CORCEPT THERAPEUTICS INC
Form 10-K
April 02, 2007
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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2006

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: 000-50679

CORCEPT THERAPEUTICS INCORPORATED

(Exact Name of Corporation as Specified in Its Charter)

Delaware	**77-0487658**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

149 Commonwealth Drive

Menlo Park, CA 94025

(Address of principal executive offices, including zip code)

(650) 327-3270

(Registrant s telephone number, including area code)

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 LLC

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 x

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 x

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

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

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

Large Accelerated Filer ¨ Accelerated Filer ¨ Non-accelerated filer x

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

The aggregate market value of voting and non-voting common equity held by non-affiliates of the Registrant was approximately $38,000,000 as of June 30, 2006 based upon the closing price on the Nasdaq Stock Market reported for such date. This calculation does not reflect a determination that certain persons are affiliates of the Registrant for any other purpose.

On March 30, 2007 there were 34,731,766 shares of common stock outstanding at a par value $.001 per share.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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Form 10-K

For the year ended December 31, 2006

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PART I

This Annual Report on Form 10-K, or Form 10-K, contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. All statements contained in this Form 10-K, other than statements of historical fact, are forward-looking statements. When used in this report or elsewhere by management from time to time, the words believe, anticipate, intend, plan, estimate, expect, and similar expressions are forward-looking statements. Such forward-statements are based on current expectations, but the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements made in this Form 10-K include, but are not limited to, statements about:

- *the progress of our research, development and clinical programs and timing of the introduction of CORLUX® and future product candidates;*
- *estimates of the dates by which we expect to report results of our clinical trials;*
- *our ability to market, commercialize and achieve market acceptance for CORLUX or other future product candidates;*
- *uncertainties associated with obtaining and enforcing patents;*
- *our estimates for future performance; and*
- *our estimates regarding our capital requirements and our needs for additional financing.*

Our current capital is not sufficient to fund operations beyond early 2008. We need additional capital in order to continue operations and capital may not be available to us at all or on favorable terms.

Forward-looking statements are not guarantees of future performance and involve risks and uncertainties. Actual events or results may differ materially from those discussed in the forward-looking statements as a result of various factors. For a more detailed discussion of such forward-looking statements and the potential risks and uncertainties that may impact upon their accuracy, see the Risk Factors section of this Form 10-K and the Overview and Liquidity and Capital Resources sections of the Management s Discussion and Analysis of Financial Condition and Results of Operations section of this Form 10-K. These forward-looking statements reflect our view only as of the date of this report. Except as required by law, we undertake no obligations to update any forward looking statements. Accordingly, you should also carefully consider the factors set forth in other reports or documents that we file from time to time with the Securities and Exchange Commission.

ITEM 1. BUSINESS

Overview

Corcept Therapeutics Incorporated is a pharmaceutical company headquartered in Menlo Park, California engaged in the development of drugs for the treatment of severe psychiatric and metabolic diseases. Our current focus is on the development of drugs for disorders that are associated with a steroid hormone called cortisol. Elevated levels and abnormal release patterns of cortisol have been implicated in a broad range of human disorders. Our scientific founders are responsible for many of the critical discoveries illustrating the link between psychiatric and metabolic disorders and aberrant cortisol.

Our lead product candidate, CORLUX, modulates the effect of cortisol by selectively blocking the binding of cortisol to one of its two known receptors, the GR-II receptor, also known as the Type II or GR receptor. We have been granted fast track status by the United States Food and Drug Administration, or FDA, and, in the last two and one half years ran three double-blind studies to test the efficacy of CORLUX for the treatment of the psychotic features of psychotic major depression, or PMD. These three clinical trials have been completed. The primary endpoint was not met in any of these trials but the results were sufficiently instructive to enable the company to design a Phase 3 trial that we believe will demonstrate the efficacy of CORLUX in this indication. We expect to initiate this trial later in 2007.

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In the first quarter of 2006, we initiated a proof-of-concept clinical study evaluating the ability of CORLUX to mitigate weight gain associated with the use of Zyprexa® (olanzapine), a commercially successful antipsychotic medication.

PMD is a serious psychiatric disorder that affects approximately three million people annually in the United States. It is more prevalent than either schizophrenia or bipolar I disorder. PMD is characterized by severe depression accompanied by psychosis (delusions and/or hallucinations). People with PMD are approximately 70 times more likely to commit suicide in their lifetime than the general population and often require lengthy and expensive hospital stays.

There is no FDA-approved treatment for PMD. However, there are two treatment approaches for PMD currently used by psychiatrists: electroconvulsive therapy, or ECT, commonly referred to as electroshock therapy, and combination drug therapy. ECT involves passing an electrical current through the brain until the patient has a seizure. Combination drug therapy involves the simultaneous use of antidepressant and antipsychotic medications. Both ECT and combination drug therapy almost always have slow onsets of action and debilitating side effects.

