NEUROCRINE BIOSCIENCES INC
Form 10-K
February 08, 2010
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# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# Form 10-K

**(Mark One)**

**þ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the fiscal year ended December 31, 2009**

**OR**

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

**Commission file number: 0-22705**

# NEUROCRINE BIOSCIENCES, INC.

**(Exact name of registrant as specified in its charter)**

| **Delaware** | **33-0525145** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification Number)** |
| **12780 El Camino Real, San Diego, CA** | **92130** |
| **(Address of principal executive offices)** | **(Zip Code)** |

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

**(858) 617-7600**

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

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

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨

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

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

| Large accelerated filer ¨ | Accelerated filer þ | Non-accelerated filer ¨ | Smaller reporting company ¨ |
|---|---|---|---|

(Do not check if a smaller reporting company)

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

The aggregate market value of the common equity held by non-affiliates of the registrant as of June 30, 2009 totaled approximately $87,502,515 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, 2009. The identification of 10% or greater

stockholders as of June 30, 2009 is based on Schedule 13G and amended Schedule 13G reports publicly filed before June 30, 2009. This calculation does not reflect a determination that such parties are affiliates for any other purposes.

As of January 29, 2010, there were 44,061,902 shares of the registrant s Common Stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

| **Document Description** | **10-K Part** |
|---|---|
| Portions of the registrant s notice of annual meeting of stockholders and proxy statement to be filed pursuant to Regulation 14A within 120 days after registrant s fiscal year end of December 31, 2009 are incorporated by reference into Part III of this report | III |

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**PART I**

**FORWARD-LOOKING STATEMENTS**

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

Forward-looking statements can be identified by the use of forward-looking words such as believes, expects, hopes, may, will, plan, estimates, could, should, would, continue, seeks, pro forma, or anticipates, or other similar words (including their use in the ne discussions of future matters such as the development of new products, technology enhancements, possible changes in legislation and other statements that are not historical. These statements include but are not limited to statements under the captions Risk Factors, Management s Discussion and Analysis of Financial Condition and Results of Operations and Business as well as other sections in this report. You should be aware that the occurrence of any of the events discussed under the heading Item 1A. Risk Factors and elsewhere in this report could substantially harm our business, results of operations and financial condition and that if any of these events occurs, the trading price of our common stock could decline and you could lose all or a part of the value of your shares of our common stock.

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

**ITEM 1.** ***BUSINESS***

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

We discover, 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, anxiety, depression, pain, diabetes, irritable bowel syndrome, insomnia, and other neurological and endocrine-related diseases and disorders. We currently have eight 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 a collaboration for two of our programs. Our lead clinical development program, *elagolix*, is a drug candidate for the treatment of endometriosis.

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**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:

| Program | Target Indication(s) | Status | Commercial Rights |
|---|---|---|---|
| ***Products in clinical development:*** | | | |
| *Elagolix* | Endometriosis | Phase II | Neurocrine |
| $CRF_1$ Antagonist (561679) | Mood Disorders | Phase II | GlaxoSmithKline/ Neurocrine |
| $CRF_2$ Peptide Agonist urocortin 2 | Cardiovascular | Phase II | Neurocrine |
| $CRF_1$ Antagonist (586529) | Mood Disorders, Irritable Bowel Syndrome | Phase I | GlaxoSmithKline/ Neurocrine |
| Vesicular Monoamine Transporter 2 Inhibitor (VMAT2) | Movement Disorders, Schizophrenia | Phase I | Neurocrine |
| *Elagolix* | Uterine Fibroids Men s and Women s Health | Phase I | Neurocrine |
| ***Research programs:*** | | | |
| Glucose Dependent Insulin Secretagogues | Type II Diabetes | Research | Neurocrine |
| Antiepileptic Drugs | Epilepsy, Bipolar Disorder | Research | Neurocrine |
| GnRH Antagonists | Hormone Dependent Diseases, Oncology | Research | Neurocrine |
| ***Products subject to regulatory review:*** | | | |
| Indiplon 5mg and 10mg capsules | Insomnia | FDA has deemed approvable | Neurocrine/Dainippon Sumitomo Pharma Co. |
| Indiplon 15mg tablets | Insomnia | FDA has deemed not approvable | Neurocrine |

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.

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

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

$CRF_1$ and $CRF_2$ refer to two CRF receptor subtypes.

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**Products Under Clinical Development**

***Elagolix Gonadotropin-Releasing Hormone (GnRH) Antagonist***

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

Orally active, nonpeptide GnRH antagonists potentially offer several advantages over injectable GnRH peptide drugs, including rapid onset of hormone suppression without 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 approximately 100 million women worldwide who suffer from endometriosis. Datamonitor (2007) estimates that there are approximately 7.5 million women in the United States who suffer from the symptoms of endometriosis. With annual healthcare costs and endometriosis-related productivity losses of approximately $4,000 per patient, the annual direct and indirect costs of endometriosis are estimated to exceed $20 billion in the United States alone (Simoens *et al* Human Reproduction Update 2007, 13:395). 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 higher treatment rate.

In 2005-2006, early clinical trials of our lead, orally active nonpeptide GnRH antagonist, *elagolix*, for endometriosis were completed. These studies demonstrated that *elagolix* was safe and well tolerated. Dose-dependent hormonal suppression with once a day *elagolix* was observed in doses ranging from 50mg to 400mg a day. These studies also showed a dose related reduction in pain and other symptoms of endometriosis.

During 2007, we completed a bridging study comparing *elagolix* drug formulations (tablets and solutions) we had used in clinical trials to date to new formulations of tablets. The successful completion of this study that allowed us to select what we anticipate will be our final commercial tablet formulation of *elagolix*.

During 2008, we completed the dosing and 6-month follow up of a Phase IIb study (603 study) in which 252 patients, with a laparoscopic diagnosis of endometriosis, were treated over the initial 6-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

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dual energy x-ray absorptiometry (DXA) scan at the conclusion of treatment and at 6 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.

This study confirmed our decision to move forward with once daily dosing as *elagolix* displayed approximately the same efficacy whether given once or twice daily and demonstrated a superior safety profile for bone mineral density when given once daily. Patient follow up both 6 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.

We conducted two additional Phase IIb trials of *elagolix* to fully explore its dose range, to evaluate modified endpoints as proposed by the U.S. Food and Drug Administration (FDA), for dysmenorrhea, non-menstrual pelvic pain and dyspareunia as measured on a daily basis (rather than the CPSSS monthly recall) and to evaluate *elagolix* in a comparator trial with a monthly injection of leuprorelin (Prostap® SR). Both of these trials utilized our selected commercial formulation tablet for six months of treatment. These two trials were designed to assess *elagolix* against placebo (and Prostap® SR) 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 study 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 placebo controlled portion of the 702 study concluded in early 2009, and showed that *elagolix* provides endometriosis sufferers with clinical improvement of symptoms, coupled with an excellent safety and tolerability profile. As shown with all previous *elagolix* trials, symptoms of dysmenorrhea as measured by the FDA proposed daily scale improved significantly in both *elagolix* treatment groups compared to placebo (*elagolix* 150 mg, $p<0.01$; *elagolix* 250 mg, $p<0.001$). However, the FDA-proposed non-menstrual pelvic pain daily scale was relatively insensitive to treatment effects. The non-menstrual pelvic pain score of 0.83 was low at baseline and decreased across all treatment groups by approximately 0.25 points.

During the 702 study, the frequency of treatment-related adverse events was 8% in the placebo group and 14% and 15% in the two *elagolix* treatment groups. There were no serious adverse events during the treatment period. The two most common adverse events were headache and nausea, which were typically mild and transient and consistent with our previous studies. Additionally, the 150mg dose of *elagolix* did not have any significant impact on bone mineral density, consistent with the results of the 603 study.

During 2009, the second additional Phase IIb trial (Tulip PETAL study or 703 study) completed the three-month placebo controlled portion in Central Eastern Europe which consisted of four arms, *elagolix* 150mg once daily, *elagolix* 250mg once daily, Prostap® SR 3.75mg (leuprorelin), and placebo. We enrolled 174 subjects, with a laparoscopic diagnosis of endometriosis, in this trial. The placebo controlled portion of the 703 study confirms that *elagolix* and leuprorelin are associated with reductions in dysmenorrhea and non-menstrual pelvic pain daily scores when compared to placebo. As shown with all previous *elagolix* trials, symptoms of dysmenorrhea improved significantly in both *elagolix* treatment groups and with leuprorelin compared to placebo ($p<0.0001$). Additionally, the percentage of dysmenorrhea pain-free days was markedly higher in the *elagolix* treatment groups when compared to placebo (*elagolix* 150mg, *elagolix* 250mg, and leuprorelin, $p<0.0001$). However, the FDA proposed non-menstrual pelvic pain daily scale numeric changes and dynamic range were small.

The most common adverse events reported in the 703 trial as occurring more often with *elagolix* than with placebo were nausea and headache ($\leq$12%), consistent with previous clinical studies of *elagolix*. These events

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were generally mild or moderate, transient and not 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 pain and dysmenorrhea daily scale and launched a new clinical trial, the Daisy PETAL Study (901 Study) in the United States. This double-blind placebo-controlled clinical trial is designed to provide an assessment of the modified scale over a two-month treatment period of 150mg *elagolix*, followed by twenty weeks of open-label treatment. This trial will randomize approximately 120 subjects at 36 centers. Preliminary review of blinded data from the screening period indicates that the non-menstrual pain scale has a wide dynamic range and therefore should be more appropriate for pivotal trials than the scale used in the 702 and 703 studies. We will use the top-line data, expected in May 2010, from the Daisy PETAL Study to inform our Phase III protocol design which we intend to submit as a Special Protocol Assessment to the FDA.

We expect to have an end of Phase II meeting with the FDA in mid-2010, the purpose of which would be to agree with the FDA on the design of the pivotal Phase III program for *elagolix* in endometriosis. Subject to agreement with the FDA on the trial design, we expect *elagolix* to be ready for Phase III clinical trials in late 2010. We do not intend on initiating the *elagolix* Phase III studies until we have partnered the *elagolix* program.

***Corticotropin-Releasing Factor (CRF) Receptor$_1$ Antagonist***

According to Datamonitor (2007), the prevalence of major depressive disorder exceeds 20 million in the United States alone with an estimated 121 million sufferers worldwide. Estimates based on data from the National Institute of Mental Health and the U.S. Census Bureau, Population Division also indicate that in 2007 over 20 million Americans suffer from a debilitating anxiety disorder. In 2008, the worldwide branded market for depression therapeutics exceeded $15 billion (Datamonitor 2009).

*Depression.* Depression is one of a group of neuropsychiatric disorders that is characterized by extreme feelings of despair, loss of body weight, decreased aggressiveness and sexual behavior, and loss of sleep. Researchers believe that depression results from a combination of environmental factors, including stress, as well as an individual s biochemical vulnerability, which is genetically predetermined. The most frequently prescribed antidepressant therapies are drugs that inhibit the reuptake of the neurotransmitters serotonin, norepinephrine and dopamine and include drugs such as Zoloft®, Paxil®, Lexapro®, Prozac®, Cymbalta®, Pristiq®, Wellbutrin® and Effexor® as well as certain generic equivalents. These compounds act by inhibiting the reuptake of neurotransmitters back into presynaptic neurons thus effectively increasing their levels and enhancing activity in the brain. However, because these drugs affect a wide range of neurotransmitters, they have been associated with a number of adverse side effects. While newer, more selective drugs offer some safety improvement, side effects remain problematic. Two of the biggest limitations of most existing antidepressant therapies are their slow onset of action and their negative effects on libido.

*Anxiety.* Anxiety is among the most commonly observed group of central nervous system disorders, which includes phobias or irrational fears, panic attacks, and other syndromes. Of the pharmaceutical agents that other companies currently market for the treatment of anxiety disorders, benzodiazepines, such as Valium® and Xanax® and the anxiolytics BuSpar® and Effexor® as well as certain generic equivalents are the most frequently prescribed. Several side effects, however, limit the utility of these anti-anxiety drugs. Most problematic among these are drowsiness, memory difficulties, drug dependency and withdrawal reactions following the termination of therapy.

Researchers have identified what they believe to be the central mediator of the body s stress responses or stress-induced disorders (including depression and anxiety). This mediator is a brain chemical known as corticotropin-releasing factor, or CRF. CRF is overproduced in clinically depressed patients and may be dysregulated in individuals with anxiety disorders. Current research indicates that clinically depressed patients

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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 depression or anxiety. 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 depression. We also believe that CRF offers a novel mechanism of action and the advantage of being more selective, thereby providing increased efficacy with reduced side effects in anxiety when compared to benzodiazepines.

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 $CRF_1$ and $CRF_2$, and we have pending patent applications on small molecule organic compounds modulating the CRF receptors.

The first clinical trial to offer evidence of proof of concept of CRF antagonists in addressing depression (and anxiety as a co-examined variable) was a Phase IIa open label trial we conducted in 1999 pursuant to collaborations with Janssen Pharmaceutica (Janssen) in the field of CRF antagonists. Results from this trial indicated that the drug candidate was safe and well tolerated and demonstrated anti-depressant activity as measured by a widely-accepted depression scale known as the Hamilton Depression Scale. In this trial, the drug candidate was administered to 20 patients with major depressive disorder. Results from the trial, as reported in the Journal of Psychiatric Research, showed that treatment response, as defined by more than a 50% reduction in Hamilton Depression Scores, occurred in 50% of the patients in the low dose group and 80% of the patients in the higher dose group. Additionally, the drug candidate demonstrated a reduction in Hamilton Anxiety Scores from baseline in both treatment groups at all times after dosing. While development of our first generation CRF antagonist was discontinued for safety reasons by our collaborator Janssen, we were encouraged by these results which we believe support the hypothesized mechanism of action. Our CRF antagonist research collaboration with Janssen was terminated in March 2002.

In July 2001, we announced our second CRF antagonist collaboration, 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 our current lead compounds, as well as novel back-up candidates and second generation compounds identified through the collaborative research. The sponsored research portion of the collaboration was completed in 2005.

GSK advanced one of the lead $CRF_1$ receptor antagonist compounds, 561679, into a Phase II depression study during 2008. This multicenter randomized, double-blind, placebo-controlled trial is designed to assess the safety and efficacy of 561679 in approximately 150 women with Major Depressive Disorder over six weeks of treatment. This study is scheduled to complete the treatment phase in mid-2010, with top-line results available thereafter.

Emory University of Atlanta and Mt. Sinai Medical Center in New York, in conjunction with GSK, through a grant from the National Institute of Mental Health, have recently initiated a second 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 is expected to take several years to complete.

Additionally, the National Institute on Alcohol Abuse and Alcoholism, in conjunction with GSK, is planning to initiate 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 50 patients for a four-week treatment period. This study is expected to take two years to complete.

GSK has also successfully completed a Phase I single dose escalating clinical trial with 586529, an additional $CRF_1$ receptor antagonist compound.

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*Irritable Bowel Syndrome.* Research has also suggested that CRF plays a role in the control or modulation of the gastrointestinal system. Studies have demonstrated that central administration of CRF acts to inhibit emptying of the stomach while stimulating bowel activity, and suggest that overproduction of CRF in the brain may be a main contributor to stress-related gastrointestinal disorders.

IBS is a gastrointestinal inflammatory disease that affects between 25 to 45 million people in the United States, accounting for over $20 billion in direct and indirect costs each year, according to the International Foundation for Functional Gastrointestinal Disorders. IBS can be a lifelong, intermittent disease, involving chronic or recurrent abdominal pain and frequent diarrhea or constipation. Some patients with IBS report the onset of symptoms of the disease following a major life stress event, such as death in the family, which suggests that the causes of IBS may be related to stress. In addition, most IBS sufferers also experience anxiety and depression.

During 2008, GSK completed a Phase II clinical trial assessing the safety and efficacy of $CRF_1$ receptor antagonist compound 876008 in patients with IBS. In this double-blind, randomized, placebo controlled study, no statistically significant differences were observed in the key efficacy endpoints between 876008 and placebo. Approximately 130 patients meeting established diagnostic criteria for IBS were entered into this cross-over design trial.

***$CRF_2$ 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 2008 data from the American Heart Association, over 5 million people experience CHF and about 660,000 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 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. There are in excess of one million hospitalizations each year in the United States for CHF (AMA 2009).

Urocortin 2 is an endogenous peptide ligand of the $CRF_2$ 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.

During 2005, we completed a Phase II placebo controlled dose-escalation study 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%.

During 2008, we completed the necessary preclinical work to allow for periods of infusion of urocortin 2 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.

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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 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 vasodialators) will be compared to standard of care treatment plus a four hour infusion of urocortin 2; enrollment of subjects is currently underway. A subset of 10 subjects will also undergo right heart catheterization for more detailed evaluation of their cardiac status and response to treatment. Enrollment in this study began in September 2009 and is expected to take approximately one year depending on recruitment activities.

Additional urocortin 2 studies are to be conducted by the Centre for Cardiovascular Sciences at The University of Edinburgh through a British Heart Foundation grant. Nine studies will be conducted in both healthy volunteers and patients with stable CHF to determine the impact of urocortin 2 infusions on biomarkers of cardiovascular function and dysfunction. The studies are anticipated to begin in early 2010.

***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 monamines (dopamine, norepinephrine, serotonin, and histamine) among nerve cells. Specifically, dopamine enables neurotransmission among nerve cells that are involved in voluntary and involuntary motor control.

We have identified a highly selective VMAT2 inhibitor that is effective in pre-clinical testing in regulating the levels of dopamine release during nerve communication, while at the same time having minimal impact on the other monoamines thereby reducing the likelihood of off target side effects.

During 2009, our VMAT2 inhibitor completed a Phase I single ascending dose clinical trial in healthy male volunteers in Canada under an approved Clinical Trial Application with Health Canada. This trial showed our VMAT2 inhibitor to be generally safe and well tolerated. There were no serious adverse events, clinically significant drug-related laboratory abnormalities or clinically significant ECG findings. The characteristics of our VMAT2 inhibitor 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.

