until 2013.

As of December 31, 2012, the Company has \$18.3 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. Prior to July 1, 2009, the Company matched 50% of employee contributions up to 6% of eligible compensation, with cliff vesting of the employer match after three years. Effective July 1, 2009, the Company cancelled the matching contribution on the 401(k) Plan. The Company has reinstated the employer match effective January 1, 2011 on the same terms as prior to July 1, 2009. Employer contributions were \$0.2 million, \$0.2 million, and \$0 million for the years ended December 31, 2012, 2011 and 2010, respectively.

**NOTE 12. SUBSEQUENT EVENTS**

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

**NOTE 13. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)**

The following is a summary of the quarterly results of the Company for the years ended December 31, 2012 and 2011 (*unaudited, in thousands, except for per share data*):

	First Quarter	Year Ended December 31,			Year Ended December 31
		Second Quarter	Third Quarter	Fourth Quarter	
<b>2012:</b>					
Revenues	\$ 11,267	\$ 10,569	\$ 9,357	\$ 21,947	\$ 53,140
Operating expenses	13,059	11,949	13,319	13,365	51,692
Net income (loss)	(886)	(501)	(3,078)	9,490	5,025
Net income (loss) per share:					
Basic	\$ (0.01)	\$ (0.01)	\$ (0.05)	\$ 0.14	\$ 0.08
Diluted	\$ (0.01)	\$ (0.01)	\$ (0.05)	\$ 0.14	\$ 0.08
Shares used in the calculation of net income (loss) per share:					
Basic	63,409	66,309	66,342	66,406	65,619
Diluted	63,409	66,309	66,342	67,720	66,946
<b>2011:</b>					
Revenues	\$ 12,512	\$ 12,157	\$ 41,634	\$ 11,110	\$ 77,413
Operating expenses	10,573	11,061	11,194	10,663	43,491
Net income	2,882	1,976	31,382	1,331	37,571
Net income per share:					
Basic	\$ 0.05	\$ 0.04	\$ 0.57	\$ 0.02	\$ 0.68
Diluted	\$ 0.05	\$ 0.04	\$ 0.56	\$ 0.02	\$ 0.67
Shares used in the calculation of net income per share:					
Basic	54,983	55,209	55,248	55,259	55,176
Diluted	56,114	56,434	56,378	56,461	56,347

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**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

Not applicable.

**ITEM 9A. CONTROLS AND PROCEDURES**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the timelines specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the year covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

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**Management's Report on Internal Control Over Financial Reporting**

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

- (1) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- (2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and
- (3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

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

Management has used the framework set forth in the report entitled Internal Control-Integrated Framework published by the Committee of Sponsoring Organizations of the Treadway Commission, 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, 2012. 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, 2012, which is included herein.

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



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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of

Neurocrine Biosciences, Inc.

We have audited Neurocrine Biosciences, Inc.'s internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (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, 2012, 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, 2012 and 2011, and the related consolidated statements of comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2012 of Neurocrine Biosciences, Inc. and our report dated February 8, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, CA

February 8, 2013

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

None.

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**PART III**

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

Information required by this item will be contained in our Definitive Proxy Statement for our 2013 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2012. 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](http://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 2013 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2012. 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 2013 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2012. 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 2013 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2012. 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 2013 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2012. Such information is incorporated herein by reference.

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**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

**(a) Documents filed as part of this report.**

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

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2012 and 2011

Consolidated Statements of Comprehensive Income (Loss) for the years ended December 31, 2012, 2011 and 2010

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2012, 2011 and 2010

Consolidated Statements of Cash Flows for the years ended December 31, 2012, 2011 and 2010

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**

<b>Number</b>	<b>Description</b>
3.1	Certificate of Incorporation
3.2	Certificate of Amendment to Certificate of Incorporation
3.3	Bylaws, as amended
4.1	Form of Common Stock Certificate(1)
10.1**	1996 Director Option Plan, as amended, and form of stock option agreement(10)
10.2*	Research and License Agreement dated October 15, 1996, between the Company and Eli Lilly and Company(2)
10.3*	Sub-License and Development Agreement dated June 30, 1998, by and between DOV Pharmaceutical, Inc. and the Company(3)
10.4*	Collaboration and License Agreement dated January 1, 1999, by and between American Home Products Corporation acting through its Wyeth Laboratories Division and the Company(4)
10.5**	2001 Stock Option Plan, as amended August 6, 2002 and October 15, 2002(5)
10.6**	Neurocrine Biosciences, Inc. 2003 Incentive Stock Plan, as amended and form of stock option agreement and restricted stock unit agreement(12)