We have an exclusive license to the patent for the use of GR-II antagonists to treat the psychotic features of PMD. We also own or have exclusively licensed issued patents and patent applications relating to the treatment of several disorders that we believe also result from, or are negatively affected by, prolonged exposure to elevated cortisol. These include patents for the use of GR-II antagonists for the treatment of weight gain following treatment with antipsychotic medication, early dementia, such as early dementia associated with Alzheimer s disease, mild cognitive impairment, stress disorders and psychosis associated with cocaine addiction. We have also filed patent applications for additional diseases that may benefit from treatment with a drug that blocks the GR-II receptor.

Once we obtain FDA approval, we initially intend to market and sell CORLUX for PMD in the United States directly to hospitals with in-patient psychiatric units, first focusing on those that use ECT. We then intend to expand our sales efforts to address the larger group of PMD patients currently undergoing combination drug therapy. Given the concentrated nature of the initial target audience, we believe that we will be able to generate significant revenue with a relatively small, highly-focused medical education and commercialization team.

The Role of Cortisol in Disease

Cortisol is a steroid hormone that plays a significant role in the way the body reacts to stressful conditions and is essential for survival. Cortisol significantly influences metabolism, exerts a clinically useful anti-inflammatory effect and contributes to emotional stability. Insufficient levels of cortisol may lead to dehydration, hypotension, shock, fatigue, low resistance to infection, trauma, stress and hypoglycemia. Excessive levels of cortisol may lead to edema, hypertension, fatigue and impaired glucose tolerance.

Elevated levels and abnormal release patterns of cortisol have also been linked to a broad range of psychiatric and metabolic conditions, such as mood changes, psychosis and cognitive impairment. Cognition, including attention, concentration and memory, is impaired by elevated levels and abnormal release patterns of cortisol. Prolonged elevated levels of cortisol are neurotoxic and may accelerate the dementia process in patients with cognitive disorders such as Alzheimer s disease.

Many studies have shown that PMD patients have elevated levels and abnormal release patterns of cortisol. This abnormal cortisol pattern is not usually present in patients with nonpsychotic depression. More than 15 years ago, one of our scientific co-founders postulated that elevated levels of cortisol in PMD patients lead to elevated levels of dopamine, an important chemical substance found in the brain. Elevated levels of dopamine have been implicated in both delusional thinking and hallucinations. This was a clinically relevant hypothesis because it led to the concept that antipsychotic medications, which act by blocking dopamine, in combination

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with antidepressant medications, could be useful in treating PMD. The hypothesis also led to the concept that by regulating the level and release patterns of cortisol, one could normalize dopamine levels in the brain, which may, in turn, ameliorate the symptoms of PMD. In addition to cortisol s effect on dopamine levels, research has shown that prolonged elevated cortisol may also play a direct role in causing the symptoms of PMD.

The challenge in regulating levels of cortisol, however, is that it is needed for natural processes in the human body. Destroying the ability of the body to make cortisol or to drastically reduce its presence would result in serious detrimental effects. To have a viable therapeutic effect, a compound must be able to selectively modulate cortisol effects.

Glucocorticoid Receptor Antagonists

Cortisol is produced by the adrenal glands and is carried via the bloodstream to the brain, where it directly influences neuronal function. In the brain, cortisol binds to two receptors, Glucocorticoid Receptor I and Glucocorticoid Receptor II, also known as GR-I and GR-II. GR-I is a high-affinity receptor that is involved in the routine functions of cortisol. It has approximately ten times the affinity of GR-II for cortisol and its binding sites are filled with cortisol nearly all the time. In general, GR-II binding sites do not fill until levels of cortisol become elevated. Short-term activation of GR-II has benefits, which include helping the individual to be more alert and better able to function under stressful conditions. Long-term activation of GR-II, however, has been shown to have significant toxicity and appears to be linked to multiple psychiatric disease states, particularly PMD. The action of cortisol can be moderated by the use of blockers, or antagonists, that prevent the binding of the hormone to its receptors. These antagonists, referred to as glucocorticoid receptor antagonists, may prevent the undesirable effects of elevated levels and abnormal release patterns of cortisol.

The discovery that the brain has high affinity and low affinity receptors for cortisol was critical to our scientific approach in treating the psychosis manifested by PMD patients because it allowed for a specific target for a potential medication. CORLUX, also known as mifepristone or RU-486, works by selectively blocking the binding of cortisol to GR-II while not affecting GR-I. Because of its selective affinity, we believe that CORLUX can have a therapeutic benefit by modulating the effects of abnormal levels and release patterns of cortisol without compromising the necessary normal functions of cortisol.