The next step in our VMAT2 development program is to complete a multiple, repeated dose Phase I study in healthy male volunteers. Assuming successful completion of the study, we intend to approach the FDA regarding the filing of an Investigational New Drug application in the United States with the express purpose of initiating a proof-of-concept study in patients with tardive dyskinesia in late 2010.

Tardive dyskinesia is characterized by involuntary movements of the muscles of the face, trunk or limbs which arise after months or years of dopamine antagonist treatment, e.g. typical and atypical antipsychotics for schizophrenia, bipolar, and refractory depression, and metoclopramide for nausea and vomiting. While the prevalence rates of tardive dyskinesia can vary greatly in accordance with the population being studied, it is estimated that 150,000-250,000 individuals are affected by tardive dyskinesia in the United States alone.

In addition to tardive dyskinesia, we believe that this clinical candidate may be effective in the management of other hyperkinetic movement disorders characterized by involuntary bodily movements such as Tourette s syndrome, tardive dystonia, and Huntington s disease. Additionally, the modulation of dopamine pathways may also be useful for patients suffering from schizophrenia, one population at risk for tardive dyskinesia.

**Research Programs**

Our research and development focus is on addressing diseases and disorders of the central nervous system and endocrine system, which include therapeutic categories ranging from diabetes to stress-related disorders and

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neurodegenerative diseases. Central nervous system and endocrinology drug therapies are among the largest therapeutic categories, accounting for over $60 billion in worldwide drug sales in 2007 according to Med Ad News.

***Glucose Dependent Insulin Secretagogues***

Type II diabetes affects more than 23 million Americans (Datamonitor 2007), and is growing at epidemic proportions world-wide. The 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. Our scientists are optimizing small molecule compounds that act in this way in order to discover novel oral therapies for glucose control in diabetes.

***Antiepileptic Drugs***

Anticonvulsants are utilized in the treatment of epileptic seizures by suppressing the rapid firing of neurons that initiate a seizure. Anticonvulsants also have additional effects within the central nervous system that have proven beneficial in bipolar disease, neuropathic pain and essential tremor. In 2008, worldwide sales of anticonvulsants totaled approximately $11 billion (EvaluatePharma).

***GnRH Antagonists***

As previously mentioned, GnRH antagonists may be useful in treating certain hormone dependent diseases. Our discovery work in nonpeptide GnRH antagonists continues to focus on endometriosis, uterine fibroids and oncology indications as we continue to develop additional candidates for preclinical and clinical trials.

**Programs Subject to Regulatory Review**

***Indiplon***

Indiplon is a non-benzodiazepine $GABA_A$ 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 (FDA Not Approvable Letter).

The FDA Not Approvable Letter for the tablets requested that we reanalyze certain safety and efficacy data and questioned the sufficiency of the objective sleep maintenance clinical data with the 15mg tablet in view of the fact that the majority of our indiplon tablet studies were conducted with doses higher than 15mg. We held an end-of-review meeting with the FDA related to the FDA Not Approvable Letter in October 2006. This meeting was specifically focused on determining the actions needed to bring indiplon tablets from Not Approvable to Approval in the resubmission of the NDA for indiplon tablets. The FDA has requested additional long-term safety and efficacy data with the 15mg dose for the adult population and the development of a separate dose for the elderly population.

The 2006 FDA Approvable Letter requested that we reanalyze data from certain preclinical and clinical studies to support approval of indiplon 5mg and 10mg capsules for sleep initiation and middle of the night

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dosing. The 2006 FDA Approvable Letter also requested reexamination of the safety analyses. We held an end-of-review meeting with the FDA related to the 2006 FDA Approvable Letter in August 2006. This meeting was specifically focused on determining the actions needed to bring indiplon capsules from Approvable to Approval in the resubmission of the NDA for indiplon capsules. At the meeting, the FDA requested that the resubmission include further analyses and modifications of analyses previously submitted to address questions raised by the FDA in the initial review. This reanalysis was completed. The FDA also requested, and we completed, a supplemental pharmacokinetic/food effect profile of indiplon capsules including several meal types.

On June 12, 2007, we resubmitted our NDA for indiplon 5mg and 10mg capsules seeking clearance to market indiplon capsules for the treatment of insomnia. The FDA accepted the NDA resubmission and established a Prescription Drug User Fee Act (PDUFA) date of December 12, 2007. On December 12, 2007 we received an action letter from the FDA stating the indiplon 5mg and 10mg capsules are approvable (2007 FDA Approvable Letter). The 2007 FDA Approvable Letter acknowledged that the resubmitted NDA had addressed the issues raised in the 2006 FDA Approvable Letter, but set forth new requirements. The new requirements set forth in the 2007 FDA Approvable Letter are the following: (i) an objective/subjective clinical trial in the elderly, (ii) a safety study assessing the rates of adverse events occurring with indiplon when compared to a marketed product, and (iii) a preclinical study to evaluate indiplon administration during the third trimester of pregnancy.

In July 2008 we held an end-of-review meeting with the FDA to discuss the 2007 FDA Approvable Letter. We have not received the final minutes of this meeting. 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 are currently evaluating 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 eight 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 Drug Targets to Address Unmet Market Opportunities.* We seek to identify and validate novel drug targets for internal development or collaboration. For example, the novel drug candidates we have identified to regulate CRF, which is believed to be the central mediator of the body s stress response, may represent the first new breakthrough for anxiety and depression in over 25 years. 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. The creativity and productivity of our discovery research group will continue to be a critical component for our continued success. Our team has a goal of delivering one innovative clinical compound each year to fuel our research and development pipeline. Research and development costs were $35.8 million, $55.3 million, and $82.0 million for the years ended December 31, 2009, 2008 and 2007, respectively.

*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.

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*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. For example, during 2003, we licensed our urocortin 2 product candidate from the Research Development Foundation.

**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:

*GlaxoSmithKline (GSK).* In July 2001, we announced a worldwide collaboration with an affiliate of 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 collaborate in the development of our current lead compounds, as well as novel back-up candidates and second generation compounds identified through the collaborative research. In addition, we will be eligible to receive milestone payments as compounds progress through the research and development process, royalties on future product sales and co-promotion rights in the U.S. in some circumstances. GSK may terminate the agreement at its discretion upon 90 days prior written notice to us. In such event, we may be entitled to specified payments and all product rights would revert to us. As of December 31, 2009, we had recorded revenues of $4.5 million in license fees, $29.8 million in milestone payments, $19.5 million in sponsored research payments and $1.4 million in reimbursement of development costs, over the life of the agreement. The sponsored research portion of this collaboration agreement concluded in 2005.

*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 $20.0 million and is responsible for all future development, marketing and commercialization costs of indiplon in Japan. We will be eligible to receive additional milestone payments upon specified future events related to the development and commercialization of indiplon in Japan. Should all milestones be achieved, we may be entitled to additional payments totaling up to $115.0 million. We are also entitled to royalties from DSP on future sales of indiplon in Japan. As of December 31, 2009, we had recorded revenues of $6.3 million in license fees from DSP over the life of the agreement.

**Intellectual Property**

We seek to protect our lead compounds, compound libraries, expressed proteins, synthetic organic processes, formulations, assays, cloned targets, screening technology and other technologies by filing, or by causing to be filed on our behalf, patent applications in the United States and abroad. These applications have resulted in the issuance of approximately 75 United States patents of which approximately 55 were in force as of February 3, 2010. 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.

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**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. Under our collaboration agreement with GSK we may have the opportunity to co-promote any products resulting from the collaboration in the United States. To market any of our other 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.

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, reevaluate, alter, suspend or terminate the testing based upon the data

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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, 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.

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, anxiety, depression, pain, diabetes, irritable bowel syndrome, insomnia, and other neurological and endocrine-related diseases and disorders.

Lupron Depot®, marketed by Abbott Laboratories, and Synarel® and Depo-Provera®, marketed by Pfizer, are products that have been approved for the treatment of endometriosis, infertility, and central precocious puberty. These drugs may compete with any small molecule gonadotropin-releasing hormone antagonists we develop for these indications.

Potential indications for our small molecule CRF antagonists include anxiety disorders, depression, and irritable bowel syndrome, among others, our drug candidates will be commercialized in well-established markets. In the area of anxiety disorders, our product candidates will compete with products such as Valium®, marketed by Hoffman-La Roche, Xanax®, marketed by Pfizer, BuSpar®, marketed by Bristol-Myers Squibb, Zoloft®, marketed by Pfizer, Wellbutrin®, marketed by GSK and Effexor®, marketed by Pfizer, among others, as well as any generic alternatives for each of these products.

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In the area of depression, our product candidates will compete with products in the antidepressant class, including Prozac® and Cymbalta®, marketed by Eli Lilly, Zoloft®, marketed by Pfizer, Paxil®, marketed by GSK, Effexor®, marketed by Pfizer, and Lexapro®, marketed by Forest Laboratories, among others.

In the area of irritable bowel syndrome, our product candidates will compete with such products as Lotronex® marketed by Prometheus Laboratories Inc. in the United States. Some technologies under development by other pharmaceutical companies could result in additional commercial treatments for depression and anxiety. In addition, a number of companies also are conducting research on molecules to block CRF, which is the same mechanism of action employed by our compounds.

In the area of insomnia, competitive products include Ambien®, Sonata®, Lunesta®, and Rozerem®, which are currently marketed by Sanofi-Aventis, King Pharmaceuticals, Inc., Sepracor, Inc., and Takeda Pharmaceutical Company, respectively. During 2006, Sanofi-Aventis launched a controlled-release formulation of Ambien® called Ambien CR® and during 2007, generic Ambien® or zolpidem also entered the insomnia market.

In the area of schizophrenia, our product candidates will compete with such products as Geodon®, marketed by Pfizer, Zyprexa®, marketed by Eli Lilly, Risperdal® , marketed by Janssen, and Seroquel®, marketed by AstraZeneca, among others.

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
- production facilities.

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

**Employees**

As of January 31, 2010, we had approximately 65 employees, of which 16 hold Ph.D., M.D. or equivalent degrees. None of our employees are represented by a collective bargaining arrangement, and we believe our relationship with our employees is good. Recruiting and retaining qualified scientific personnel to perform research and development work in the future will be critical to our success. We may not be able 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 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

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coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. In addition, we may not be able to obtain commercially reasonable product liability insurance for any products approved for marketing.

**Available Information**

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

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

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

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

**Risks Related to Our Company**

***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 an effective shelf registration statement on file with the Securities and Exchange Commission which allows us to issue shares of our common stock from time to time for an aggregate initial offering price of up to an additional

$140 million, and we have a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge) covering the potential sale of shares of our common stock for up to $75 million in gross proceeds. In addition, we have previously financed capital purchases and may continue to pursue opportunities to obtain additional debt financing in the future. Recently, the credit markets and the financial services industry have been experiencing 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,

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additional equity or debt financing might not be available on reasonable terms, if at all. Any additional equity financings, including funds raised under the CEFF, will be dilutive to our stockholders and any additional debt financings may involve operating covenants that restrict our business.

***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, particularly as it relates to our GnRH and urocortin 2 programs. We have active collaboration agreements with GlaxoSmithKline and Dainippon Sumitomo Pharma Co. Ltd. and previously have had collaborations with Pfizer, 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. 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 corporate collaborators, the development and commercialization of our programs would be substantially delayed if we are unable to enter into additional collaborations in a timely manner and on acceptable terms, or 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.

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.

***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.

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

- 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;
- the results may not replicate the results of earlier, smaller trials;
- the FDA 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.

For example, if the modified wording of the non-menstrual pain and dysmenorrhea daily scales used in our *elagolix* Daisy PETAL Study (901 study) are not sensitive to treatment effects, additional Phase II trials will be necessary and the development of *elagolix* will be delayed or otherwise adversely affected. Similarly, there is uncertainty regarding future development of indiplon as described below under the risk factor entitled *There is uncertainty regarding future development of our product candidate, indiplon, which may never receive regulatory approval or be commercialized.*

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

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

Since our inception, we have incurred significant net losses, including net losses of $51.0 million and $88.6 million for the years ended December 31, 2009 and 2008, respectively. As a result of ongoing operating losses, we had an accumulated deficit of $754.3 million as of December 31, 2009. We do not expect to be profitable for the year ending December 31, 2010 or 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 also expect to experience negative cash flow for the near future as we fund our operating losses, in-licensing or acquisition opportunities, and capital expenditures. We will need to generate significant revenues

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to achieve and maintain profitability and positive cash flow. We may not be able to generate these revenues, and we may never achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the market price of our common stock. Even if we become profitable, we cannot assure you that we would be able to sustain or increase profitability on a quarterly or annual basis.

***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 in registration with 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;

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.

***The CEFF that we entered into with Kingsbridge may not be available to us if we elect to make a draw down, may require us to make additional blackout or other payments to Kingsbridge, could cause our stock price to decline and may result in dilution to our stockholders.***

The CEFF entitles us to sell and obligates Kingsbridge to purchase, from time to time over a period of three years, newly issued shares of our common stock up to the lesser of an aggregate of approximately 7.8 million shares or $75 million, subject to certain conditions and restrictions. Kingsbridge will not be obligated to purchase shares under the CEFF unless certain conditions are met, which include a minimum price for our common stock; the accuracy of representations and warranties made to Kingsbridge; compliance with laws; effectiveness of the registration statement filed by us with the SEC with respect to the CEFF; and the continued listing of our stock on the NASDAQ Global Select Market or other specified markets. In addition, Kingsbridge is permitted to terminate the CEFF if it obtains actual knowledge that a material and adverse event has occurred affecting our business, operations, properties or financial condition. If we are unable to access funds through the CEFF, or if the CEFF is terminated by Kingsbridge, we may be unable to access capital on favorable terms or at all.

We are entitled, in certain circumstances, to deliver a blackout notice to Kingsbridge to suspend the registration statement filed by us with the SEC with respect to the CEFF and prohibit Kingsbridge from selling shares. If we deliver a blackout notice in the 15 calendar days following the settlement of a draw down, or if the registration statement is not effective in circumstances not permitted by the registration rights agreement, then we must make a payment to Kingsbridge, calculated on the basis of the number of shares held by Kingsbridge acquired by way of the most recent drawdown prior to the blackout notice and actually held by Kingsbridge multiplied by the change in the market price of our common stock during the period in which the use of the registration statement is suspended. If the trading price of our common stock declines during a suspension of the registration statement, the blackout or other payment could be significant.

Should we continue to sell shares to Kingsbridge under the CEFF, or issue shares in lieu of a blackout payment, it will have a dilutive effect on the holdings of our current stockholders, and may result in downward pressure on the price of our common stock. If we draw down under the CEFF, we will issue shares to

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Kingsbridge at a discount of up to 10 percent from the volume weighted average price of our common stock. If we draw down amounts under the CEFF when our share price is decreasing, we will need to issue more shares to raise the same amount than if our stock price was higher. Issuances in the face of a declining share price will have an even greater dilutive effect than if our share price were stable or increasing, and may further decrease our share price.

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

On December 12, 2007 we received an action letter from the FDA stating that indiplon 5mg and 10mg capsules are approvable (2007 FDA Approvable Letter). The 2007 FDA Approvable Letter acknowledged that our resubmitted NDA for indiplon 5mg and 10mg capsules had addressed the issues raised in a previous approvable letter, but set forth new requirements. The new requirements set forth in the 2007 FDA Approvable Letter are the following: (i) an objective/subjective clinical trial in the elderly, (ii) a safety study assessing the rates of adverse events occurring with indiplon when compared to a marketed product and (iii) a preclinical study to evaluate indiplon administration during the third trimester of pregnancy. 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 met with the FDA in July 2008 to discuss the 2007 FDA Approvable Letter. We have not received the final minutes of this meeting. We are currently evaluating 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 of the 2007 FDA Approvable Letter, 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 (REMS) 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.

***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 $2.00 per share to approximately $4.00 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 our strategic alliance 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 approval process for indiplon;

future sales of our common stock by existing stockholders (and Kingsbridge, if we elect to draw down under our CEFF with Kingsbridge);

comments by securities analysts;

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fluctuations in our operating results;

government regulation;

health care reimbursement;

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

public concern as to the safety of our drugs.

***Our restructuring activities could result in management distractions, operational disruptions and other difficulties.***

In order to focus efforts on our clinical programs, we initiated restructuring activities in an effort to reduce operating costs, including a work force reduction announced in May 2009. Employees whose positions were eliminated in connection with this reduction may have sought, or may seek, employment with our competitors. Although all employees are required to sign a confidentiality agreement with us at the time of hire, we cannot assure you that the confidential nature of our proprietary information will be maintained in the course of such employment. We cannot assure you that we will not undertake additional restructuring activities, that any of our restructuring efforts will be successful, or that we will be able to realize the cost savings and other anticipated benefits from our previous or future restructuring plans. In addition, if we continue to reduce our workforce, it may adversely impact our ability to respond rapidly to any new growth opportunities.

***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 Pharmaceutical, Inc. (DOV). 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 $CRF_1$ 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, 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

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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.

***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 DEA, 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.

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***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 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 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.

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***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, 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 the commitment of significant financial and managerial resources. We expect these efforts to require the continued commitment of significant 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 Securities and Exchange Commission. Any such action could adversely affect our financial results and the market price of our common stock.