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**Exhibit**

<b>Number</b>	<b>Description</b>
10.7**	Form of Indemnity Agreement entered into between the Company and its officers and directors(9)
10.8	Assignment and License Agreement dated February 26, 2004 by and among Wyeth Holdings Corporation and the Company(6)
10.9	Consent Agreement and Amendment dated February 25, 2004 by and among Wyeth Holdings Corporation, the Company and DOV Pharmaceutical, Inc.(6)
10.10	License Agreement dated February 25, 2004 by and among Wyeth Holdings Corporation and DOV Pharmaceutical, Inc.(6)
10.11**	Employment Commencement Nonstatutory Stock Option Agreement dated October 31, 2005 between the Company and Christopher O Brien(8)
10.12*	License Agreement dated October 31, 2007 between the Company and Dainippon Sumitomo Pharma Co. Ltd.(11)
10.13*	Amendment dated October 29, 2007 to Sub-License and Development Agreement dated June 30, 1998, by and between DOV Pharmaceutical, Inc. and the Company(11)
10.14	Amended and Restated Lease dated November 1, 2011 between Neurocrine Biosciences, Inc. and DMH Campus Investors, LLC.(14)
10.15	Letter of Credit dated December 3, 2007, issued by Wells Fargo Bank, N.A. for the benefit of DMH Campus Investors, LLC, as amended on November 3, 2011. (14)
10.16**	Amended and Restated Employment Agreement effective August 1, 2007 between the Company and Kevin C. Gorman, Ph.D.(7)
10.17**	Transition and Separation Agreement dated August 31, 2011 between the Company and Margaret E. Valeur-Jensen, Ph.D., J.D.(15)
10.18**	Amended and Restated Employment Agreement effective August 1, 2007 between the Company and Timothy P. Coughlin(7)
10.19**	Amended and Restated Employment Agreement effective August 6, 2007 between the Company and Christopher F. O Brien M.D.(11)
10.20**	Amended and Restated Employment Agreement effective August 23, 2007 between the Company and Dimitri E. Grigoriadis, Ph.D.(11)
10.21**	Amended and Restated Employment Agreement effective August 14, 2007 between the Company and Haig Bozigian, Ph.D.(11)
10.22**	2011 Equity Incentive Plan, 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(16)
10.23*	Collaboration Agreement dated June 15, 2010 by and between Abbott International Luxembourg S.a.r.l. and the Company(13)
10.24*	First Amendment to Collaboration and License Agreement dated August 31, 2011 between the Company and Abbott International Luxembourg S.à r.l.(15)
10.25*	Collaboration and License Agreement dated June 16, 2010 by and between Boehringer Ingelheim International GmbH and the Company(13)
10.26**	Form of Amendment to Employment Agreement for executive officers(17)
21.1	Subsidiaries of the Company
23.1	Consent of Independent Registered Public Accounting Firm

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**Exhibit**

<b>Number</b>	<b>Description</b>
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 Annual Report on Form 10-K filed on March 31, 1997 (Commission File No. 333-03172)
- (3) Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed on August 14, 1998
- (4) Incorporated by reference to the Company's Annual Report on Form 10-K filed on March 31, 1999
- (5) Incorporated by reference to the Company's Annual Report on Form 10-K filed on March 4, 2003
- (6) Incorporated by reference to the Company's Current Report on Form 8-K filed on March 17, 2004
- (7) Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed on August 3, 2007
- (8) Incorporated by reference to the Company's Current Report on Form 8-K filed on November 1, 2005
- (9) Incorporated by reference to the Company's Current Report on Form 8-K filed on September 1, 2009
- (10) Incorporated by reference to the Company's Registration Statement on Form S-8 filed on June 26, 1998 (Commission File No. 333-57875)
- (11) Incorporated by reference to the Company's Annual Report on Form 10-K filed on February 11, 2008
- (12) Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed on July 30, 2009
- (13) Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed on July 29, 2010
- (14) Incorporated by reference to the Company's Current Report on Form 8-K filed on January 18, 2012
- (15) Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed on October 31, 2011
- (16) Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed on July 29, 2011
- (17) Incorporated by reference to the Company's Annual Report on Form 10-K filed on February 10, 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.
- \*\*\*\* Pursuant to applicable securities laws and regulations, we are deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and are not subject to liability under any anti-fraud provisions of the federal securities laws as long as we have made a good faith attempt

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to comply with the submission requirements and promptly amend the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. Users of this data are advised that, pursuant to Rule 406T, these interactive data files are deemed not filed and otherwise are not subject to liability.

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.

**Table of Contents****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 8, 2013

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:

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Kevin C. Gorman	President, Chief Executive Officer and Director	February 8, 2013
Kevin C. Gorman	(Principal Executive Officer)	
/s/ Timothy P. Coughlin	Chief Financial Officer	February 8, 2013
Timothy P. Coughlin	(Principal Financial and Accounting Officer)	
/s/ William H. Rastetter	Chairman of the Board of Directors	February 8, 2013
William H. Rastetter		
/s/ Gary A. Lyons	Director	February 8, 2013
Gary A. Lyons		
/s/ W. Thomas Mitchell	Director	February 8, 2013
W. Thomas Mitchell		
/s/ Joseph A. Mollica	Director	February 8, 2013
Joseph A. Mollica		
/s/ Corinne H. Nevinny	Director	February 8, 2013
Corinne H. Nevinny		
/s/ Richard F. Pops	Director	February 8, 2013
Richard F. Pops		



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/s/ Stephen A. Sherwin

Director

February 8, 2013

Stephen A. Sherwin

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