Overview of Psychotic Major Depression

PMD is a serious psychiatric disease in which a patient suffers from severe depression accompanied by delusions, hallucinations or both. These psychotic features typically develop after the onset of a depressed mood, but may develop concurrently as well. Once psychotic symptoms occur, they usually reappear with each subsequent depressive episode. Of particular importance, when the patient s mood returns to normal the psychosis also resolves.

PMD is not a simple combination of psychosis and depression, but rather a complex interaction between a predisposition to become psychotic and a predisposition to become severely depressed. In addition to psychosis, clinical features and outcomes that distinguish psychotic from nonpsychotic depression include elevated levels and abnormal release patterns of cortisol, motor abnormalities, a substantially higher suicide rate, more prominent sleep abnormalities and more potential for brain injury.

Data from the National Institutes of Mental Health published in 2005 indicate that depressive disorders affect an estimated 9.5% of adults in the United States, or about 19 million people each year. Of these 19 million people, many published studies show that approximately 15-20%, or about three million people, have PMD. Most PMD patients suffer their first episode of major depression between the ages of 30 and 40 and the majority will experience more than one episode in their lifetime.

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We believe that people afflicted with PMD are, as a group, unrecognized and undertreated because of:

- reluctance on the part of patients with PMD to accurately report their psychotic symptoms;
- misdiagnosis of the disease by primary care physicians;
- reluctance of patients and their families to be associated with the stigma of hospitalization for psychiatric care; and
- adverse side effects associated with current treatments for PMD.

Current Treatments for PMD

There are two treatment approaches for PMD currently used by psychiatrists: ECT and combination drug therapy. Neither of these treatments has been approved by the FDA for PMD and both approaches almost always have slow onsets of action and debilitating side effects. Of the two treatments, ECT is generally considered to be more effective.

ECT involves passing an electrical current through the brain until the patient has a seizure. At least 100,000 patients receive ECT each year in the United States, with each patient requiring approximately six to twelve procedures over a period of three to five weeks. ECT is administered while the patient is under general anesthesia and the procedure requires the use of an operating room, as well as the participation of a psychiatrist, an anesthesiologist and a nurse. General anesthesia and paralytic agents are necessary to avoid fractures of the spine that otherwise could result from the seizures caused by ECT. Although ECT provides a reduction in depressive and psychotic symptoms, the procedure can result in cognitive impairment, including permanent memory loss, cardiovascular complications, headache, muscle ache and nausea, in addition to complications related to general anesthesia.

Combination drug therapy is an alternative treatment for PMD that involves taking antipsychotic drugs such as olanzapine, haloperidol or chlorpromazine in combination with antidepressant medication. Patients on combination drug therapy often require three weeks or more to show improvement in their symptoms and treatment can take months to complete. Antipsychotic drugs can cause significant adverse side effects, including weight gain, diabetes, sedation, permanent movement disorders and sexual dysfunction.

Because a therapeutic response to ECT and combination drug therapy does not occur for several weeks, neither approach prevents lengthy and expensive hospital stays in patients who are seriously ill. Consequently, a significant need exists for a medication that provides rapid relief from the psychotic symptoms of PMD, as such a medication would substantially reduce the length of suffering associated with the illness. We believe that people suffering from PMD would prefer a treatment that did not involve the risks of anesthesia and stigma associated with ECT or the adverse side effects and slow onset of action associated with both ECT and combination drug therapy. If an alternative treatment was approved by the FDA and had secured third-party reimbursement, we believe PMD patients would choose that alternative.

CORLUX for the Psychotic Features of PMD

CORLUX is an oral medication that we are developing to treat the psychotic features of PMD. CORLUX is a GR-II antagonist that appears to mitigate the effects of the elevated and abnormal release patterns of cortisol in PMD patients. We intend CORLUX to be a once-daily treatment given to PMD patients over 7 consecutive days in a controlled setting, such as a hospital or physician s office. Mifepristone, the active ingredient in CORLUX, in addition to blocking GR-II, blocks the progesterone receptor and has been approved by the FDA for termination of early pregnancy.

We believe that CORLUX may significantly reduce psychotic symptoms of PMD in many patients within one week and allow patients to be more easily maintained on antidepressant therapy alone without the need for ECT or antipsychotic medication. We believe that CORLUX may be superior to currently available treatments

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because we believe that CORLUX will enable PMD patients to improve their quality of life more quickly and with fewer side effects than with ECT or combination drug therapy.

CORLUX for PMD Clinical Trials

Psychiatric Rating Scales. In our clinical trials, we assess the efficacy of CORLUX utilizing psychiatric rating scales commonly used to support regulatory approval of new antipsychotic and antidepressant medications. These scales include the:

BPRS: The Brief Psychiatric Rating Scale is an 18-item instrument to assess psychopathology. It incorporates a range of psychiatric symptoms, including anxiety, depression, guilt, hostility and suicidality. Each of the 18 symptoms is scored on a numeric scale ranging from 1 (not present) to 7 (extremely severe).