***Negative conditions in the global credit markets may impair the liquidity of a portion of our investment portfolio.***

Our investment securities consist of auction rate securities, FDIC-insured certificates of deposit, and money market securities. As of December 31, 2009, our investments included (at par value) $20.4 million of auction rate securities issued by student loan providers. All of these auction rate securities have experienced failed auctions due to lack of liquidity at the time their interest rates were to reset. The recent negative conditions in the global credit markets have prevented some investors from liquidating their holdings, including their holdings of auction rate securities. As a result, certain of these types of securities are not fully liquid and we could be required to hold them until they are redeemed by the issuer, a future auction for these securities is successful, another secondary market evolves for these securities, or they mature. In the event we need to access the funds that are in an illiquid state, we may not be able to do so without a potential loss of principal. As of December 31, 2009, the carrying value of all auction rate securities had been reduced by $2.4 million, from $20.4 million to $18.0 million, reflecting an estimated change in fair market value due primarily to a lack of liquidity. During the first three months of 2009, certain ratings agencies downgraded two of our auction rate securities and we recognized an additional other-than-temporary impairment loss of $1.4 million in our consolidated statement of operations. During the second, third, and fourth quarters of 2009, global credit markets improved and the credit spreads narrowed resulting in an increase in the fair value of the investments of approximately $1.4 million which is recorded as an unrealized gain and is a component of other comprehensive income as of December 31, 2009. If the credit ratings of the security issuers deteriorate or if uncertainties in these markets continue and any decline in market value is determined to be other-than-temporary, we would be required to adjust the carrying value of the investment through an impairment charge, which could negatively affect our financial condition, cash flow and reported earnings.

**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

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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.

***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, anxiety, depression, pain, diabetes, irritable bowel syndrome, 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.

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

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

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

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

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

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

***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, there are a number of health care reform proposals currently under consideration by the Federal government and we expect that there will continue to be a number of federal and state proposals to implement government control over the pricing of prescription pharmaceuticals. In addition, increasing emphasis on managed 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 unable to predict what additional legislation or regulation, if any, relating to the health care

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industry or third-party coverage and reimbursement may be enacted in the future or what effect such 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.

***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 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 70,000 square feet of office space located at 12790 El Camino Real (Front Building) and approximately 140,000 square feet of laboratory and office space located at 12780 El Camino Real (Rear Building) in San Diego, California. We sold our facility and associated real property for $109.0 million in a sale-leaseback transaction in December 2007 and entered into a twelve year lease with the purchaser, DMH Campus Investors, LLC (DMH). In December 2008, we entered into a first amendment to the lease (First Lease Amendment) that provided for the renovation of the Front Building in a manner that facilitates multiple tenant usage and establishes a mechanism for us to terminate our use of the Front Building. We are obligated to reimburse the landlord for the total cost of renovating the Front Building so that it becomes suitable for multiple tenant usage. The amendment also terminated our prior right to repurchase the facility and associated real property.

Effective September 25, 2009, we entered into a second amendment to the lease (Second Lease Amendment). The Second Lease Amendment obligated us to vacate the Front Building and make an immediate payment of $4.0 million to DMH as an initial release fee, which was paid October 2, 2009. We continue to occupy the entire Rear Building. Upon payment of the initial release fee, we were released from our obligations with respect to the Front Building, except with respect to 1) certain indemnity obligations for events prior to the payment of the initial release fee, 2) certain operating expenses for the Front Building in accordance with the terms of the Lease through July 2011, and 3) 50% of tenant improvement costs between $65 and $100 per square foot in connection with initial leases between DMH and other third parties for space in the Front Building which amounts were paid in 2009. Pursuant to the Second Lease Amendment, we are also obligated to pay DMH an amount equivalent to the rent on the Front Building through July 2011 and then approximately $44,000 per month beginning in August 2011 through December 2019 as a rent differential payment for the Front Building, which such rent differential amounts may be prepaid by us in our sole discretion. Should we be in monetary default under our lease agreement with DMH beyond the normal cure periods and prior to repaying the entire rent differential balance, the rent differential payment will double.

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.** ***SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS***

Not applicable.

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**PART II**

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

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

| | High | Low |
|---|---|---|
| **Year Ended December 31, 2008** | | |
| 1st Quarter | $ 5.96 | $ 4.41 |
| 2nd Quarter | 6.10 | 4.16 |
| 3rd Quarter | 6.05 | 4.00 |
| 4th Quarter | 5.07 | 2.13 |
| **Year Ended December 31, 2009** | | |
| 1st Quarter | $ 4.25 | $ 3.02 |
| 2nd Quarter | 3.97 | 2.87 |
| 3rd Quarter | 3.67 | 2.93 |
| 4th Quarter | 3.10 | 1.94 |

As of January 29, 2010, there were approximately 65 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 2009 that have not been previously disclosed in a Current Report on Form 8-K.

**Stock Performance Graph and Cumulative Total Return**

The graph below shows the cumulative total stockholder return assuming the investment of $100 on the date specified (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 12/31/04 IN STOCK OR INDEX INCLUDING REINVESTMENT OF DIVIDENDS AT FISCAL YEARS ENDING DECEMBER 31.**

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

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

| | 2009 | 2008 | 2007 | 2006 | 2005 |
|---|---|---|---|---|---|
| | (In thousands, except for loss per share data) | | | | |
| **STATEMENT OF OPERATIONS DATA** | | | | | |
| Revenues: | | | | | |
| Sponsored research and development | $ 34 | $ 47 | $ 139 | $ 6,716 | $ 9,187 |
| Milestones and license fees | 2,919 | 3,919 | 986 | 16,038 | 92,702 |
| Sales force allowance | | | | 16,480 | 22,000 |
| Grant income and other revenues | | 9 | 99 | | |
| Total revenues | 2,953 | 3,975 | 1,224 | 39,234 | 123,889 |
| Operating expenses: | | | | | |
| Research and development | 35,810 | 55,291 | 81,985 | 97,678 | 106,628 |
| Sales, general and administrative | 14,829 | 20,240 | 37,481 | 54,873 | 42,333 |
| Cease-use expense | 5,984 | 15,742 | | | |
| Asset impairment | | | 94,000 | | |
| Total operating expenses | 56,623 | 91,273 | 213,466 | 152,551 | 148,961 |
| Loss from operations | (53,670) | (87,298) | (212,242) | (113,317) | (25,072) |
| Other income: | | | | | |
| Gain (loss) on sale/disposal of assets | 3,626 | 3,570 | 129 | (473) | 23 |
| Other (expense) income, net | (994) | (4,885) | 4,814 | 6,585 | 2,858 |
| Total other income (expense) | 2,632 | (1,315) | 4,943 | 6,112 | 2,881 |
| Net loss | $ (51,038) | $ (88,613) | $ (207,299) | $ (107,205) | $ (22,191) |
| Net loss per common share: | | | | | |
| Basic and diluted | $ (1.30) | $ (2.30) | $ (5.45) | $ (2.84) | $ (0.60) |
| Shares used in calculation of net loss per common share: | | | | | |
| Basic and diluted | 39,137 | 38,449 | 38,009 | 37,722 | 36,763 |
| **BALANCE SHEET DATA** | | | | | |
| Cash, cash equivalents and short-term investments | $ 53,464 | $ 80,473 | $ 179,385 | $ 182,604 | $ 273,068 |
| Working capital | 35,426 | 55,329 | 153,041 | 173,542 | 245,617 |
| Total assets | 70,818 | 118,182 | 276,654 | 389,677 | 483,123 |
| Long-term debt | | | | 49,152 | 53,590 |
| Accumulated deficit | (754,301) | (703,263) | (614,650) | (407,351) | (300,146) |
| Total stockholders equity | 3,954 | 36,774 | 118,697 | 314,716 | 390,104 |

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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, pre-clinical 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, anxiety, depression, pain, diabetes, irritable bowel syndrome, 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 agreements. We are developing certain products with corporate collaborators and intend to rely on existing and future collaborators to meet funding requirements. We expect to generate future net losses due to increases in operating expenses as product candidates are advanced through the various stages of clinical development. As of December 31, 2009, we had an accumulated deficit of $754.3 million and expect to incur operating losses in the near future, which may be greater than losses in prior years. We currently have eight programs in various stages of research and development, including six programs in clinical development. While we independently develop many of our product candidates, we are in a collaboration for two of our programs. Our lead clinical development program, *elagolix*, is a drug candidate for the treatment of endometriosis.

**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 and grants, clinical trial accruals (research and development expense), share-based compensation, investments, and fixed assets. Estimates are based on historical experience, information received from third parties and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The items in our financial statements requiring significant estimates and judgments are as follows:

***Revenue Recognition***

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. Upfront, nonrefundable payments for license fees and advance payments for sponsored research revenues received in excess of amounts earned are classified as deferred revenue and recognized as income over

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the contract or development period. Estimating the duration of the development period includes continual assessment of development stages and regulatory requirements. 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. Revenues from grants are recognized based on a percentage-of-completion basis as the related costs are incurred.

***Clinical Trial Costs***

Research and development (R&D) expenses include related salaries, contractor fees, facilities costs, administrative expenses and allocations of corporate costs. 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, grants 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 to completion. 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 costs, 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 Payments***

We grant stock options to purchase our common stock to our employees and directors under our 2003 Incentive Stock Plan (the 2003 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 2003 Plan. Additionally, we have outstanding options that were granted under option plans from which we no longer make grants. The benefits provided under all of these plans are subject to the provisions of ASC 718, Compensation Stock Compensation (ASC 718). Our results of operations for fiscal 2009 were impacted by the recognition of non-cash expense related to the fair value of our share-based compensation awards. Share-based compensation expense recognized under ASC 718 for the years ended December 31, 2009, 2008 and 2007 was $5.5 million, $8.0 million and $10.0 million, respectively.

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 stock plans, 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 under ASC 718, and therefore individual share-based compensation awards may impact earnings disproportionately in any individual fiscal quarter.

The determination of fair value of stock-based payment awards on the date of grant using the Black-Scholes model is affected by our stock price, as well as the input of other subjective assumptions. These assumptions include, but are not limited to, the expected term of stock options and our expected stock price volatility over the term of the awards. Our stock options have characteristics significantly different from those of traded options, and changes in the assumptions can materially affect the fair value estimates.

ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. If actual forfeitures vary from our estimates, we will recognize the difference in compensation expense in the period the actual forfeitures occur or at the time of vesting.

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***Real Estate***

In December 2007, we closed the sale of our facility and associated real property for a purchase price of $109.0 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 first lease amendment (First Lease Amendment) in December 2008 and a second lease amendment (Second Lease Amendment) in September 2009 (collectively, Amendments).

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, etc. 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 $5.7 million. The letter of credit is secured by a deposit of $6.3 million with the same bank. We have the right to extend the Lease for two consecutive ten-year terms and will have the first right of refusal to lease, at market rates, any facilities built on the sold vacant lot. Additionally, we had a repurchase right to all of the properties which could have been exercised during the fourth year of the Lease but this right was subsequently terminated.

In accordance with ASC 840-40, Leases Sale-Leaseback Transactions Involving Real Estate (ASC 840-40) and ASC 360-20, Property, Plant and Equipment Real Estate Sales (ASC 360-20), at the close of the transaction, we initially deferred the gain on the sale of the building and related vacant parcel due to the repurchase right. We also established a long-term liability of $108.7 million, essentially the gross proceeds from the real estate sale, and continued to carry the conveyed real estate assets on our balance sheet as of December 31, 2007.

Effective December 10, 2008, we entered into the First Lease Amendment which provided for the renovation of the Front Building in a manner that facilitates multiple tenant usage and establishes a mechanism for us to terminate our use of the Front Building. We continue to occupy the Rear Building.

Pursuant to the terms of the First Lease Amendment, we are obligated to reimburse the landlord for the total cost of renovating a portion of the Front Building such that the Front Building becomes suitable for multiple tenant usage. We made a one-time payment of $1.0 million toward renovation costs in January 2009 and are reimbursing the landlord for the balance of the renovation costs over a four-year period through an increase in monthly rental payments (currently estimated at $108,000 per month) which began in October 2008. Furthermore, the First Lease Amendment provided that the landlord shall seek to enter into leases with replacement tenants for portions of the Front Building. In connection with each replacement lease, we were to be granted a pro rata reduction in rent under the Lease. We were required to pay all tenant improvement costs, lease termination costs and leasing commissions in connection with each replacement lease under the First Lease Amendment.

The First Lease Amendment also terminated our right to repurchase any portion of the facility or real property. As a result of the termination of the repurchase right, during the fourth quarter of 2008, we removed from our balance sheet the long-term liability of $108.7 million and the related previously conveyed real estate assets of $69.6 million. Additionally, we began to recognize the deferred gain of $39.1 million on the sale of the real estate in accordance with ASC 840-40 and ASC 360-20. During 2009 and 2008, we recognized $2.8 million and $3.5 million, respectively, of the deferred gain and will recognize the balance of the deferred gain over the remaining lease term.

As a result of signing the First Lease Amendment and physically vacating the Front Building, we triggered a cease-use date for the Front Building and have estimated lease termination costs in accordance with ASC 420-10,

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Exit or Disposal Cost Obligations (ASC 420-10). Estimated lease termination costs for the Front Building under the First Lease Amendment included the net present value of future minimum lease payments, taxes, insurance, construction, and maintenance costs from the cease-use date to the end of the remaining lease term net of estimated sublease rental income. During the fourth quarter of 2008, we recorded an expense of $15.7 million for the net present value of these estimated lease termination costs, of which $0.3 million was paid in 2008. During 2009, we increased the liability by approximately $6.0 million in response to the declining economic conditions in San Diego by extending the expected period to lease the Front Building.

Effective September 25, 2009, we and DMH entered into the Second Lease Amendment. The Second Lease Amendment obligated us to vacate the Front Building and make an immediate payment of $4.0 million to DMH as an initial release fee, which was paid October 2, 2009. We continue to occupy the entire Rear Building. Upon payment of the initial release fee, we were released from our obligations with respect to the Front Building, except with respect to 1) certain indemnity obligations for events prior to the payment of the initial release fee, 2) certain operating expenses for the Front Building in accordance with the terms of the Lease through July 2011, and 3) 50% of tenant improvement costs between $65 and $100 per square foot in connection with initial leases between DMH and other third parties for space in the Front Building. As of December 31, 2009, we had completely satisfied our obligation with respect to payment of tenant improvement costs. Pursuant to the Second Lease Amendment, we are also obligated to pay DMH an amount equivalent to the rent on the Front Building through July 2011 and then approximately $44,000 per month beginning in August 2011 through December 2019 as a rent differential payment for the Front Building, which such rent differential amounts may be prepaid by us at our sole discretion. Should we be in monetary default under the Lease beyond the normal cure periods and prior to repaying the entire rent differential balance, the rent differential payment will double.

***Asset Impairment***

In accordance with ASC 360-10-15, Impairment or Disposal of Long-Lived Assets (ASC 360-10-15), 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.

During the fourth quarter of 2007, we recognized a non-cash impairment charge to earnings related to the impairment of a prepaid royalty. This prepaid royalty arose out of our acquisition, in February 2004, of Wyeth s financial interest in indiplon for approximately $95.0 million, consisting of $50.0 million in cash and $45.0 million in our common stock. This transaction decreased our overall royalty obligation on sales of indiplon from six percent to three and one-half percent. The receipt of the 2007 FDA Approvable Letter in December 2007 raised a significant amount of uncertainty regarding future development of indiplon. Based on this significant uncertainty, we determined that the prepaid royalty was impaired, and that a non-cash charge of $94.0 million related to this impairment was required under ASC 360-10-15.

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**Results of Operations for Years Ended December 31, 2009, 2008 and 2007**

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2009 | 2008 | 2007 |
| | (In thousands) | | |
| Revenues under collaboration agreements: | | | |
| GlaxoSmithKline (GSK) | $ 34 | $ 1,034 | $ 126 |
| Dainippon Sumitomo Pharma Co. Ltd. (DSP) | 2,919 | 2,932 | 487 |
| Other | | | 512 |
| Total revenue under collaboration agreements | 2,953 | 3,966 | 1,125 |
| Grant income | | 9 | 99 |
| Total revenues | $ 2,953 | $ 3,975 | $ 1,224 |

Our revenues for the year ended December 31, 2009 were $3.0 million compared with $4.0 million in 2008. This decrease in revenues was primarily due to revenue recognized in 2008 under our collaboration agreement with GSK. During 2008, we recognized a $1.0 million milestone payment under our GSK collaboration agreement related to clinical advancements of our CRF program. Under our exclusive licensing agreement with DSP for indiplon in Japan, we recognized $2.9 million in license fee revenue during both years ended December 31, 2009 and 2008.

Our revenues for the year ended December 31, 2008 were $4.0 million compared with $1.2 million in 2007. This increase in revenues was primarily due to revenue recognized in 2008 under our collaboration agreements with DSP and GSK. License fees revenue recognized under our DSP agreement was $2.9 million in 2008. Additionally, during 2008, we recognized a $1.0 million milestone payment under our GSK collaboration agreement related to clinical advancements of our CRF program. During 2007, we entered into an exclusive licensing agreement with DSP for indiplon in Japan, under which we recognized $0.5 million in revenue, as well as $0.5 million in revenue related to the out-licensing of our IL-4 program.

Research and development expenses decreased to $35.8 million during 2009 compared to $55.3 million in 2008. The $19.5 million decrease in research and development expenses was primarily due to cost savings related to our staff reductions in 2009 as well as lower external development expenses. The decrease in research and development staff levels reduced personnel costs by $5.8 million in 2009 compared to 2008. External development costs decreased by $9.4 million to $9.8 million in 2009 compared to $19.2 million in 2008. External development costs for our GnRH clinical program decreased to $8.9 million in 2009 compared to $16.0 million during 2008. External development costs related to our VMAT2 and urocortin 2 programs decreased by $1.3 million and $1.1 million, respectively, in 2009 compared to 2008. Additionally, laboratory costs decreased by $2.4 million during 2009 compared to 2008, primarily due to the staff reductions mentioned above. We currently have eight programs in various stages of research and development, including six programs in clinical development.

Research and development expenses decreased to $55.3 million during 2008 compared to $82.0 million in 2007. The $26.7 million decrease in research and development expenses was primarily due to cost savings related to our staff reductions in 2007. The decrease in research and development staff levels reduced personnel costs by $15.2 million (44%) in 2008 compared to 2007. External development costs decreased by $5.1 million to $19.2 million in 2008 compared to $24.3 million in 2007. External development costs related to our VMAT2 and urocortin 2 programs increased by $1.5 million and $1.2 million, respectively, in 2008 compared to 2007. External development costs related to our subsequently suspended or halted indiplon and valnoctamide programs included expenses of $6.3 million during 2007. Additionally, laboratory costs decreased by $2.2 million during 2008 compared to 2007, primarily due to the staff reductions mentioned above.

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We expect research and development expenses to decrease during 2010 compared to 2009, primarily due to cost savings efforts, and the winding down of the Phase II program for *elagolix*.

General and administrative expenses decreased to $14.8 million in 2009 compared to $20.2 million during 2008 and $37.5 million during 2007. The $5.4 million decrease in expenses from 2008 to 2009 resulted primarily from the severance program enacted in 2009 and company-wide cost containment efforts. The $17.3 million decrease in expenses from 2007 to 2008 resulted primarily from staff reductions in 2007 and a reduction in costs for pre-commercialization activities related to indiplon in 2007.

We expect general and administrative expenses to decrease during 2010 primarily due to cost savings efforts.

During 2009 and 2008, we recognized $6.0 million and $15.7 million, respectively, in cease-use expense, related to the front building of our corporate headquarters and the amendment of the Lease as discussed above.

During 2007, we recognized a $94.0 million non-cash impairment charge to earnings related to the impairment of a prepaid royalty as discussed above.

Other income (expense) increased to $2.6 million in 2009 compared with ($1.3) million during 2008. Other income was $4.9 million during 2007. The change from 2008 to 2009 resulted primarily from rental payments made during 2008 under our sale-leaseback agreement which were recorded as interest expense under sale-leaseback accounting rules. These rental payments are components of operating expense during 2009. Additionally, interest income was lower due to lower overall interest rates and lower cash balances. The change from 2007 to 2008 resulted primarily from rent payments of $7.0 million made under our facilities sale-leaseback agreement that were recorded as interest expense. Additionally, investment income for 2008 was lower than in the prior year period, primarily due to lower cash balances coupled with lower overall interest rates. Additionally, during 2009 and 2008, we recognized $2.8 million and $3.5 million in gains on sale of assets related to the real estate transaction discussed above.

Our net loss for 2009 was $51.0 million, or $1.30 per share, compared to $88.6 million, or $2.30 per share, in 2008 and $207.3 million, or $5.45 per share, in 2007. The decrease in net loss from 2008 to 2009 was primarily due to cost containment efforts and staff reductions in early 2009, coupled with lower external development costs. The decrease in net loss from 2007 to 2008 was primarily due to the impairment charge of $94.0 million in 2007 and cost savings in 2008 related to the staff reductions in 2007.

*Restructuring programs.* In December 2007, after receipt of the 2007 indiplon FDA Approvable Letter, we announced a restructuring program to implement cost containment measures and to focus research and development efforts. As a result, we reduced our research and development and general and administrative staff in San Diego by approximately 125 employees. In connection with this restructuring, we recorded a one-time charge of approximately $6.9 million in the fourth quarter of 2007, of which $4.9 million was included in research and development expense and $2.0 million was included in general and administrative expense. Restructuring charges are comprised of salary continuation, outplacement services, and other miscellaneous costs related to these reductions in force. Substantially all of these expenses were paid in cash during the first quarter of 2008.

During 2008, we incurred an additional one-time net charge of $2.1 million for severance related to certain executives and other personnel departing the Company, primarily all of which was included in general and administrative expense.

In May 2009, we announced a restructuring program to implement cost containment measures and to focus research and development efforts. As a result, we reduced our research and development and general and administrative staff in San Diego by approximately 65 employees and incurred a net restructuring charge of

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approximately $2.6 million (of which $2.1 million was classified as research and development expense and $0.5 million was classified as general and administrative expense), which was comprised of salary continuation, outplacement services, and other miscellaneous costs related to this reduction in force. Substantially all of these expenses were paid in cash during 2009.

*Indiplon developments.* 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 (FDA Not Approvable Letter).

The FDA Not Approvable Letter for the tablets requested that we reanalyze certain safety and efficacy data and questioned the sufficiency of the objective sleep maintenance clinical data with the 15mg tablet in view of the fact that the majority of our indiplon tablet studies were conducted with doses higher than 15mg. We held an end-of-review meeting with the FDA related to the FDA Not Approvable Letter in October 2006. This meeting was specifically focused on determining the actions needed to bring indiplon tablets from Not Approvable to Approval in the resubmission of the NDA for indiplon tablets. The FDA has requested additional long-term safety and efficacy data with the 15mg dose for the adult population and the development of a separate dose for the elderly population. In discussions, we and the FDA noted positive efficacy data for sleep maintenance with both indiplon capsules and tablets. The evaluation of indiplon for sleep maintenance includes both indiplon capsules and tablets.

The 2006 FDA Approvable Letter requested that we reanalyze data from certain preclinical and clinical studies to support approval of indiplon 5mg and 10mg capsules for sleep initiation and middle of the night dosing. The 2006 FDA Approvable Letter also requested reexamination of the safety analyses. We held an end-of-review meeting with the FDA related to the 2006 FDA Approvable Letter in August 2006. This meeting was specifically focused on determining the actions needed to bring indiplon capsules from Approvable to Approval in the resubmission of the NDA for indiplon capsules. At the meeting the FDA requested that the resubmission include further analyses and modifications of analyses previously submitted to address questions raised by the FDA in the initial review. This reanalysis was completed. The FDA also requested, and we completed, a supplemental pharmacokinetic/food effect profile of indiplon capsules including several meal types.

On June 12, 2007, we resubmitted our NDA for indiplon 5mg and 10mg capsules seeking clearance to market indiplon capsules for the treatment of insomnia. The FDA accepted the NDA resubmission and established a Prescription Drug User Fee Act (PDUFA) date of December 12, 2007. On December 12, 2007 we received an action letter from the FDA stating the indiplon 5mg and 10mg capsules are approvable (2007 FDA Approvable Letter). The 2007 FDA Approvable Letter acknowledged that the resubmitted NDA had addressed the issues raised in the 2006 FDA Approvable Letter, but set forth new requirements. The new requirements set forth in the 2007 FDA Approvable Letter are the following: (i) an objective/subjective clinical trial in the elderly, (ii) a safety study assessing the rates of adverse events occurring with indiplon when compared to a marketed product and (iii) a preclinical study to evaluate indiplon administration during the third trimester of pregnancy.

On October 31, 2007, we entered into an exclusive license agreement with DSP, under which we 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, we received an up-front license fee of $20 million. We are also eligible to receive additional milestone payments upon specified future events related to the development and commercialization of indiplon in Japan. Should all milestones be achieved, we may be entitled to payments totaling an additional $115 million. Additionally, we are entitled to royalties from DSP on future sales of indiplon in Japan.

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In July 2008 we held an end-of-review meeting with the FDA to discuss the 2007 FDA Approvable Letter. We have not received the final minutes of this meeting. 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 are currently evaluating various alternatives for the indiplon program.

**Liquidity and Capital Resources**

At December 31, 2009, our cash, cash equivalents, and investments totaled $59.9 million compared with $101.5 million at December 31, 2008. This $41.6 million decrease was primarily a result of our operating loss of $51.0 million for the year ended December 31, 2009, offset by net cash received from our common stock sale of $9.9 million. At December 31, 2008, our cash, cash equivalents, and investments totaled $101.5 million compared with $179.4 million at December 31, 2007. This decrease was primarily a result of our operating loss of $88.6 million for the year ended December 31, 2008.

Net cash used in operating activities during 2009 was $53.1 million compared to $74.2 million in 2008. This decrease was primarily due to lower operating losses in 2009. Net cash used in operating activities during 2008 was $74.2 million compared to $59.3 million in 2007. This increase was primarily due to severance payments of $7.4 million, and the timing of accounts payable and reductions in accounts receivable.

Net cash provided by investing activities during 2009 was $12.1 million compared to $44.4 million in 2008 and $20.8 million in 2007. These fluctuations resulted primarily from timing differences in investment purchases, sales and maturities and the fluctuations in our portfolio mix between cash equivalents and short-term investment holdings. We expect similar fluctuations to continue in future periods. Capital equipment purchases for 2009, 2008 and 2007 were $0.1 million, $1.3 million, and $0.6 million, respectively. Gross receipts from sales of equipment in 2009 and 2008 totaled $1.2 million and $0.6 million, respectively. Net capital equipment purchases for 2010 are expected to be $0.2 million.

Net cash provided by financing activities during 2009 was $9.9 million compared to net cash used of $1.5 million in 2008 and net cash provided of $57.2 million in 2007. During 2009, we sold approximately 4.8 million shares of common stock for net cash proceeds of $9.9 million. During 2007, we closed the sale of our facility and associated real property for a purchase price of $109.0 million and retired $47.7 million in mortgage debt related to the property. Other debt repayments (primarily related to equipment loans) were $1.5 million and $4.5 million in 2008 and 2007, respectively. We had no outstanding debt at December 31, 2009. Additionally, cash proceeds from the issuance of common stock upon exercise of outstanding stock options were $34,000 and $0.6 million in 2008 and 2007, respectively. The amount and frequency of stock-related transactions are dependent upon the market performance of our common stock.

*.Auction Rate Securities.* Our investments at December 31, 2009 included (at par value) $20.4 million of auction rate securities. With the liquidity issues experienced in global credit and capital markets, these auction rate securities have experienced multiple failed auctions as the amount of securities submitted for sale has exceeded the amount of purchase orders, and as a result, these affected securities are currently not liquid. All of our auction rate securities are secured by student loans, which are backed by the full faith and credit of the federal government (up to approximately 98% of the value of the student loan). All of these securities continue to pay interest according to their stated terms (generally 120 basis points over the ninety-one day United States Treasury bill rate) with interest rates resetting every 7 to 28 days. While it is not our intent to hold these securities until their stated maturity dates, these investments are scheduled to ultimately mature between 2030 and 2047.

The valuation of our auction rate securities investment portfolio is subject to uncertainties that are difficult to predict. The fair values of these securities were estimated utilizing a discounted cash flow analysis as of December 31, 2009. The significant assumptions of this valuation model were discount margins ranging from 152 to 320 basis points which are based on industry recognized student loan sector indices, an additional liquidity

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discount of 150 basis points and an estimated term to liquidity of 5 to 7 years. Other items this analysis considers are the collateralization underlying the security investments, the creditworthiness of the counterparty, and the timing of expected future cash flows. These securities were also compared, when possible, to other observable market data with similar characteristics as the securities held by us. The auction rate security investments continue to pay interest according to their stated terms. The carrying value for these auction rate securities at December 31, 2009 was $18.0 million.

During the fourth quarter of 2008, UBS AG (UBS) extended an offer of Auction Rate Securities Rights (ARS Rights) to holders of illiquid auction rate securities that were maintained by UBS as of February 13, 2008. The ARS Rights provide the holder with the ability to sell the auction rate securities, along with the ARS Rights, to UBS at the par value of the auction rate securities, during an applicable exercise period. The ARS Rights grant UBS the sole discretion and right to sell or otherwise dispose of auction rate securities at any time up until July 2, 2012, without any prior notification of the holder, so long as the holder receives a payment of par upon any sale or disposition. The ARS Rights are not transferable, not tradeable, and will not be quoted or listed on any securities exchange or any other trading network. The offer period for the ARS Rights closed on November 14, 2008 and ARS Rights were issued by UBS during the fourth quarter of 2008.

We have elected to participate in the ARS Rights program for all of our outstanding auction rate securities maintained by UBS. We have $12.8 million (at par value) of ARS that are maintained by UBS. Under the terms of the ARS Rights offer, our applicable exercise period begins on June 30, 2010 and ends July 2, 2012. Additionally, we are eligible for a loan of up to 75% of the market value of the auction rate securities, should a loan be needed. It is our intention to sell the auction rate securities and ARS Rights to UBS on June 30, 2010.

We elected to measure the ARS Rights under the fair value option of ASC 825-10, Financial Instruments (ASC 825-10), to mitigate volatility in reported earnings due to their linkage to the auction rate securities. The ARS Rights were valued in a similar fashion to the auction rate securities as described above. Simultaneously, due to the ARS Rights granted by UBS, we made a one-time election to transfer the related auction rate security holdings from available-for-sale securities to trading securities in the fourth quarter of 2008. Trading securities are carried at fair value with unrealized gains and losses reported in other income and expense in the consolidated statement of operations. We anticipate that any changes in the fair value of the ARS Rights will be offset by the changes in the fair value of the related auction rate securities with no material net impact to our consolidated statement of operations. The ARS Rights will continue to be measured at fair value under ASC 825-10 until the earlier of their maturity or exercise. We valued these ARS Rights at $1.2 million and $2.4 million at December 31, 2009 and 2008, respectively. These ARS Rights, together with the auction rate securities held at UBS (which had a fair value of $11.6 million and $12.0 million as of December 31, 2009 and 2008, respectively), are carried as short-term investments on our consolidated balance sheet at December 31, 2009 and were carried as long-term investments on the consolidated balance sheet at December 31, 2008.

The two remaining auction rate securities continue to be treated as available-for-sale investments. These auction rate securities have a par value of $7.6 million and are carried on our balance sheet at estimated fair values of $6.4 million at December 31, 2009. During the first quarter of 2009, certain ratings agencies downgraded these auction rate securities and we recognized an other-than-temporary impairment charge of $1.4 million in the consolidated statement of operations. Subsequent to this downgrade, global credit markets improved and the credit spreads related to these types of investments narrowed resulting in an increase in the fair value of the investments of approximately $1.4 million which we have recorded as an unrealized gain in other comprehensive income for the year ended December 31, 2009. During 2008, we recognized an unrealized loss of $1.3 million for an other-than-temporary impairment in the consolidated statement of operations.

Changes to estimates and assumptions used in estimating the fair value of the auction rate securities and related ARS Rights may provide materially different values. In addition, actual market exchanges, if any, may occur at materially different amounts. For example, a reduction of the expected term to redemption assumption by 2 years for the auction rate securities and related ARS Rights yielded a net increase in the valuation of these

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investments of $0.3 million. Other factors that may impact the valuation of our auction rate securities and related ARS Rights include changes to credit ratings of the securities as well as to the underlying assets supporting those securities, rates of default of the underlying assets, underlying collateral value, discount rates, counterparty risk and ongoing strength and quality of market credit and liquidity.

At present, in the event we need to access the funds that are in an illiquid state, we may not be able to do so without the possible loss of principal, until a future auction for these investments is successful, another secondary market evolves for these securities, until they are redeemed by the issuer or until they mature. If we are unable to sell these securities in the market or they are not redeemed, we could be required to hold them to maturity. We do not have a need to access these funds for operational purposes prior to June 30, 2010, the beginning of the ARS Rights exercise period. We will continue to monitor and evaluate these investments on an ongoing basis for impairment.

*Equity Financing.* On December 16, 2009, we entered into a privately negotiated transaction to sell approximately 4.8 million shares of our common stock to an institutional investor at a price of $2.09 per share, raising total gross proceeds of approximately $10.0 million. The shares were sold pursuant to our effective shelf registration statement with the Securities and Exchange Commission (SEC). This transaction closed on December 22, 2009. Total stock issuance costs related to this financing were approximately $100,000.

*Committed Equity Financing Facility.* In September 2009, we entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge) pursuant to which Kingsbridge committed to purchase, subject to certain conditions, up to the lesser of 7.8 million newly issued shares of our common stock or an aggregate of $75.0 million newly issued shares over the three-year term of the CEFF. We may access capital under the CEFF by making draw downs up to a maximum of the lesser of (i) $15 million and (ii) the greater of (x) 1.75% of our market capitalization as of the date of delivery of the draw down notice once per calendar quarter and up to 1.25% of our market capitalization as of the date of delivery of the draw down notice for any additional draw downs during such calendar quarter and (y) the lesser of (a) 2.75% of our market capitalization as of the date of delivery of the draw down notice and (b) a number of shares determined by a formula based in part on the average trading volume and trading price of our common stock prior to the delivery of the draw down notice issued by us with respect to that draw down pricing period, subject to certain conditions, including a minimum share price threshold of $1.00. Kingsbridge may purchase shares of common stock pursuant to the CEFF at discounts ranging from 5 to 10 percent, depending on the average market price of our common stock during the applicable pricing period for a draw down. As of December 31, 2009, we had not issued any shares under the CEFF.

*Shelf Registration Statement.* In November 2007, we filed a shelf registration statement with the SEC, which was declared effective in December 2007. 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 an additional $140 million. The specific terms of offerings, if any, under the shelf registration statement would be established at the time of such offerings.

**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.

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Our license, research and clinical development agreements are generally cancelable with written notice in 0-180 days. In addition to the minimum payments due under our license and research agreements, we may be required to pay approximately $18.0 million in milestone payments, plus sales royalties, in the event that all scientific research under these agreements is successful.

We lease our office and research laboratories under an operating lease with an initial term of twelve years, expiring in 2019. We are responsible for base rent, plus additional operating costs which comprise the estimated minimum lease payments. Additionally, our facility lease agreement calls for us to maintain $50.0 million in cash and investments at all times, or to increase our security deposit by $5.0 million.

As of December 31, 2009, the total estimated future annual minimum lease payments under our non-cancelable building lease are as follows:

| | Payment Amount (In thousands) |
|---|---|
| Year ending: | |
| 2010 | $ 11,188 |
| 2011 | 10,224 |
| 2012 | 8,347 |
| 2013 | 7,580 |
| 2014 | 7,792 |
| Thereafter | 42,362 |
| Total future minimum lease payments | $ 87,493 |

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. This process may cost in excess of $1 billion and can take in excess of 10 years to complete for each product candidate.