BPRS Positive Symptom Subscale (BPRS PSS): This subscale, which is based on four items of the BPRS, assesses a patient s psychotic features by measuring the patient s conceptual disorganization, suspiciousness, hallucinatory behavior and unusual thought content.

HAM-D: This is an instrument designed to measure the severity of a number of depressive symptoms such as insomnia, depressed mood, concentration, ability to experience pleasure, and agitation. Each question has 3 to 5 possible responses, with associated scores ranging from 0 to 4. The total score is calculated from all items.

Clinical Trials. We initiated two Phase 3 trials in the United States in September 2004 (Corcept 07) and October 2004 (Corcept 06) and an additional Phase 3 trial in Europe in the second quarter of 2005 (Corcept 09) to evaluate the safety and efficacy of CORLUX. These three studies have been completed. The details of the results of these trials are discussed below. Prior to initiating these trials, we completed the following four clinical trials with CORLUX for the treatment of psychotic features of PMD:

In 2001, we completed our first trial, a dose finding clinical trial evaluating the efficacy, tolerability and dose response of CORLUX for the treatment of the psychotic features of PMD. After one week of treatment, approximately two-thirds of the patients in the two higher dosage groups experienced clinically meaningful reductions in psychosis, as measured by the BPRS. A clinically meaningful reduction in psychosis represents a reduction of symptoms that are readily recognizable by patients and physicians.

Later in 2001, we initiated two clinical trials designed to evaluate the safety and efficacy of CORLUX for the treatment of PMD. The two trials, which we call Study 02 and Study 03, were double-blind, placebo-controlled safety and efficacy studies.

Study 02, in which 208 patients were enrolled, showed that CORLUX was well tolerated and that there were no discernable problems with drug interactions between CORLUX and commonly prescribed antipsychotic and antidepressant medications.

Study 03, in which 221 patients were enrolled, demonstrated with statistical significance that patients in the CORLUX group were more likely to achieve a rapid and sustained reduction in psychotic symptoms than patients in the control group, as measured by a 30% reduction in the BPRS at 7 days sustained to 28 days (p value = 0.01) and a 50% reduction in the BPRS PSS at 7 days sustained to 28 days (p value = 0.01). The term p value is a statistical term that indicates the probability that an observed result is random. A p value of 0.05 or less is considered statistically significant. All p values for Study 03 are based on an observed cases, per protocol analysis, which takes into account only those patients who received at least 6 doses of study medication, had the BPRS assessed at day 0 and day 7 and had no major violations of the inclusion/exclusion criteria or other protocol specified criteria.

In our fourth trial, we evaluated the safety of retreatment in patients with a favorable response to treatment in Study 02 and Study 03, and our analysis indicates that patients tolerated their retreatment well.

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Dose Finding Study. In January 2001, we concluded our first study, which was an open-label study designed to measure clinically meaningful reductions in the psychiatric rating scales. The 33 patients with psychotic depression enrolled in the study were randomly assigned to receive daily doses of 50 mg, 600 mg, or 1200 mg of CORLUX orally for 7 days. There was no placebo control group. After 7 days of treatment, clinically meaningful reductions in the psychiatric rating scales were observed for patients in the 600 mg and 1200 mg treatment groups, as summarized below.

	50 mg Dose Group		600 mg Dose Group		1200 mg Dose Group		600 mg and 1200 mg Dose Groups Combined	
30% or greater reduction in BPRS	4/11	(36)%	7/10	(70)%	6/9	(67)%	13/19	(68)%
50% or greater reduction in positive symptom subscale of BPRS	3/11	(27)%	6/10	(60)%	6/9	(67)%	12/19	(63)%
50% or greater reduction in Ham-D scale	2/11	(18)%	5/10	(50)%	3/9	(33)%	8/19	(42)%

Results were similar in the 600 mg and 1200 mg dose groups, but there was an apparent dose-response relationship when the results of the 50 mg group were compared to the two higher dose groups. Sixty-eight percent of patients in the higher dose groups (600 mg and 1200 mg combined) had a clinically meaningful 30% or greater reduction in the BPRS, compared to 36% in the 50 mg group. The items in the BPRS that are most specific to PMD are contained in the BPRS positive symptom subscale. Every PMD patient experiences one or more of these subscale symptoms. More than 60% of patients in the higher dosage groups had a 50% or greater reduction in the BPRS positive symptom subscale within one week of treatment. Each of the reductions in the psychiatric rating scales that the study measured is a clinically meaningful reduction in symptoms that would be readily recognized by patients, family members, physicians and hospital staff. None of the patients in the trial experienced clinically consequential side effects and none dropped out of the trial due to side effects.