We test our potential product candidates in numerous pre-clinical 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;

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

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

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

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

continued scientific progress in our research and development programs;

the magnitude of our research and development programs;

progress with preclinical testing and clinical trials;

the time and costs involved in obtaining regulatory approvals;

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

competing technological and market developments;

the establishment of additional collaborations and strategic alliances;

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

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

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

We will require additional funding to continue our research and product development programs, to conduct preclinical studies and clinical trials, for operating expenses, to pursue regulatory approvals for our product candidates, for the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims, if any, for the cost of product in-licensing and for any possible acquisitions, and we may require additional funding to establish manufacturing and marketing capabilities in the future. We may seek to access the public or private equity markets whenever conditions are favorable. For example, we have an effective shelf registration statement on file with the Securities and Exchange Commission which allows us to issue shares of

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our common stock from time to time for an aggregate initial offering price up to an additional $140 million. We may also seek additional funding through strategic alliances and other financing mechanisms such as our CEFF with Kingsbridge. We cannot assure you that adequate funding will be available on terms acceptable to us, if at all. Any additional equity financings will be dilutive to our stockholders and any additional debt may involve operating covenants that may restrict our business. If adequate funds are not available through these means, we may be required to curtail significantly one or more of our research or development programs or obtain funds through arrangements with collaborators or others. This may require us to relinquish rights to certain of our technologies or product candidates. To the extent that we are unable to obtain third-party funding for such expenses, we expect that increased expenses will result in increased 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 36 months. If a 10% change in interest rates were to have occurred on December 31, 2009, 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 April 2009, the FASB issued several pronouncements related to fair value measurement, recording and disclosure in financial reporting.

FASB ASC 825-10 Financial Instruments and ASC 270-10, Interim Reporting, were issued to outline the required financial statement disclosures relating to fair value of financial instruments during interim reporting periods. FASB ASC 820-10, Fair Value Measurements and Disclosures, was issued to provide additional guidance in evaluating the fair value of a financial instrument when the volume and level of activity for the asset or liability has significantly decreased. FASB ASC 320-10, Recognition Investments Debt & Equity Securities, was issued to provide additional guidance on presenting impairment losses on securities.

All of the fair value measurement pronouncements were effective for interim and annual reporting periods ending after June 15, 2009. The adoption of these new pronouncements did not have a material effect on our consolidated results of operations or financial condition.

In May 2009, the FASB issued ASC 855-10, Subsequent Events . ASC 855-10 is intended to establish general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. It requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for selecting that date, that is, whether that date represents the date the financial statements were issued or were available to be issued. ASC 855-10 is effective for interim or annual financial periods ending after June 15, 2009. The adoption of ASC 855-10 did not have a material effect on our consolidated results of operations or financial condition.

In June 2009, the Financial Accounting Standards Board (FASB) issued SFAS No. 168, The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles , a replacement of FASB 162. The FASB Accounting Standards Codification (Codification) will become the source of authoritative U.S. generally accepted accounting principles (GAAP) recognized by the FASB to be applied by nongovernmental entities. Rules and interpretive releases of the SEC under authority of federal securities laws

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are also sources of authoritative GAAP for SEC registrants. On the effective date of this Statement, the Codification will supersede all then-existing non-SEC accounting and reporting standards. All other nongrandfathered non-SEC accounting literature not included in the Codification will become nonauthoritative. SFAS 168 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The adoption of SFAS 168 did not have a material effect on our consolidated results of operations or financial condition.

**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 FINANCIAL STATEMENTS**


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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Shareholders of

Neurocrine Biosciences, Inc.

We have audited the accompanying consolidated balance sheets of Neurocrine Biosciences, Inc. as of December 31, 2009 and 2008, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2009. 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 consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Neurocrine Biosciences, Inc. at December 31, 2009 and 2008, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, in conformity with U.S. generally accepted accounting principles.

We have also 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, 2009, based on the criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 5, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, CA

February 5, 2010

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**NEUROCRINE BIOSCIENCES, INC.**

**Consolidated Balance Sheets**

| | December 31, 2009 | 2008 |
|---|---|---|
| | (In thousands, except for par value and share totals) | |
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 37,329 | $ 68,467 |
| Short-term investments, available-for-sale | 16,135 | 12,006 |
| Receivables under collaborative agreements | | 39 |
| Other current assets | 1,923 | 911 |
| Total current assets | 55,387 | 81,423 |
| Property and equipment, net | 2,695 | 6,191 |
| Long-term investments | 6,411 | 21,057 |
| Restricted cash | 6,325 | 6,409 |
| Other non-current assets | | 3,102 |
| Total assets | $ 70,818 | $ 118,182 |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,188 | $ 1,599 |
| Accrued liabilities | 6,240 | 10,905 |
| Current portion of deferred revenues | 2,941 | 2,936 |
| Current portion of cease-use liability | 4,289 | 7,870 |
| Current portion of deferred gain on sale of real estate | 2,867 | 2,784 |
| Other liabilities | 1,436 | |
| Total current liabilities | 19,961 | 26,094 |
| Deferred revenues | 8,757 | 11,676 |
| Deferred gain on sale of real estate | 29,999 | 32,867 |
| Deferred rent | 906 | 110 |
| Cease-use liability | 7,241 | 7,527 |
| Other liabilities | | 3,134 |
| Total liabilities | 66,864 | 81,408 |
| 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 43,991,565 at December 31, 2009 and 38,598,789 at December 31, 2008 | 44 | 39 |
| Additional paid-in capital | 757,002 | 741,568 |
| Accumulated other comprehensive gain (loss) | 1,209 | (1,570) |
| Accumulated deficit | (754,301) | (703,263) |
| Total stockholders equity | 3,954 | 36,774 |
| Total liabilities and stockholders equity | $ 70,818 | $ 118,182 |

See accompanying notes.

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**NEUROCRINE BIOSCIENCES, INC.**

**Consolidated Statements of Operations**

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2009 | 2008 | 2007 |
| | (In thousands, except loss per share data) | | |
| Revenues: | | | |
| Sponsored research and development | $ 34 | $ 47 | $ 139 |
| Milestones and license fees | 2,919 | 3,919 | 986 |
| Grant income | | 9 | 99 |
| Total revenues | 2,953 | 3,975 | 1,224 |
| Operating expenses: | | | |
| Research and development | 35,810 | 55,291 | 81,985 |
| General and administrative | 14,829 | 20,240 | 37,481 |
| Cease-use expense | 5,984 | 15,742 | |
| Asset impairment | | | 94,000 |
| Total operating expenses | 56,623 | 91,273 | 213,466 |
| Loss from operations | (53,670) | (87,298) | (212,242) |
| Other income and (expense): | | | |
| Gain on sale/disposal of assets | 3,626 | 3,570 | 129 |
| Investment income and (expense) | (1,451) | 2,132 | 8,737 |
| Interest expense | | (7,025) | (3,923) |
| Other income | 457 | 8 | |
| Total other income and (expense) | 2,632 | (1,315) | 4,943 |
| Net loss | $ (51,038) | $ (88,613) | $ (207,299) |
| Net loss per common share: | | | |
| Basic and diluted | $ (1.30) | $ (2.30) | $ (5.45) |
| Shares used in the calculation of net loss per common share: | | | |
| Basic and diluted | 39,137 | 38,449 | 38,009 |

See accompanying notes.

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**NEUROCRINE BIOSCIENCES, INC.**

**Consolidated Statements of Stockholders Equity**

| | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Income (Loss) | Accumulated Deficit | Total Stockholders Equity |
|---|---|---|---|---|---|---|
| | Shares | Amount | | (In thousands) | | |
| BALANCE AT DECEMBER 31, 2006 | 37,906 | $ 38 | $ 721,930 | $ 99 | $ (407,351) | $ 314,716 |
| Net loss | | | | | (207,299) | (207,299) |
| Unrealized loss on investments | | | | (332) | | (332) |
| Comprehensive loss | | | | | | (207,631) |
| Issuance of common stock for option exercises | 78 | | 591 | | | 591 |
| Issuance of common stock for restricted share units vested | 290 | | 105 | | | 105 |
| Share-based compensation | | | 9,983 | | | 9,983 |
| Reclassification of share-based compensation liability | | | 933 | | | 933 |
| BALANCE AT DECEMBER 31, 2007 | 38,274 | 38 | 733,542 | (233) | (614,650) | 118,697 |
| Net loss | | | | | (88,613) | (88,613) |
| Unrealized loss on investments | | | | (1,337) | | (1,337) |
| Comprehensive loss | | | | | | (89,950) |
| Share-based compensation | | | 7,993 | | | 7,993 |
| Issuance of common stock for restricted share units vested | 316 | 1 | | | | 1 |
| Issuance of common stock for option exercises | 9 | | 33 | | | 33 |
| BALANCE AT DECEMBER 31, 2008 | 38,599 | 39 | 741,568 | (1,570) | (703,263) | 36,774 |
| Net loss | | | | | (51,038) | (51,038) |
| Unrealized gain on investments | | | | 2,779 | | 2,779 |
| Comprehensive loss | | | | | | (48,259) |
| Share-based compensation | | | 5,539 | | | 5,539 |
| Issuance of common stock for restricted share units vested | 608 | | | | | |
| Issuance of common stock, net of offering costs | 4,785 | 5 | 9,895 | | | 9,900 |
| BALANCE AT DECEMBER 31, 2009 | 43,992 | $ 44 | $ 757,002 | $ 1,209 | $ (754,301) | $ 3,954 |

See accompanying notes.

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**NEUROCRINE BIOSCIENCES, INC.**

**Consolidated Statements of Cash Flows**

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2009 | 2008 | 2007 |
| | | (In thousands) | |
| CASH FLOW FROM OPERATING ACTIVITIES | | | |
| Net loss | $ (51,038) | $ (88,613) | $ (207,299) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and amortization | 3,179 | 7,610 | 9,404 |
| Gain on sale of assets | (3,626) | (3,570) | (129) |
| Fair value adjustment for auction rate security rights | 815 | (2,350) | |
| Loss/(gain) on sale of investments | 1,086 | 412 | (812) |
| Fair value adjustment of auction rate securities | (1,047) | 2,583 | |
| Realized gain on sale of auction rate securities | (124) | | |
| Other-than-temporary impairment for auction rate securities | 1,431 | 1,311 | |
| Cease-use expense | 5,984 | 15,742 | |
| Deferred revenues | (2,914) | (2,911) | 17,523 |
| Deferred rent | 796 | 110 | |
| Asset impairment | | | 94,000 |
| Loan forgiveness on notes receivable | | | 305 |
| Non-cash stock compensation expense | 5,539 | 7,993 | 9,983 |
| Change in operating assets and liabilities: | | | |
| Accounts receivable and other assets | 2,449 | 2,428 | 7,769 |
| Cease-use liability | (9,851) | (345) | |
| Other liabilities | (1,698) | (1,576) | 56 |
| Accounts payable and accrued liabilities | (4,076) | (12,989) | 9,866 |
| Net cash used in operating activities | (53,095) | (74,165) | (59,334) |
| CASH FLOW FROM INVESTING ACTIVITIES | | | |
| Purchases of investments | (16,800) | (36,986) | (94,638) |
| Sales/maturities of investments | 27,615 | 82,132 | 117,130 |
| Deposits and restricted cash | 84 | 1 | (1,161) |
| Proceeds from sales of property and equipment | 1,193 | 595 | 129 |
| Purchases of property and equipment, net | (35) | (1,322) | (624) |
| Net cash provided by investing activities | 12,057 | 44,420 | 20,836 |
| CASH FLOW FROM FINANCING ACTIVITIES | | | |
| Issuance of common stock | 9,900 | 34 | 591 |
| Principal payments on debt | | (1,486) | (52,155) |
| Leaseback financing obligation | | | 108,745 |
| Net cash provided by (used in) financing activities | 9,900 | (1,452) | 57,181 |
| Net (decrease) increase in cash and cash equivalents | (31,138) | (31,197) | 18,683 |
| Cash and cash equivalents at beginning of the year | 68,467 | 99,664 | 80,981 |
| Cash and cash equivalents at end of the year | $ 37,329 | $ 68,467 | $ 99,664 |
| SUPPLEMENTAL DISCLOSURES | | | |
| Supplemental disclosures of cash flow information: | | | |
| Interest paid on debt obligations | $ | $ 74 | $ 3,090 |
| Taxes paid | $ | $ | $ |

See accompanying notes.

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**NEUROCRINE BIOSCIENCES, INC.**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**December 31, 2009**

**NOTE 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

***Business Activities.*** Neurocrine Biosciences, Inc. (the Company or Neurocrine) 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, anxiety, depression, pain, diabetes, irritable bowel syndrome, insomnia, and other neurological and endocrine-related diseases and disorders. While the Company independently develops many of its product candidates, it has entered into a collaboration for two of its programs. The Company s lead clinical development program, *elagolix*, is a drug candidate for the treatment of endometriosis.

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

During 2008, the Company dissolved Science Park Center LLC and Neurocrine International LLC, which previously were subsidiaries of the Company. During 2009, the Company dissolved Neurocrine HQ, Inc, a former subsidiary of the Company.

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

***Use of Estimates.*** The preparation of financial statements in conformity with accounting principles generally accepted in the United States 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.

***Reclassifications.*** Certain reclassifications have been made to previously reported amounts to conform to current presentations.

***Cash Equivalents.*** The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents.

***Trading Securities.*** The Company considers all securities that are bought and held principally for the purpose of selling them in the near term to be trading securities. Available-for-sale securities are carried at fair value, with unrealized gains and losses reported in earnings in accordance with Accounting Standards Codification (ASC 320-10), Investments - Debt and Equity Securities (ASC 320-10).

***Short-Term Investments Available-for-Sale.*** Certain short-term investments are classified as available-for-sale in accordance with ASC 320-10. Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in other comprehensive loss. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in investment income. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income or expense. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in investment income.

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***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, 2009, 2008 and 2007, collaborative research and development agreements accounted for substantially 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. Building costs were depreciated over an average estimated useful life of 25 years and equipment is over three to seven years. Leasehold improvements are depreciated over the shorter of their estimated useful lives or the remaining lease term.

***Industry Segment and Geographic Information.*** The Company operates in a single industry segment the discovery and development of therapeutics for the treatment of neurological and endocrine-related diseases and disorders. The Company had limited foreign based operations for the years ended December 31, 2009, 2008 and 2007.

***Other Assets.*** Other current assets include $1.3 million (current) and $3.1 million (long-term) of mutual fund investments related to the Company s Nonqualified Deferred Compensation Plan (the Deferred Compensation Plan ) for certain employees as of December 31, 2009 and 2008, respectively. Net unrealized losses related to these mutual funds were approximately $0.2 million and $1.6 million as of December 31, 2009 and December 31, 2008, respectively. All of the assets held in the Deferred Compensation Plan are recorded at fair value in accordance with ASC 820-10, Fair Value Measurements and Disclosures (ASC 820-10) (as described in Note 4). The values are categorized as Level 1 assets as they have been obtained from quoted prices in active markets for identical assets. Additionally, the Company has recorded a corresponding liability for the Deferred Compensation Plan in other liabilities.

The participants in the Deferred Compensation Plan may select from a variety of deemed investment options and have the ability to make changes in such deemed investments on a daily basis, subject to plan limitations. During 2009, the Company elected to terminate the Deferred Compensation Plan. In connection with such termination, the account balances of participants in the Deferred Compensation Plan will be distributed to such participants in accordance with the provisions of the Deferred Compensation Plan.

***Impairment of Long-Lived Assets.*** In accordance with ASC 360-10-15, Impairment or Disposal of Long-Lived Assets (ASC 360-10-15), 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.

The Company carried as a long-lived asset on its balance sheet a prepaid royalty arising from its acquisition in February 2004 of Wyeth s financial interest in the Company s drug candidate, indiplon, for $95.0 million, consisting of $50.0 million in cash and $45.0 million in the Company s common stock. During the fourth quarter of 2007, the Company received a second approvable letter from the United States Food and Drug Administration with respect to indiplon. This second letter requested additional preclinical and clinical trials, which raised a significant amount of uncertainty regarding future clinical development of indiplon. Based on this significant uncertainty, the Company determined that the prepaid royalty was impaired, and a non-cash charge of $94.0 million related to this impairment was required under ASC 360-10-15 to write the value down to zero.

***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.

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***Revenue Recognition.*** Revenues under collaborative research agreements are recognized as research costs and 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 received from the Company s collaborative partners are nonrefundable. Upfront, nonrefundable payments for license fees and advance payments for sponsored research revenues received in excess of amounts earned are 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. 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.

License fees are received in exchange for a grant to use the Company s proprietary technologies on an as-is basis for the term of the collaborative agreement. Milestones are received for specific scientific achievements determined at the beginning of the collaboration. These achievements are substantive and are based on the success of scientific efforts.

***Comprehensive Income/Loss.*** Comprehensive income/loss is calculated in accordance with ASC 220-10, Comprehensive Income (ASC 220-10). ASC 220-10 requires the disclosure of all components of comprehensive income/loss, including net income/loss and changes in equity during a period from transactions and other events and circumstances generated from non-owner sources. The Company s other comprehensive income/loss consisted of the net loss and unrealized gains and losses on available-for-sale investments and is reported in the statements of stockholders equity.

***Research and Development Expenses.*** Research and development (R&D) expenses include related salaries, contractor fees, clinical trial costs, facilities costs, administrative expenses and allocations of corporate costs. 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 to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

***Restructuring.*** During 2009, the Company announced a restructuring program to implement cost containment measures and to focus research and development efforts. As a result, the Company reduced its research and development and general and administrative staff in San Diego by approximately 65 employees. Pursuant to ASC 712-10, Nonretirement Postemployment Benefits (ASC 712-10) and ASC 420-10, Exit or Disposal Cost Obligations (ASC 420-10), the Company incurred a net restructuring charge of approximately $2.6 million, of which $2.1 million was classified as research and development expense and $0.5 million was classified as general and administrative expense. Substantially all of these expenses were paid in cash during 2009.

During 2008, the Company incurred a net charge of $2.1 million, primarily included in general and administrative expense, for severance related to certain executives and other personnel departing the Company.

During 2007, the Company announced staff reductions of approximately 125 employees at its San Diego campus, as part of its restructuring program to prioritize its research and development programs. As a result, the Company communicated to affected employees a plan of organizational restructuring through involuntary terminations. Pursuant to ASC 712-10 and ASC 420-10, the Company recorded a charge of approximately

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$6.9 million in 2007, of which $4.9 million was included in research and development expense and $2.0 million was included in general and administrative expense. Substantially all of these expenses were paid in cash during 2008.

As of December 31, 2009, the Company had a remaining balance of approximately $0.3 million of accrued restructuring expenses included in the condensed consolidated balance sheet. The liability will be paid over the remaining contractual period of certain severance agreements. The changes to the accrued liability during 2009 and 2008 are as follows (in thousands):

| | Years Ended December 31, | |
|---|---|---|
| | 2009 | 2008 |
| Beginning accrual balance | $ 1,578 | $ 6,924 |
| Additional accruals | 2,563 | 2,463 |
| Payments | (3,885) | (7,397) |
| Adjustments | (6) | (412) |
| Ending accrual balance | $ 250 | $ 1,578 |

***Retention Program.*** On February 27, 2008, the Board of Directors of the Company approved an employee retention program (Retention Program) to provide the Company with a mechanism to retain its non-officer and executive officer employees who were not subject to the Company s restructuring programs. As part of the Retention Program, the Board approved a one-time cash retention payment totaling $3.2 million, 60% of which was paid in the first quarter of 2008 and the remaining 40% of which was paid in the fourth quarter of 2008. In addition, the Board approved the issuance of restricted stock units (RSUs) covering an aggregate of 1.2 million shares and stock options covering an aggregate of 501,000 shares to its executive officers and certain employees, all of which were issued in the first quarter of 2008.

***Share-Based Compensation.*** The Company records compensation expense associated with stock options and other equity-based compensation in accordance with ASC 718 Compensation Stock Compensation (ASC 718). The Company recognizes compensation expense 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.

On August 1, 2007, the Company amended and restated the Neurocrine Biosciences, Inc. Nonqualified Deferred Compensation Plan (the Plan). Under the terms of the amended and restated Plan, the Company is required to distribute shares in order to settle any share-based compensation deferred into the Plan by participants. Additionally, participants are no longer permitted to diversify share-based awards that are placed into the Plan. In accordance with ASC 718 and ASC 710-10-05-8, Compensation General Deferred Compensation Rabbi Trusts (ASC 710-10-05-8), the Company reclassified the portion of the liability representing its obligation related to share-based compensation that had vested as of the date of the Plan modification to additional paid-in-capital. There was no effect on the Company s previously reported net loss or accumulated deficit.

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

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2009 | 2008 | 2007 |
| Interest income | 691 | 4,039 | 7,817 |
| Dividends | 37 | 70 | 108 |
| Realized (losses)/gains, net | (2,179) | (1,977) | 812 |
| Total | $ (1,451) | $ 2,132 | $ 8,737 |

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***Net Loss Per Share.*** The Company computes net loss per share in accordance with ASC 260-20, Earnings Per Share (ASC 260-20). Under the provisions of ASC 260-20, basic net income (loss) per share is computed by dividing the net income (loss) for the period by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share is computed by dividing the net income (loss) for the period by the weighted average number of common and common equivalent shares outstanding during the period. Additionally, potentially dilutive securities, composed of incremental common shares issuable upon the exercise of stock options and warrants and the vesting of RSUs, were excluded from historical diluted loss per share because of their anti-dilutive effect. Potentially dilutive securities totaled less than 0.1 million for the years ended December 31, 2009 and 2008 and 1.2 million for the year ended December 31, 2007.

***Impact of Recently Issued Accounting Standards.*** In April 2009, the Financial Accounting Standards Board (FASB) issued several pronouncements related to fair value measurement, recording and disclosure in financial reporting.

ASC 825-10 Financial Instruments and ASC 270-10, Interim Reporting, were issued to outline the required financial statement disclosures relating to fair value of financial instruments during interim reporting periods. ASC 820-10, Fair Value Measurements and Disclosures, was issued to provide additional guidance in evaluating the fair value of a financial instrument when the volume and level of activity for the asset or liability has significantly decreased. ASC 320-10, Recognition Investments Debt & Equity Securities, was issued to provide additional guidance on presenting impairment losses on securities.

All of the fair value measurement pronouncements were effective for interim and annual reporting periods ending after June 15, 2009. The adoption of these new pronouncements did not have a material effect on the Company s consolidated results of operations or financial condition.

In May 2009, the FASB issued ASC 855-10, Subsequent Events. ASC 855-10 is intended to establish general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. It requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for selecting that date, that is, whether that date represents the date the financial statements were issued or were available to be issued. ASC 855-10 is effective for interim or annual financial periods ending after June 15, 2009. The adoption of ASC 855-10 did not have a material effect on the Company s consolidated results of operations or financial condition.

In June 2009, the FASB issued SFAS No. 168, The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles, a replacement of FASB 162 (SFAS 168). The FASB Accounting Standards Codification (Codification) will become the source of authoritative U.S. generally accepted accounting principles (GAAP) recognized by the FASB to be applied by nongovernmental entities. Rules and interpretive releases of the SEC under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. On the effective date of this Statement, the Codification will supersede all then-existing non-SEC accounting and reporting standards. All other non-grandfathered non-SEC accounting literature not included in the Codification will become non-authoritative. SFAS 168 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The adoption of SFAS 168 did not have a material effect on the Company s consolidated results of operations or financial condition.

**NOTE 2. INVESTMENTS**

Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in comprehensive income. 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 interest income. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income or expense. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income. The Company also has investments classified as trading securities (See Note 3).

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Investments at December 31, 2009 and 2008 consist of the following (in thousands):

| | 2009 | 2008 |
|---|---|---|
| Certificates of deposit | $ 3,360 | $ |
| Securities of government-sponsored enterprises | | 9,999 |
| Corporate debt securities | | 2,007 |
| Auction rate securities, available-for-sale | 6,411 | 6,689 |
| Auction rate securities, trading | 11,569 | 12,018 |
| Auction rate security rights, trading | 1,206 | 2,350 |
| Ending balance | $ 22,546 | $ 33,063 |

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

| | Amortized Cost | Gross Unrealized Gains(1) | Gross Unrealized Losses(1) | Aggregate Estimated Fair Value |
|---|---|---|---|---|
| **December 31, 2009** | | | | |
| Certificates of deposit | $ 3,360 | $ 1 | $ (1) | $ 3,360 |
| Auction rate securities | 5,031 | 1,380 | | 6,411 |
| Total available-for-sale securities | $ 8,391 | $ 1,381 | $ (1) | $ 9,771 |
| **December 31, 2008** | | | | |
| Securities of government-sponsored enterprises | $ 9,919 | $ 80 | $ | $ 9,999 |
| Corporate debt securities | 2,039 | | (32) | 2,007 |
| Auction rate securities | 6,689 | | | 6,689 |
| Total available-for-sale securities | $ 18,647 | $ 80 | $ (32) | $ 18,695 |

(1) Unrealized gains and losses on available-for-sale securities are included as a component of other comprehensive loss.

The amortized cost and estimated fair value of debt securities classified as available-for-sale by contractual maturity at December 31, 2009 and December 31, 2008 are presented below (in thousands):

| | Maturing in less than 12 months | | Maturing in more than 12 Months | |
|---|---|---|---|---|
| | Amortized Cost | Estimated Fair Value | Amortized Cost | Estimated Fair Value |
| **December 31, 2009** | | | | |
| Certificates of deposit | $ 3,360 | $ 3,360 | $ | $ |
| Auction rate securities classified as available-for-sale | | | 5,031 | 6,411 |
| Total available-for-sale securities | $ 3,360 | $ 3,360 | $ 5,031 | $ 6,411 |

| | | | | |
|---|---|---|---|---|
| **December 31, 2008** | | | | |
| Securities of government-sponsored enterprises | $ 9,919 | $ 9,999 | $ | $ |
| Corporate debt securities | 2,039 | 2,007 | | |
| Auction rate securities classified as available-for-sale | | | 6,689 | 6,689 |
| Total available-for-sale securities | $ 11,958 | $ 12,006 | $ 6,689 | $ 6,689 |

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

| | Twelve Months Ended December 31, 2009 | Twelve Months Ended December 31, 2008 | Twelve Months Ended December 31, 2007 |
|---|---|---|---|
| Proceeds from sales/maturities of available-for-sale securities | $ 25,790 | $ 76,349 | $ 117,130 |
| Gross realized gains on sales of available-for-sale securities | 124 | 9 | |
| Gross realized losses on sales of available-for-sale securities | | (26) | |
| Gains reclassified out of accumulated other comprehensive loss into earnings | | 8 | |
| Losses reclassified out of accumulated other comprehensive loss into earnings | | (2) | |
| Unrealized gains (losses), net, included in accumulated other comprehensive loss | 1,380 | 9 | (23) |
| Gains (losses) included in earnings from transfers of securities from available-for-sale to trading | | (2,583) | |

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

| | Less Than 12 Months | | 12 Months or Greater | | Total | |
|---|---|---|---|---|---|---|
| | Estimated Fair Value | Unrealized Losses | Estimated Fair Value | Unrealized Losses | Estimated Fair Value | Unrealized Losses |
| **December 31, 2009** | | | | | | |
| Certificates of deposit(1) | $ 1,439 | $ (1) | $ | $ | $ 1,439 | $ (1) |
| Total | $ 1,439 | $ (1) | $ | $ | $ 1,439 | $ (1) |
| **December 31, 2008** | | | | | | |
| Corporate debt securities | $ 2,007 | $ (32) | $ | $ | $ 2,007 | $ (32) |
| Total | $ 2,007 | $ (32) | $ | $ | $ 2,007 | $ (32) |

(1) The Company holds 6 certificates of deposit (CDs) at December 31, 2009 that are in an unrealized loss position due to valuations assigned based on market data. All of the Company s CD holdings are fully guaranteed by the Federal Deposit Insurance Corporation. The Company has the ability and intent to hold these CDs until a recovery of fair value, which may be at maturity, and therefore does not consider these investments to be other-than-temporarily impaired at December 31, 2009.

**NOTE 3. AUCTION RATE SECURITIES**

The Company s investments at December 31, 2009 included (at par value) $20.4 million of auction rate securities. With the liquidity issues experienced in global credit and capital markets, these auction rate securities have experienced multiple failed auctions as the amount of securities submitted for sale has exceeded the amount of purchase orders, and as a result, these affected securities are currently not liquid. All of the Company s auction rate securities are secured by student loans, which are backed by the full faith and credit of the federal government (up to approximately 98% of the value of the student loan). All of these securities continue to pay interest according to their stated terms (generally 120 basis points over the ninety-one day United States Treasury bill rate) with interest rates resetting every 7 to 28 days. While it is not the Company s intent to hold these securities until their stated maturity dates, these investments are scheduled to ultimately mature between 2030 and 2047.

The valuation of the Company s auction rate securities investment portfolio is subject to uncertainties that are difficult to predict. The fair values of these securities are estimated utilizing a discounted cash flow analysis

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as of December 31, 2009. The significant assumptions of this valuation model were discount margins ranging from 152 to 320 basis points which are based on industry recognized student loan sector indices, an additional liquidity discount of 150 basis points and an estimated term to liquidity of 5 to 7 years. Other items this analysis considers are the collateralization underlying the security investments, the creditworthiness of the counterparty, and the timing of expected future cash flows. These securities were also compared, when possible, to other observable market data with similar characteristics as the securities held by the Company. The auction rate security investments continue to pay interest according to their stated terms. The carrying value for these auction rate securities at December 31, 2009 is $18.0 million.

During the fourth quarter of 2008, UBS AG (UBS) extended an offer of Auction Rate Securities Rights (ARS Rights) to holders of illiquid auction rate securities that were maintained by UBS as of February 13, 2008. The ARS Rights provide the holder with the ability to sell the auction rate securities, along with the ARS Rights, to UBS at the par value of the auction rate securities, during an applicable exercise period. The ARS Rights grant UBS the sole discretion and right to sell or otherwise dispose of auction rate securities at any time up until July 2, 2012, without any prior notification of the holder, so long as the holder receives a payment of par upon any sale or disposition. The ARS Rights are not transferable, not tradeable, and will not be quoted or listed on any securities exchange or any other trading network. The offer period for the ARS Rights closed on November 14, 2008 and ARS Rights were issued by UBS during the fourth quarter of 2008.

The Company has elected to participate in the ARS Rights program for all of its outstanding auction rate securities maintained by UBS. The Company has $12.8 million (par value) of ARS that are maintained by UBS. Under the terms of the ARS Rights offer, the applicable exercise period begins on June 30, 2010 and ends July 2, 2012. Additionally, the Company is eligible for a loan of up to 75% of the market value of the auction rate securities, should a loan be needed. It is the Company s intention to sell the auction rate securities and ARS Rights to UBS on June 30, 2010.

The Company elected to measure the ARS Rights under the fair value option of ASC 825-10, Financial Instruments (ASC 825-10), to mitigate volatility in reported earnings due to their linkage to the auction rate securities. The ARS Rights were valued in a similar fashion to the auction rate securities as described above. Simultaneously, due to the ARS Rights granted by UBS, the Company made a one-time election to transfer the related auction rate security holdings from available-for-sale securities to trading securities in the fourth quarter of 2008. Trading securities are carried at fair value with unrealized gains and losses reported in other income and expense in the consolidated statement of operations. The Company anticipates that any future changes in the fair value of the ARS Rights will be offset by the changes in the fair value of the related auction rate securities with no material net impact to the consolidated statement of operations. The ARS Rights will continue to be measured at fair value under ASC 825-10 until the earlier of their maturity or exercise. The Company valued these ARS Rights at $1.2 million and $2.4 million at December 31, 2009 and 2008, respectively. These ARS Rights, together with the auction rate securities held at UBS (which had a fair value of $11.6 million and $12.0 million as of December 31, 2009 and 2008, respectively) are carried as short-term investments on the condensed consolidated balance sheet at December 31, 2009 and were carried as long-term investments on the condensed consolidated balance sheet at December 31, 2008. Gain and losses resulting from adjustments to the fair value of the ARS Rights were $(0.8) million and $2.4 million for the years ended December 31, 2009 and 2008, respectively, and were included in other income and expense in the consolidated statement of operations. These changes were offset by changes in the fair value of the related auction rate securities with no material net impact to the consolidated statements of operations.

The two remaining auction rate securities continue to be treated as available-for-sale investments. These auction rate securities have a par value of $7.6 million and are carried on the Company s balance sheet at an estimated fair value of $6.4 million at December 31, 2009. During the first quarter of 2009, certain ratings agencies downgraded these auction rate securities and the Company recognized an other-than-temporary impairment charge of $1.4 million in the consolidated statement of operations. Subsequent to this downgrade, global credit markets improved and the credit spreads related to these types of investments narrowed resulting in

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an increase in the fair value of the investments of approximately $1.4 million which the Company has recorded as an unrealized gain in other comprehensive income for the year ended December 31, 2009. During 2008, the Company recognized an unrealized loss of $1.3 million for an other-than-temporary impairment in the consolidated statement of operations.

Changes to estimates and assumptions used in estimating the fair value of the auction rate securities and related ARS Rights may provide materially different values. In addition, actual market exchanges, if any, may occur at materially different amounts. For example, a reduction of the expected term to redemption assumption by 2 years for the auction rate securities and related ARS Rights yielded a net increase in the valuation of these investments of $0.3 million. Other factors that may impact the valuation of the Company s auction rate securities and related ARS Rights include changes to credit ratings of the securities as well as to the underlying assets supporting those securities, rates of default of the underlying assets, underlying collateral value, discount rates, counterparty risk and ongoing strength and quality of market credit and liquidity.

At present, in the event the Company needs to access the funds that are in an illiquid state, it may not be able to do so without the possible loss of principal, until a future auction for these investments is successful, another secondary market evolves for these securities, until they are redeemed by the issuer or they mature. If the Company is unable to sell these securities in the market or they are not redeemed, it could be required to hold them to maturity. The Company does not have a need to access these funds for operational purposes prior to June 30, 2010, the beginning of the ARS Rights exercise period. The Company will continue to monitor and evaluate these investments on an ongoing basis for impairment.

**NOTE 4. FAIR VALUE MEASUREMENTS**

The Company follows ASC 820-10, Fair Value Measurements and Disclosures (ASC 820-10), which among other things, defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. 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, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

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Assets measured at fair value as of December 31, 2009 and 2008 are classified below based on the three fair value hierarchy tiers described above (in millions):

| | | Fair Value Measurements Using | | |
|---|---|---|---|---|
| | Carrying Value | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| **December 31, 2009:** | | | | |
| Money market funds | $ 43.4 | $ 43.4 | $ | $ |
| Certificates of deposit(1) | 3.3 | 3.3 | | |
| Auction rate securities(Note 3) | 18.0 | | | 18.0 |
| ARS Rights (Note 3) | 1.2 | | | 1.2 |
| Total | $ 65.9 | $ 46.7 | $ | $ 19.2 |
| **December 31, 2008:** | | | | |
| Money market funds | $ 64.6 | $ 64.6 | $ | $ |
| Commercial paper(1) | 10.0 | 10.0 | | |
| Corporate debt securities(1) | 2.0 | 2.0 | | |
| Securities of government-sponsored enterprises(1) | 10.0 | 10.0 | | |
| Auction rate securities(Note 3) | 18.7 | | | 18.7 |
| ARS Rights (Note 3) | 2.4 | | | 2.4 |
| Total | $ 107.7 | $ 86.6 | $ | $ 21.1 |

(1) Securities are classified as available-for-sale.

Activity for assets measured at fair value during the twelve month period ended December 31, 2009 using significant unobservable inputs (Level 3) is presented in the table below (in millions):

| | Fair Value Measurements Using Significant Unobservable Inputs (Level 3) |
|---|---|
| Beginning balance as of December 31, 2008 | $ 21.1 |
| Transfers into Level 3 | |
| Sales and settlements, net | (2.2) |
| Total unrealized gains included in other comprehensive income | 1.4 |
| Total other-than-temporary impairments included in other income and (expense) | (1.1) |
| Ending balance | $ 19.2 |

**NOTE 5. PROPERTY AND EQUIPMENT**

Property and equipment at December 31, 2009 and 2008 consist of the following (in thousands):

| | 2009 | 2008 |
|---|---|---|
| Tenant improvements | 1,118 | 1,108 |
| Furniture and fixtures | 1,309 | 1,989 |
| Equipment | 37,598 | 42,059 |
| | 40,025 | 45,156 |
| Less accumulated depreciation | (37,330) | (38,965) |
| Property and equipment, net | $ 2,695 | $ 6,191 |

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For the years ended December 31, 2009, 2008 and 2007, depreciation expense was $3.2 million, $7.6 million and $9.4 million, respectively. During 2009, 2008 and 2007, the Company recognized a gain of approximately $841,000, $105,000 and $129,000, respectively, related to disposal of capital equipment.