Double-blind Clinical Trials. In June and July 2001, we initiated two double-blind, randomized clinical trials, Study 02 and Study 03, each of which was designed to enroll 200 patients and to evaluate the safety and efficacy of CORLUX in patients with PMD. In each study, patients received either CORLUX or placebo. Both studies were designed and powered to test the hypothesis that the group of patients treated with CORLUX would be superior to the control group in achieving a rapid (within 7 days) and sustained (to 28 days) reduction in their BPRS score of at least 30%.

The two studies were identical in design except for one of the key entry criteria. Patients enrolled in Study 02 were allowed to receive any antipsychotic or antidepressant medications deemed appropriate by their treating physicians prior to entry into the study and throughout the week of administration of the study drugs, CORLUX or placebo. Therefore, in Study 02, patients received their usual treatment plus CORLUX or placebo. In Study 03, patients were not allowed to receive any antipsychotic or antidepressant medication for at least 7 days prior to administration of the study drug or during the week of study drug administration. All patients enrolled in the studies were treated in the hospital. After day 7, while the studies remained blinded, each treating physician was allowed to add any additional treatment, including ECT or antipsychotic, antidepressant or other psychotropic medications.

Study 02

The results of Study 02 indicated that CORLUX was well tolerated and that there were no discernable problems with drug interactions when CORLUX was taken in combination with other antipsychotic or antidepressant medications. The median number of psychotropic medications that patients in Study 02 were receiving in addition to CORLUX was four. Although patients in the usual treatment plus CORLUX group more frequently achieved the study s primary endpoint, a rapid and sustained reduction in psychotic symptoms as measured by a 30% decline in the BPRS at Day 7 sustained to Day 28, than did patients in the usual treatment plus placebo group**,** the difference between the groups was not statistically significant. The study did demonstrate with statistical significance (p value = 0.02) that the usual treatment plus placebo group required ECT or more

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antipsychotic medication between Day 7 and Day 28 and was less likely to be discharged from the hospital during the week of dosing (p value = 0.05) relative to the usual treatment plus CORLUX group. Post-hoc analysis of Study 02 data further revealed that patients in the usual treatment plus CORLUX group were more likely than patients in the usual treatment plus placebo group to achieve a rapid and sustained asymptomatic condition, as measured by a BPRS score of 25 or less. Although the number of patients achieving this result was small, the difference between the usual treatment plus CORLUX group and the usual treatment plus placebo group was statistically significant (p value = 0.01). All p values for Study 02 are based on an intent-to-treat analysis, which takes into account patients in the trial who received at least one dose of study medication.

Study 03

The results of Study 03 indicated that CORLUX was well tolerated as demonstrated by the finding that there was no statistically significant difference in adverse events observed between the CORLUX group and the placebo group. Study 03 also demonstrated with statistical significance (p value = 0.01) that patients who received CORLUX were more likely than patients who received placebo to achieve a rapid and sustained reduction in psychosis as measured by the study s original primary endpoint, a 30% reduction in the BPRS at Day 7 sustained to Day 28. Study 03 also showed with statistical significance (p value = 0.01) that patients in the CORLUX group were more likely than patients in the placebo group to achieve a 50% reduction in the BPRS PSS at Day 7 sustained to Day 28. In addition, patients in the placebo group were more likely than patients in the CORLUX group to receive antipsychotic medication between Day 7 and Day 28, although this difference was not statistically significant. All p values for Study 03 are based on an observed cases, per protocol analysis, which takes into account only those patients who received at least 6 doses of study medication, had the BPRS assessed at Day 0 and Day 7 and had no major violations of the inclusion/exclusion criteria or other protocol specified criteria.

At the request of the FDA, we followed the last third of patients enrolled in this trial to Day 56. Of those patients who exhibited at least mild psychotic symptoms on Day 0 (score ≥ 12 on the BPRS PSS), Study 03 showed with statistical significance that patients receiving CORLUX were more likely than patients receiving placebo to achieve a 50% reduction in the BPRS PSS at Day 7 sustained to day 56 (p value = 0.03).

We indicated to the FDA shortly before the study concluded that we would use as our primary endpoint for the study the number of patients who became asymptomatic at the end of one week as measured by the BPRS, a differentiating characteristic that we had noted in post-hoc Study 02 analysis. In Study 03, as in Study 02, only a small number of patients became asymptomatic at the end of one week and, in Study 03, there was no statistically significant difference between the CORLUX and placebo groups.

Of the approximately 480 patients who were enrolled in these completed Phase 2 studies, over 240 individuals were treated with CORLUX. The drug seemed to be well tolerated by these patients, with a low incidence of adverse events. In Studies 02 and 03, the most commonly reported adverse events were headache, dizziness, nausea and sedation. The incidence of these adverse events was similar in the control and CORLUX groups. In Study 02, rash was the only adverse event where there was a statistically significant difference (p value = 0.05) between groups: 4% occurrence in the CORLUX group compared to no occurrences in the control group. In Study 03, there was no statistically significant difference in the occurrence of any adverse event.