**NOTE 6. ACCRUED LIABILITIES**

Accrued liabilities at December 31, 2009 and 2008 consist of the following (in thousands):

| | 2009 | 2008 |
|---|---|---|
| Accrued employee benefits | $ 877 | $ 2,879 |
| Accrued severance costs | 250 | 1,578 |
| Accrued development costs | 2,032 | 2,985 |
| Other accrued liabilities | 3,081 | 3,463 |
| | $ 6,240 | $ 10,905 |

**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 $109.0 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 entered into a first lease amendment (First Lease Amendment) in December 2008 and a second lease amendment (Second Lease Amendment) in September 2009 (collectively, Amendments). This lease has been characterized as an operating lease for financial reporting purposes.

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, etc. 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 $5.7 million. The letter of credit is secured by a deposit of $6.3 million with the same bank, which is carried as restricted cash on the consolidated balance sheet. The Company has the right to extend the Lease for two consecutive ten-year terms and will have the first right of refusal to lease, at market rates, any facilities built on the sold vacant lot. Additionally, the Company had a repurchase right to all of the properties which could have been exercised during the fourth year of the Lease, but this right was subsequently terminated.

In accordance with ASC 840-40, Leases Sale-Leaseback Transactions Involving Real Estate (ASC 840-40) and ASC 360-20, Property, Plant and Equipment Real Estate Sales (ASC 360-20), at the close of the transaction, the Company initially deferred the gain on the sale of the building and related vacant parcel due to the repurchase right. The Company also established a long-term liability of $108.7 million, essentially the gross proceeds from the real estate sale, and the conveyed real estate assets remained on the Company s balance sheet as of December 31, 2007.

Effective December 10, 2008, the Company entered into the First Lease Amendment which provided for the renovation of the Front Building in a manner that facilitates multiple tenant usage and also establishes a mechanism for the Company to terminate its use of the Front Building. The Company continues to occupy the Rear Building.

Pursuant to the terms of the First Lease Amendment, the Company is obligated to reimburse the landlord for the total cost of renovating a portion of the Front Building such that the Front Building becomes suitable for multiple tenant usage. The Company made a one-time payment of $1.0 million toward renovation costs in

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January 2009 and is reimbursing the landlord for the balance of the renovation costs over a four-year period through an increase in monthly rental payments (currently estimated at $108,000 per month) which began in October 2008. Furthermore, the First Lease Amendment provided that the landlord would seek to enter into leases with replacement tenants for portions of the Front Building. In connection with each replacement lease, the Company would be granted a pro rata reduction in rent under the Lease. The Company was required to pay all tenant improvement costs, lease termination costs and leasing commissions in connection with each replacement lease under the First Lease Amendment.

The First Lease Amendment also terminated the Company s right to repurchase any portion of the facility or real property. As a result of the termination of the repurchase right, during the fourth quarter of 2008, the Company removed from its balance sheet the long-term liability of $108.7 million and the related previously conveyed real estate related assets of $69.6 million. Additionally, the Company began to recognize the deferred gain of $39.1 million on the sale of the real estate in accordance with ASC 840-40 and ASC 360-20. During 2009 and 2008, the Company recognized $2.8 million and $3.5 million, respectively, of the deferred gain and will recognize the balance of the deferred gain over the remaining lease term.

As a result of signing the First Lease Amendment and physically vacating the Front Building, the Company triggered a cease-use date for the Front Building and has estimated lease termination costs in accordance with ASC 420-10. Estimated lease termination costs for the Front Building under the First Lease Amendment included the net present value of future minimum lease payments, taxes, insurance, construction, and maintenance costs from the cease-use date to the end of the remaining lease term net of estimated sublease rental income. During the fourth quarter of 2008, the Company recorded an expense of $15.7 million for the net present value of these estimated lease termination costs, of which $0.3 million was paid in 2008. During 2009, the Company increased the liability by $6.0 million in response to the declining economic conditions in San Diego by extending the expected period to lease the Front Building.

Effective September 25, 2009, the Company and DMH entered into the Second Lease Amendment which obligated the Company to vacate the Front Building and make an immediate payment of $4.0 million to DMH as an initial release fee, which was paid October 2, 2009. The Company continues to occupy the entire Rear Building. Upon payment of the initial release fee, the Company was released from its obligations with respect to the Front Building, except with respect to 1) certain indemnity obligations for events prior to the payment of the initial release fee, 2) certain operating expenses for the Front Building in accordance with the terms of the Lease through July 2011, and 3) 50% of tenant improvement costs between $65 and $100 per square foot in connection with initial leases between DMH and other third parties for space in the Front Building. As of December 31, 2009, the Company had completely satisfied its obligation with respect to payment of tenant improvement costs. Pursuant to the Second Lease Amendment, the Company is also obligated to pay DMH an amount equivalent to the rent on the Front Building through July 2011 and then approximately $44,000 per month beginning in August 2011 through December 2019 as a rent differential payment for the Front Building, which such rent differential amounts may be prepaid by the Company at its sole discretion. Should the Company be in monetary default under the Lease beyond the normal cure periods and prior to repaying the entire rent differential balance, the rent differential payment will double.

Changes to the accrued cease-use liability during 2009 and 2008 are as follows (in thousands):

| | Years Ended December 31, | |
|---|---|---|
| | 2009 | 2008 |
| Beginning balance | $ 15,397 | $ |
| Accrued lease termination costs | 5,984 | 15,742 |
| Payments | (9,851) | (345) |
| Ending balance | $ 11,530 | $ 15,397 |

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***Rent Expense.*** Rent expense was $6.5 million, $1.1 million and $0.3 million for the years ended December 31, 2009, 2008 and 2007, respectively. Rent paid under the leaseback for the facility was treated as interest expense in accordance with ASC 840-40 for the period where the repurchase right existed. This charge totaled $7.0 million and $0.6 million in 2008 and 2007, respectively. The Company recognizes rent expense on a straight-line basis.

***Lease Commitments.*** The Company leases its office and research laboratories under an operating lease with an initial term of twelve years, expiring in 2019. The Company is responsible for base rent, plus additional operating costs which comprise the estimated minimum lease payments. Additionally, the Company s facility lease agreement calls for it to maintain $50.0 million in cash and investments at all times, or to increase the security deposit by $5.0 million.

As of December 31, 2009, the total estimated future annual minimum lease payments under the Company s non-cancelable building lease are as follows:

| | Payment Amount (In thousands) |
|---|---|
| Year ending: | |
| 2010 | $ 11,188 |
| 2011 | 10,224 |
| 2012 | 8,347 |
| 2013 | 7,580 |
| 2014 | 7,792 |
| Thereafter | 42,362 |
| Total future minimum lease payments | $ 87,493 |

***Equipment Loans.*** The Company had entered into equipment financing arrangements with lenders to finance equipment purchases, which expired on various dates through the year 2008 and bore interest at rates between 6.3% and 7.3%. The debt obligations were repayable in monthly installments and were secured by the financed equipment. Amounts outstanding under these loans at December 31, 2007 totaled $1.5 million. These equipment loans were fully repaid during 2008.

***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 licensing 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 licensed technology. The Company continually reassesses the value of the license agreements and cancels them when research efforts are discontinued on these programs. If all licensed and research candidates are successfully developed, the Company may be required to pay milestone payments of approximately $18.0 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.

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***Related Party Transactions.*** The Company has entered into agreements with a research facility for technology. A director of the Company is an employee of this research facility. During the years ended December 31, 2009, 2008 and 2007, the Company paid approximately $37,000, $425,000 and $80,000, respectively, to the research facility for this technology. At December 31, 2009, the Company had $33,000 included in accrued liabilities payable to this research facility.

***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.*** The Company grants stock options, restricted stock units and stock bonuses (collectively, share-based compensation) to its employees and directors under the 2003 Incentive Stock Plan, as amended (the 2003 Plan) and grants stock options to certain employees pursuant to Employment Commencement Nonstatutory Stock Option Agreements. The benefits provided under these plans are share-based compensation subject to the provisions of ASC 718.

Since 1992, the Company has authorized approximately 15.2 million shares of common stock for issuance pursuant to its 1992 Plan, 1996 Director Option Plan, 1997 Northwest Neurologic, Inc. Restated Incentive Stock Plan, 2001 Plan, several Employment Commencement Nonstatutory Stock Option Agreements and the 2003 Plan (collectively, the Option Plans). The Option Plans provide for the grant of stock options, restricted stock, restricted stock units, and stock bonuses to officers, directors, employees, and consultants of the Company. Currently, all new grants of stock options are made from the 2003 Plan or through Employment Commencement Nonstatutory Stock Option Agreements. As of December 31, 2009, of the 15.2 million shares reserved for issuance under the Option Plans, 2.4 million of these shares were originally reserved for issuance pursuant to the terms of the Company s 1992 Plan, 1996 Director Stock Option Plan and 2001 Plan and would currently be available for issuance but for the Company s determination in 2003 not to make further grants under these plans; 7.0 million were issued upon exercise of stock options previously granted or pursuant to restricted stock or stock bonus awards; 3.6 million were subject to outstanding options and restricted stock units; and 2.2 million remained available for future grant under the 2003 Plan. Share awards made under the 2003 Plan that are later cancelled due to forfeiture or expiration return to the 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.

The Company s net loss for the years ended December 31, 2009, 2008 and 2007 includes $5.5 million, $8.0 million and $10.0 million of compensation expense, respectively, related to the Company s share-based compensation awards. The compensation expense related to the Company s share-based compensation arrangements is recorded as components of general and administrative expense and research and development expense ($3.2 million and $2.3 million, respectively, for the year ended December 31, 2009). ASC 718 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 loss position, no tax benefits have been recognized in the consolidated statements of cash flows.

***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. Stock bonuses granted under the Option Plans generally have vesting periods ranging from two to four years. Restricted stock units granted under the Option Plans generally have vesting periods of three years. The expense recognized under ASC 718 is generally recognized ratably over the vesting period. However, certain retirement provisions in the Option Plans provide that employees who are age 55 or older, and have five or more years of service with the

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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. Effective January 1, 2006, the maximum contractual term for all options granted from the 2003 Plan was reduced to seven years.

***Stock Options.*** The exercise price of all options granted during the years ended December 31, 2009, 2008 and 2007 was equal to the market value 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 valuation model with the following weighted-average assumptions for option grants during the years ended December 31, 2009, 2008 and 2007:

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2009 | 2008 | 2007 |
| Risk-free interest rate | 2.3% | 2.7% | 4.8% |
| Expected volatility of common stock | 83% | 69% | 65% |
| Dividend yield | 0.0% | 0.0% | 0.0% |
| Expected option term | 5.35 years | 4.75 years | 4.75 years |

The risk-free interest rate assumption is based upon observed interest rates appropriate for the expected term of the Company s employee stock options. The expected volatility is based on the historical volatility of the Company s stock. The Company has not paid any dividends on common stock since its inception and does not anticipate paying dividends on its common stock in the foreseeable future. The Company used the simplified method to compute the expected option term for all options granted during 2008 and 2007 as was permitted by SEC Staff Accounting Bulletin Topic 14 *Share-Based Payment* because the decline in the Company s stock price had decreased the exercise activity of option holders and there was insufficient historical exercise data to provide a more reasonable basis upon which to estimate expected term.

Share-based compensation expense recognized in the Consolidated Statement of Operations for the year ended December 31, 2009 is based on awards ultimately expected to vest, net of estimated forfeitures. ASC 718 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 2009 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 estimated at 0% in 2009 based on historical employee turnover experience. The effect of the 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, 2009, 2008 and 2007, estimated as of the grant date using the Black-Scholes option valuation model, were $2.10, $2.86 and $6.60, respectively.

A summary of the status of the Company s stock options as of December 31, 2009 and of changes in options outstanding under the plans during the year ended December 31, 2009 is as follows (in thousands, except for weighted average exercise price data):

| | 2009 | | 2008 | | 2007 | |
|---|---|---|---|---|---|---|
| | Options | Weighted Average Exercise Price | Options | Weighted Average Exercise Price | Options | Weighted Average Exercise Price |
| Outstanding at January 1 | 3,598 | $ 21.78 | 4,144 | $ 23.74 | 4,264 | $ 28.49 |
| Granted/amended | 111 | 3.15 | 626 | 4.99 | 604 | 11.44 |
| Exercised | | | (8) | 4.17 | (78) | 7.60 |
| Canceled | (900) | 20.37 | (1,164) | 19.85 | (646) | 45.53 |
| Outstanding at December 31 | 2,809 | $ 21.50 | 3,598 | $ 21.78 | 4,144 | $ 23.74 |

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Options outstanding at December 31, 2009 have a weighted average remaining contractual term of 3.2 years.

For the year ended December 31, 2009, share-based compensation expense related to stock options was $2.1 million. As of December 31, 2009, there is approximately $0.5 million of unamortized compensation cost related to stock options. Compensation cost associated with unvested stock option awards as of December 31, 2009 is expected to be recognized over a remaining weighted-average vesting period of 1.0 years. As of December 31, 2009, there are approximately 2.4 million options exercisable with a weighted average exercise price of $24.03 and a weighted-average remaining contractual term of 2.9 years. The total intrinsic value, which is the amount (if any) 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, 2009, 2008, and 2007 was $0, $13,000 and $0.4 million, respectively. As of December 31, 2009, the total intrinsic value of options outstanding and exercisable was $0. Cash received from stock option exercises for the years ended December 31, 2009, 2008 and 2007 was $0, $33,000 and $0.6 million, respectively.

On August 28, 2009 and October 24, 2007, 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 2009 cancellations other than the $100 paid to each optionee because the cancelled options were all fully vested at the time of cancellation. The Company recognized approximately $0.4 million of compensation expense in conjunction with the 2007 cancellations.

***Restricted Stock Units.*** Beginning in January 2006, certain employees are eligible to receive restricted stock units under the 2003 Plan. In accordance with ASC 718, the fair value of restricted stock units is estimated 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, 2009, there is approximately $1.8 million of unamortized compensation cost related to restricted stock units, which is expected to be recognized over a remaining weighted-average vesting period of 1.2 years. The restricted stock units, at the election of eligible employees, may be subject to deferred delivery arrangement. For the year ended December 31, 2009, share-based compensation expense related to restricted stock units was $3.4 million. The total intrinsic value of restricted stock units converted into common shares during the years ended December 31, 2009, 2008 and 2007 was $2.0 million, $1.5 million and $2.6 million, respectively. The total intrinsic value of restricted stock units outstanding at December 31, 2009 was $1.8 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, 2009, 2008, and 2007 and of changes in restricted stock units outstanding under the plan for the three years ended December 31, 2009 is as follows (in thousands, except for weighted average grant date fair value per unit):

| | 2009 | | 2008 | | 2007 | |
|---|---|---|---|---|---|---|
| | Number of Units | Weighted Average Grant Date Fair Value per Unit | Number of Units | Weighted Average Grant Date Fair Value per Unit | Number of Units | Weighted Average Grant Date Fair Value per Unit |
| Restricted stock units outstanding at January 1 | 1,450 | $ 6.58 | 1,066 | $ 11.12 | 896 | $ 13.11 |
| Restricted stock units granted | | | 1,212 | 5.07 | 484 | 11.49 |
| Restricted stock units cancelled | (175) | 6.48 | (520) | 9.55 | (32) | 11.17 |
| Restricted stock units converted into common shares | (594) | 7.42 | (308) | 11.09 | (282) | 10.86 |
| Restricted stock units outstanding at December 31 | 681 | $ 5.88 | 1,450 | $ 6.58 | 1,066 | $ 11.12 |

***Warrants.*** The Company has outstanding warrants to purchase 3,940 shares of common stock at $52.05 that expire in December 2012.

The following shares of common stock are reserved for future issuance at December 31, 2009 (in thousands):

| | |
|---|---|
| Share based compensation plans | 5,643 |
| Warrants | 4 |
| Total | 5,647 |

**NOTE 9. STOCKHOLDERS EQUITY**

***Equity Financing***

During 2009, the Company entered into a privately negotiated transaction to sell approximately 4.8 million shares of its common stock to an institutional investor at a price of $2.09 per share, raising total proceeds of $10.0 million. The shares were sold pursuant to the Company s effective shelf registration statement with the Securities and Exchange Commission. Total stock issuance costs related to this financing were approximately $100,000.

***Committed Equity Financing Facility***

In September 2009, the Company entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge) pursuant to which Kingsbridge committed to purchase, subject to certain conditions, up to the lesser of 7.8 million newly issued shares of the Company s common stock or an aggregate of $75.0 million newly issued shares over the three-year term of the CEFF. The Company may access capital under the CEFF by making draw downs up to a maximum of the lesser of (i) $15 million and (ii) the greater of (x) 1.75% of its market capitalization as of the date of delivery of the draw down notice once per calendar quarter and up to 1.25% of its market capitalization as of the date of delivery of the draw down notice for any additional draw downs during such calendar quarter and (y) the lesser of (a) 2.75% of its market capitalization as of the date of delivery of the draw down notice and (b) a number of shares determined by a formula based in part on the average trading volume and trading price of the Company s common stock prior to the delivery of the draw down notice issued by the Company with respect to that draw down pricing period, subject to certain conditions, including a minimum share price threshold of $1.00. Kingsbridge may purchase shares of common stock pursuant to the CEFF at discounts ranging from 5 to 10 percent, depending on the average market price of the Company s common stock during the applicable pricing period for a draw down. As of December 31, 2009, the Company had not issued any

shares under the CEFF.

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**NOTE 10. SIGNIFICANT COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENTS**

***Dainippon Sumitomo Pharma Co., Ltd.*** On October 31, 2007, the Company entered into an exclusive license agreement with Dainippon Sumitomo Pharma Co. Ltd. (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 $20.0 million. The Company is also eligible to receive additional milestone payments upon specified future events related to the development and commercialization of indiplon in Japan. Should all milestones be achieved, the Company may be entitled to payments totaling an additional $115.0 million. Additionally, the Company is entitled to royalties from DSP on future sales of indiplon in Japan. For the years ending December 31, 2009, 2008 and 2007, the Company amortized into revenue $2.9 million, $2.9 million and $0.5 million, respectively, of the upfront license fee under the DSP agreement.

***GlaxoSmithKline.*** In July 2001, the Company 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, the Company and GSK conducted a collaborative research program and collaborate 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. In addition, the Company will be eligible to receive milestone payments as compounds progress through the research and development process, royalties on future product sales and co-promotion rights in the U.S. under some conditions. GSK may terminate the agreement at its discretion upon prior written notice to the Company. In such event, the Company may be entitled to certain payments and all product rights would revert to Neurocrine. For each of the years ended December 31, 2009, 2008 and 2007, the Company recognized $0.1 million, $1.0 million and $0.1 million, respectively, in revenue under the GSK agreement. The sponsored research portion of this collaboration agreement ended in 2005.

**NOTE 11. INCOME TAXES**

On July 13, 2006, the FASB issued ASC 740-10, *Accounting for Income Taxes*, formerly FASB Interpretation No. 48 (FIN 48), Accounting for Uncertainty in Income Taxes, an interpretation of FASB ASC 740, formerly FASB No. 109 . Under ASC 740-10, 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, ASC 740-10 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

The Company adopted the provisions of ASC 740-10 on January 1, 2007. There were no unrecognized tax benefits as of the date of adoption. As a result of the implementation of ASC 740-10, the Company did not recognize an increase in the liability for unrecognized tax benefits. There are no unrecognized tax benefits included in the balance sheet that would, if recognized, affect the effective tax rate. The adoption of FIN 48 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 balance sheets at December 31, 2009 or December 31, 2008, and has not recognized interest and/or penalties in the statement of operations for the year ended December 31, 2009.

The Company is subject to taxation in the United States and various state jurisdictions. The Company s tax years for 1993 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.

The adoption of ASC 740-10 did not impact the Company s financial condition, results of operations or cash flows. At December 31, 2009, the Company had net deferred tax assets of $61.4 million. Due to uncertainties surrounding the Company s ability to generate future taxable income to realize these assets, a full valuation has

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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 may have occurred previously or that could occur in the future. Although the Company determined that an ownership change had not occurred through January 31, 2007, it is possible that an ownership change occurred subsequent to that date. The Company has not completed an update of its Section 382 analysis subsequent to January 31, 2007. Until this analysis has been updated, the Company has removed the deferred tax assets for net operating losses of $253.7 million and research and development credits of $42.0 million generated through 2009 from its deferred tax asset schedule and has recorded a corresponding decrease to its valuation allowance. When this analysis is finalized, the Company plans to update its unrecognized tax benefits under ASC 740-10. Due to the existence of the valuation allowance, future changes in the Company s unrecognized tax benefits will not impact the Company s effective tax rate.

At December 31, 2009, the Company had Federal and California income tax net operating loss carry forwards of approximately $649.5 million and $578.4 million, respectively. The Federal and California tax loss carry forwards will begin to expire in 2010, unless previously utilized. In addition, the Company has Federal and California research and development tax credit carry forwards of $28.6 million and $20.7 million, respectively. The Federal research and development tax credit carry forwards began expiring in 2007 and will continue to expire unless utilized. There were $550,000 of Federal research and development tax credit carryforwards that have expired through 2009. The California research and development tax credit carryforwards carry forward indefinitely. The Company also has Federal Alternative Minimum Tax credit carryforwards of approximately $256,000, which will carry forward indefinitely. At December 31, 2009, approximately $88.3 million of the net operating loss carry forwards relate to stock option exercises, which will result in an increase to additional paid-in capital and a decrease in income taxes payable at the time when the tax loss carryforwards are utilized.

Significant components of the Company s deferred tax assets as of December 31, 2009 and 2008 are listed below. A valuation allowance of $61.4 million and $69.3 million at December 31, 2009 and 2008, respectively, has been recognized to offset the net deferred tax assets as realization of such assets is uncertain. Amounts are shown in thousands as of December 31, of the respective years (in thousands):

| | 2009 | 2008 |
|---|---|---|
| Deferred tax assets: | | |
| Capitalized research and development | $ 1,900 | $ 3,000 |
| Deferred compensation | 400 | 900 |
| FAS 123R expense | 9,400 | 9,100 |
| Unrealized losses on investments | | 600 |
| Deferred revenue | 5,600 | 6,800 |
| Deferred gain on sales leaseback | 13,400 | 14,500 |
| Intangibles | 23,400 | 26,000 |
| Cease-use expense | 4,700 | 6,300 |
| Fixed assets | 200 | |
| Other | 2,900 | 2,500 |
| Total deferred tax assets | 61,900 | 69,700 |
| Deferred tax liabilities: | | |
| Unrealized losses on investments | 500 | |
| Fixed assets | | 400 |
| Total deferred tax liabilities | 500 | 400 |
| Net deferred tax asset | 61,400 | 69,300 |
| Valuation allowance | (61,400) | (69,300) |
| Net deferred tax assets | $ | $ |

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The provision for income taxes on earnings subject to income taxes differs from the statutory Federal rate at December 31, 2009, 2008 and 2007, due to the following (in thousands):

| | 2009 | 2008 | 2007 |
|---|---|---|---|
| Federal income taxes at 35% | $ (17,863) | $ (31,014) | $ (72,472) |
| State income tax, net of Federal benefit | (2,935) | (5,095) | (11,906) |
| Tax effect on non-deductible expenses | 1,586 | 785 | 700 |
| Removal of net operating losses and R&D credits | 29,708 | 34,237 | 231,548 |
| Change in valuation allowance | (7,923) | 3,521 | (144,800) |
| Other | (2,573) | (2,434) | (3,070) |
| | $ | $ | $ |

**NOTE 12. 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. Employer contributions were $180,000, $430,000 and $690,000 for the years ended December 31, 2009, 2008, and 2007, respectively.

**NOTE 13. SUBSEQUENT EVENTS**

In accordance with ASC 855-10, *Subsequent Events*, the Company evaluated subsequent events after the balance sheet date of December 31, 2009 through February 4, 2010.

**NOTE 14. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)**

The following is a summary of the quarterly results of operations of the Company for the years ended December 31, 2009 and 2008 (unaudited, in thousands, except for loss per share data):

| | Quarters Ended | | | | Year Ended |
|---|---|---|---|---|---|
| | Mar 31 | Jun 30 | Sep 30 | Dec 31 | Dec 31 |
| **2008** | | | | | |
| Revenues | $ 1,751 | $ 734 | $ 761 | $ 729 | $ 3,975 |
| Operating expenses | 22,513 | 20,851 | 16,465 | 31,444 | 91,273 |
| Net loss | (21,077) | (20,971) | (17,711) | (28,854) | (88,613) |
| Net loss per share: | | | | | |
| Basic and diluted | $ (0.55) | $ (0.55) | $ (0.46) | $ (0.75) | $ (2.30) |
| Shares used in the calculation of net loss per share: | | | | | |
| Basic and diluted | 38,330 | 38,421 | 38,446 | 38,599 | 38,449 |
| **2009** | | | | | |
| Revenues | $ 747 | $ 733 | $ 733 | $ 740 | $ 2,953 |
| Operating expenses | 19,871 | 16,576 | 10,456 | 9,720 | 56,623 |
| Net loss | (19,665) | (15,280) | (8,177) | (7,916) | (51,038) |
| Net loss per share: | | | | | |
| Basic and diluted | $ (0.51) | $ (0.39) | $ (0.21) | $ (0.20) | $ (1.30) |
| Shares used in the calculation of net loss per share: | | | | | |
| Basic and diluted | 38,669 | 39,046 | 39,096 | 39,727 | 39,137 |

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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 Securities and Exchange Commission 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, 2009. Ernst & Young, LLP, our independent registered public accounting firm, has issued an attestation report on our internal control over financial reporting, 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**

**on Internal Control Over Financial Reporting**

The Board of Directors and Shareholders of

Neurocrine Biosciences, Inc.

We have audited Neurocrine Biosciences, Inc. s internal control over financial reporting as of December 31, 2009, 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 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, 2009, 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 as of December 31, 2009 and 2008, and the related consolidated statements of operations, stockholders equity and cash flows for each of the three years in the period ended December 31, 2009 of Neurocrine Biosciences, Inc. and our report dated February 5, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, CA

February 5, 2010

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**ITEM 9B.** ***OTHER INFORMATION***
None.

**PART III**

**ITEM 10.** ***DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE***
Information required by this item will be contained in our Definitive Proxy Statement for our 2010 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2009. Such information is incorporated herein by reference.

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

**ITEM 11.** ***EXECUTIVE COMPENSATION***
Information required by this item will be contained in our Definitive Proxy Statement for our 2010 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2009. 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 2010 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2009. 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 2010 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A, with the Securities and Exchange Commission within 120 days of December 31, 2009. 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 2010 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A, with the Securities and Exchange Commission within 120 days of December 31, 2009. Such information is incorporated herein by reference.

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**PART IV**

**ITEM 15.** ***EXHIBITS AND 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, 2009 and 2008

Consolidated Statements of Operations for the years ended December 31, 2009, 2008 and 2007

Consolidated Statements of Stockholders Equity for the years ended December 31, 2009, 2008 and 2007

Consolidated Statements of Cash Flows for the years ended December 31, 2009, 2008 and 2007

Notes to the Consolidated Financial Statements (includes unaudited Selected Quarterly Financial Data)
2. List of all Financial Statement schedules. All schedules are omitted because they are not applicable or the required information is shown in the Financial Statements or notes thereto.

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

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

**Exhibit**

| **Number** | **Description** |
|---|---|
| 3.1 | Certificate of Incorporation(1) |
| 3.2 | Certificate of Amendment to Certificate of Incorporation(15) |
| 3.3 | Bylaws(1) |
| 3.4 | Certificate of Amendment of Bylaws(8) |
| 3.5 | Certificate of Amendment to Bylaws(16) |
| 4.1 | Form of Common Stock Certificate(1) |
| 10.1** | 1992 Incentive Stock Plan, as amended(6) |
| 10.2** | 1996 Director Stock Option Plan, as amended, and form of stock option agreement(18) |
| 10.3* | Research and License Agreement dated October 15, 1996, between the Company and Eli Lilly and Company(2) |
| 10.4** | Form of incentive stock option agreement and nonstatutory stock option agreement for use in connection with 1992 Incentive Stock Plan(18) |
| 10.5* | Sub-License and Development Agreement dated June 30, 1998, by and between DOV Pharmaceutical, Inc. and the Company(3) |
| 10.6* | 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) |
| 10.7* | Collaboration and License Agreement between the Company and Glaxo Group Limited dated July 20, 2001(7) |

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|---|---|
| 10.8** | 2001 Stock Option Plan, as amended August 6, 2002 and October 15, 2002(9) |

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**Exhibit**

| Number | Description |
|---|---|
| 10.9** | Neurocrine Biosciences, Inc. Amended and Restated Nonqualified Deferred Compensation Plan(5) |
| 10.10** | Neurocrine Biosciences, Inc. 2003 Incentive Stock Plan, as amended and form of stock option agreement and restricted stock unit agreement(20) |
| 10.11** | Form of Indemnity Agreement entered into between the Company and its officers and directors(14) |
| 10.12 | Assignment and License Agreement dated February 26, 2004 by and among Wyeth Holdings Corporation and the Company(10) |
| 10.13 | Consent Agreement and Amendment dated February 25, 2004 by and among Wyeth Holdings Corporation, the Company and DOV Pharmaceutical, Inc.(10) |
| 10.14 | License Agreement dated February 25, 2004 by and among Wyeth Holdings Corporation and DOV Pharmaceutical, Inc.(10) |
| 10.15** | Employment Commencement Nonstatutory Stock Option Agreement between the Company and Christopher O Brien(13) |
| 10.16* | Amendment dated February 7, 2006 to Collaboration and License Agreement between the Registrant and Glaxo Group Limited(17) |
| 10.17* | License Agreement dated October 31, 2007 between the Company and Dainippon Sumitomo Pharma Co. Ltd.(19) |
| 10.18* | Amendment dated October 29, 2007 to Sub-License and Development Agreement dated June 30, 1998, by and between DOV Pharmaceutical, Inc. and the Company(19) |
| 10.19 | Lease dated December 4, 2007, between the Company and DMH Campus Investors, LLC(12) |
| 10.20 | Letter of Credit dated December 3, 2007, issued by Wells Fargo Bank, N.A. for the benefit of DMH Campus Investors, LLC(12) |
| 10.21** | Amended and Restated Employment Agreement effective August 1, 2007 between the Company and Gary A. Lyons(11) |
| 10.22** | Amended and Restated Employment Agreement effective August 1, 2007 between the Company and Kevin C. Gorman, Ph.D.(11) |
| 10.23** | Amended and Restated Employment Agreement effective August 1, 2007 between the Company and Margaret E. Valeur-Jensen, Ph.D.(11) |
| 10.24** | Amended and Restated Employment Agreement effective August 1, 2007 between the Company and Timothy P. Coughlin(11) |
| 10.25** | Amended and Restated Employment Agreement effective August 6, 2007 between the Company and Christopher F. O Brien M.D.(19) |
| 10.26** | Employment Agreement effective August 23, 2007 between the Company and Dimitri E. Grigoriadis, Ph.D.(19) |
| 10.27** | Amended and Restated Employment Agreement effective August 14, 2007 between the Company and Haig Bozigian, Ph.D.(19) |

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**Exhibit**

| Number | Description |
|---|---|
| 10.28* | First Amendment to Lease dated December 10, 2008 between the Company and DMH Campus Investors, LLC(21) |
| 10.29 | Second Amendment to Lease dated September 25, 2009 between the Company and DMH Campus Investors, LLC(22) |
| 10.30 | Common Stock Purchase Agreement dated September 15, 2009 between the Company and Kingsbridge Capital Limited(23) |
| 10.31 | Registration Rights Agreement dated September 15, 2009 between the Company and Kingsbridge Capital Limited(23) |
| 21.1 | Subsidiaries of the Company |
| 23.1 | Consent of Independent Registered Public Accounting Firm |
| 31.1 | Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934 |
| 31.2 | Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934 |
| 32*** | Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |

(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 Quarterly Report on Form 10-Q filed on November 2, 2007
(6) Incorporated by reference to the Company s Registration Statement on Form S-8 filed on July 16, 2001 (Commission File No. 333-65198)
(7) Incorporated by reference to the Company s Quarterly Report on Form 10-Q filed on August 14, 2001
(8) Incorporated by reference to the Company s Annual Report on Form 10-K filed on April 10, 1998
(9) Incorporated by reference to the Company s Annual Report on Form 10-K filed on March 4, 2003
(10) Incorporated by reference to the Company s Current Report on Form 8-K filed on March 17, 2004
(11) Incorporated by reference to the Company s Quarterly Report on Form 10-Q filed on August 3, 2007
(12) Incorporated by reference to the Company s Current Report on Form 8-K filed on December 10, 2007
(13) Incorporated by reference to the Company s Current Report on Form 8-K filed on November 1, 2005
(14) Incorporated by reference to the Company s Current Report on Form 8-K filed on September 1, 2009
(15) Incorporated by reference to the Company s Quarterly Report on Form 10-Q filed on August 9, 2006
(16) Incorporated by reference to the Company s Quarterly Report on Form 10-Q filed on August 9, 2004
(17) Incorporated by reference to the Company s Current Report on Form 8-K filed on February 13, 2006
(18) Incorporated by reference to the Company s Registration Statement on Form S-8 filed on June 26, 1998 (Commission File No. 333-57875)
(19) Incorporated by reference to the Company s Annual Report on Form 10-K filed on February 11, 2008
(20) Incorporated by reference to the Company s Quarterly Report on Form 10-Q filed on July 30, 2009
(21) Incorporated by reference to the Company s Annual Report on Form 10-K filed on February 4, 2009
(22) Incorporated by reference to the Company s Current Report on Form 8-K filed on October 1, 2009
(23) Incorporated by reference to the Company s Current Report on Form 8-K filed on September 15, 2009
* Confidential treatment has been granted with respect to certain portions of the exhibit.

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** Management contract or compensatory plan or arrangement.

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

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

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

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**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NEUROCRINE BIOSCIENCES, INC.

A Delaware Corporation

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

Date: February 5, 2010

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

| Signature | Title | Date |
|---|---|---|
| /s/ Kevin C. Gorman<br>Kevin C. Gorman | President, Chief Executive Officer and Director (Principal Executive Officer) | February 5, 2010 |
| /s/ Timothy P. Coughlin<br>Timothy P. Coughlin | Vice President and Chief Financial Officer (Principal Financial and Accounting Officer) | February 5, 2010 |
| /s/ Joseph A. Mollica<br>Joseph A. Mollica | Chairman of the Board of Directors | February 5, 2010 |
| /s/ Gary A. Lyons<br>Gary A. Lyons | Director | February 5, 2010 |
| /s/ Corinne H. Nevinny<br>Corinne H. Nevinny | Director | February 5, 2010 |
| /s/ W. Thomas Mitchell<br>W. Thomas Mitchell | Director | February 5, 2010 |
| /s/ Richard F. Pops<br>Richard F. Pops | Director | February 5, 2010 |
| /s/ Stephen A. Sherwin<br>Stephen A. Sherwin | Director | February 5, 2010 |

| | | |
|---|---|---|
| /s/ Wylie W. Vale | Director | February 5, 2010 |

Wylie W. Vale