We have also conducted a small open label study to evaluate the safety of retreatment in patients who had a favorable response to treatment in Study 02 and Study 03. Twenty-eight patients completed the study. Our analysis indicates that patients tolerated their retreatment well.

Phase 3 Clinical Trials. We have completed three randomized, double-blind, placebo-controlled Phase 3 clinical trials to further assess the safety and efficacy of CORLUX for the treatment of the psychotic features of PMD. Two of these trials (Study 06 and Study 07) were conducted primarily in the United States. The third trial

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(Study 09) was conducted in Europe. The design of all three trials was based on the design of Study 03, described above.

Study 06 and Study 07 were covered by Special Protocol Assessments, or SPAs, from the FDA. The SPA is a process that provides for an official FDA evaluation of Phase 3 clinical study protocols. The SPA provides trial sponsors with binding written agreement that the design and analysis of the studies are adequate to support a license application submission if the study is performed according to the SPA and the results are successful. The SPA agreement may only be changed by the sponsor company or the FDA by a written agreement, or if the FDA becomes aware of a substantial scientific issue essential to product efficacy or safety.

The primary endpoint for each of Study 06 and Study 07 was the proportion of patients with at least a 50% improvement in the BPRS PSS at both Day 7 and Day 56. Both of these endpoints are known as categorical improvements. Patients must have had at least mild psychotic symptoms (BPRS PSS $\geq$ 12) to enter the studies and were hospitalized if clinically necessary. BPRS PSS assessments were also be made at Days 14, 28 and 42. The primary endpoint for Study 09 was the proportion of patients with at least a 50% improvement in the BPRS PSS at both Day 7 and Day 28. A secondary endpoint of Study 09 was the same as the primary endpoint for Study 06 and Study 07.

Study 07

The first of these trials, Study 07, which began in September 2004, enrolled 257 patients at 25 sites in the United States and Europe with a randomized one-to-one distribution into either a treatment or a placebo arm. Patients in the treatment arm received 600 mg of CORLUX once daily for a period of seven days. Patients did not take any antidepressant or antipsychotic medication for at least one week before beginning the seven day treatment period. After the seven days of CORLUX treatment, all patients received antidepressant therapy through Day 56. Treatment with antipsychotic medications or electroconvulsive therapy was not allowed at any time during the study.

In August 2006 we announced the results of Study 07. In this study 30.5% of the patients receiving CORLUX and 28.6% of the patients receiving placebo met the primary endpoint. This was not a statistically significant difference in response rate. The two key secondary endpoints of Study 07 also failed to achieve statistical significance. There was an unusually high placebo response rate in this trial. At Day 56, for example, approximately 80% of the patients in both of the arms of the study were responders as measured by a 50% improvement in BPRS PSS score.

Even though Study 07 did not meet its primary endpoint, an analysis of the data from this clinical trial revealed some items of interest that helped us to determine the direction for the continued development of CORLUX for treating PMD. We do not expect to be able to use Study 07 as one of the two positive efficacy trials required by the FDA for a fileable New Drug Application, or NDA.

An item of interest in Study 07 was a statistically significant site by treatment effect. A site by treatment analysis is conducted for all clinical trials to know if the results seen at one site are generalizable to patients seen at another site. A statistically significant site by treatment effect indicates that the effect of treatment with a drug is not uniform at the various clinical sites participating in the clinical trial. One site may have a large difference in the response rate favoring the drug group and another site may have a large difference in the response rate favoring the comparator group. When a site by treatment interaction is statistically significant, it is not possible to know which sites represent the true activity of the drug.

Another interesting observation from Study 07 was that patient enrollment did not have an even pace. 150 patients were enrolled in the first 480 days of the study (September 2004 through December 2005) and 107 patients in the last 120 days. An analysis of the results of the first 150 patients revealed a statistically significant difference on the primary endpoint favoring patients who took CORLUX compared to those who did not. Most of the clinical sites enrolling patients during this time had participated in the conduct of Study 02 and Study 03.

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The sites that had enrolled the first 150 patients continued enrolling patients until the trial was fully enrolled at the end of April 2006. By the end of the study this group of sites had enrolled a total of 215 patients, approximately the same total number of patients enrolled in Study 03. The primary endpoint was also met with statistical significance with these 215 patients. After January 1, 2006, in order to increase the speed of enrollment we added eight additional sites. These sites had not participated previously in clinical trials sponsored by Corcept. The eight sites that joined the trial in 2006 enrolled a total of 42 patients. In this group of 42 patients, those who took placebo had a substantially higher response rate on the primary endpoint than those who took CORLUX. The disparate outcome between the group of 215 patients and the group of 42 patients resulted in a statistically significant site by treatment effect. We do not know, however, whether the populations represented by the group of 215 or the group of 42 more accurately demonstrate the activity of CORLUX. We continue to analyze the data from this trial to determine reasons for this site by treatment effect.

An important teaching from Study 07 derives from a post hoc analysis of the relationship between the concentration of CORLUX in patients blood on Day 7 and the likelihood that patients meet the response criteria of the primary endpoint. A post hoc analysis examines the data for relationships not designated before the study began. Patients with CORLUX plasma levels higher than 1650 nanograms per milliliter had statistically significantly greater response rates observed than did patients who received placebo. The response rate on the primary endpoint in patients with plasma concentrations of CORLUX of less than 1650 nanograms per milliliter did not statistically separate from the response rates observed in patients who received placebo.

Study 09

Study 09 was a randomized, double-blind, placebo-controlled study in which 247 patients were enrolled at 17 sites. The primary endpoint, a responder analysis, was the proportion of patients with at least a 50% improvement in the BPRS PSS score at both Day 7 and Day 28. We announced the results of this study in September 2006. The study revealed no meaningful separation in response between patients receiving CORLUX and patients receiving placebo on the primary endpoint. The two key secondary endpoints of Study 09 also failed to achieve statistical significance. Study 07 had an extremely high placebo response rate; the magnitude of the placebo response rate in Study 09 was unprecedented. At Day 56, for example, approximately 95% of the patients in both of the arms of the study were responders as measured by a 50% improvement in BPRS PSS score. Although not the primary or a key secondary endpoint, it is interesting to note that there was a statistically significant separation between the CORLUX group and the comparator group on their change from baseline to Day 56 on the BPRS PSS scale. Change from baseline to study end is an endpoint commonly used to measure the efficacy of antipsychotic and antidepressant medications. However, because of the already high degree of response in the comparator group, it is difficult to determine how much additional clinical utility is conferred by this finding. We do not expect to be able to use Study 09 as one of the two positive efficacy trials required by the FDA for a fileable NDA.

Study 06

Study 06, which began in October 2004, enrolled 443 patients at 45 sites in the United States and Europe. These patients were evenly distributed among three active dose groups (300 mg, 600 mg and 1200 mg) and a placebo group, with patients receiving once daily dosing for a period of seven days. The three dosing levels respond to the FDA s request to supplement data on a range of doses to augment the data provided by our open label dose ranging study completed in 2001. Patients in the study did not take any antidepressant and antipsychotic medication for at least one week before the seven day treatment period and received antidepressant therapy starting on Day 1 through Day 56. As with Study 07, treatment with antipsychotic medications or electroconvulsive therapy was not allowed at any time during this study.

We reported the initial results of this trial in March 2007. These results indicated that this study did not achieve statistical significance with respect to the primary endpoint. However, there was a statistically significant correlation between plasma levels and clinical outcome achieved during treatment. Patients whose plasma levels

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rose above a predetermined threshold statistically separated from both those patients whose plasma levels were below the threshold and those patients who received placebo. In particular, those patients in Study 06 who achieved a predetermined level of 1661 nanograms of CORLUX per milliliter of plasma separated from the placebo group with statistical significance. At substantially lower plasma levels, there was no distinguishable difference in response rates between patients who received CORLUX and those receiving placebo. This study confirms our previous similar finding in Study 07 that at higher plasma levels the drug candidate is able to demonstrate desired clinical effects. Further, the incidence of serious adverse events did not differ between placebo and any of the three CORLUX dose groups.

Upcoming Phase 3 trial. We believe that the confirmation of a drug concentration threshold for efficacy, as well as other observations from Study 06 and the company s two other recently completed Phase 3 clinical trials, will serve as a strong basis for the company s next Phase 3 study which is planned to commence later in 2007. The protocol for this trial will incorporate the learnings from the three completed trials that address the sensitivity of the model and decrease the random variability observed in the results of the psychometric instruments used to measure efficacy. We intend to meet with the FDA to discuss and seek input concerning the design of this trial. In this trial we expect to use a dose level of 1200 mg once per day for seven days because, as expected, at successively higher dosages, more patients achieved the predetermined plasma threshold concentration. In Study 06, 80% of the patients achieved a drug plasma level sufficient for a strong clinical response at that dose. In our initial review of a summary of the safety data, we have seen no difference between any of the dose levels used in Study 06. We believe that this change in dose as well as other modifications to the protocol should allow us to definitively demonstrate the efficacy of CORLUX in the treatment of the psychotic symptoms of PMD.

Given the serious nature of PMD, the lack of any approved drugs for the disorder and the data from our first clinical trial, the FDA has granted a fast track designation for CORLUX for the treatment of the psychotic features of PMD. In addition, the FDA has indicated that CORLUX will receive a priority review if no other treatment is approved for PMD at the time we submit our New Drug Application, or NDA.

Additional Non-Efficacy Trials and Pre-clinical Studies. In support of an eventual NDA submission, we plan to conduct additional clinical trials to assess the safety of retreatment of patients with CORLUX. We also plan to conduct several small trials to evaluate how the drug acts on the human body, how the human body acts on the drug and the drug s safety. In addition to our clinical trials, we have completed a standard 12-month toxicology study in the dog and a carcinogenicity study in the rat. A second carcinogenicity study in the mouse is underway. These studies are designed to meet FDA requirements and the guidelines of an international regulatory body called the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

*Clinical Trial Agreement*s. We have clinical development agreements covering the conduct of our Phase 3 clinical trials of CORLUX with Premier Research (formerly Scirex Corporation) (Premier), PPD Development, LP (PPD), and i3 Research, an Ingenix Company (i3), under which these organizations, at our request, oversee clinical trials at various institutions to test the safety and efficacy of CORLUX for the psychotic features of PMD. The Premier and PPD agreements may be terminated by us at any time upon thirty days written notice. The i3 agreement may be terminated by us at any time upon 45 days written notice.

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GR-II Antagonist Platform

We have assembled a patent portfolio covering the treatment of psychiatric and metabolic disorders that may benefit from drugs that block the GR-II receptor. In addition to PMD, we own or have exclusively licensed issued patents for the use of GR-II antagonists to treat:

- weight gain following treatment with antipsychotic medication;
- early dementia, including early Alzheimer s disease;
- mild cognitive impairment;
- the prevention and treatment of stress disorders; and
- psychosis associated with cocaine addiction.

We believe that cortisol plays a role in a variety of other diseases. We have ten pending U.S. method of use patent applications covering GR-II antagonists for the treatment of various diseases.

Clinical trials in other psychiatric and metabolic disorders.

Alzheimer s disease. We announced in September 2005 that we closed enrollment in a clinical proof-of-concept study evaluating the safety and efficacy of 4 months of CORLUX treatment to improve cognition in patients with mild to moderate Alzheimer s disease. Patients in this trial were dosed with an acetylcholinesterase inhibitor, medications that are routinely prescribed for patients with Alzheimer s disease, and CORLUX or placebo. The study protocol prohibited the concomitant use of Namenda (memantine), a recently approved treatment for Alzheimer s disease which was commercialized after the trial was initiated. Because a large number of Alzheimer s disease patients are now treated with the combination of Namenda and an acetylcholinesterase inhibitor, enrollment in our study slowed significantly. The study had enrolled 80 patients when enrollment was closed. It was originally designed to enroll 160 patients. The study was not powered to show statistically significant results with only 80 patients. Analysis of the data demonstrated that no discernable change in cognition occurred in the CORLUX treated patients. Review of the safety data from the trial revealed no serious safety findings. A post-hoc analysis identified weight reduction in obese patients as a possible effect of CORLUX treatment.

Mitigation of antipsychotic medication induced weight gain. In October 2005, we announced that we signed an agreement with Eli Lilly and Company (Lilly) in which Lilly agreed to support our proof-of-concept clinical study evaluating the ability of CORLUX to mitigate weight gain associated with the use of Zyprexa, one of six commercially available medications of the class of drugs known as atypical antipsychotics. The labels of all of the drugs in this class contain a warning for hyperglycemia and diabetes mellitus, both associated with weight gain. This study is being conducted in healthy male volunteers of normal weight.

Under the agreement, Lilly will supply Zyprexa and pay for the study. Data resulting from the study will be shared with Lilly. Neither we nor Lilly intend to pursue commercially the use of CORLUX and olanzapine in combination for the treatment of antipsychotic medication-induced weight gain. The purpose of this study is to explore the mechanism of action of GR-II antagonists for mitigating weight gain associated with atypical antipsychotic medications. Although initially placed in a small clinical research organization in the U.S., we stopped the study there, made minor modifications to the protocol and initiated the study at a site in Bangalore, India, in part to enhance the availability of male subjects of normal weight and have made minor changes in the protocol. We began screening patients in March 2007 and expect to report the results of this study at the end of the second quarter of 2007.

In May 2005, we announced results from two preclinical studies conducted in a rat model of olanzapine-induced weight gain. These studies demonstrated that CORLUX s GR-II antagonist action has the potential to both reduce the weight gain associated with olanzapine and to prevent the weight gain associated with the initiation of treatment with olanzapine.

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Discovery Research

In early 2002, we initiated a discovery research program to identify and patent more selective GR-II antagonists in order to develop a pipeline of products for proprietary use. Our discovery chemistry was conducted at a contract research organization in the United Kingdom. Through the research program, we identified and filed patent applications for three series of GR-II antagonists that, like CORLUX, block the GR-II receptor but, unlike CORLUX, do not block the progesterone receptor. These compounds bind to the GR-II receptor with a potency similar to that of CORLUX. We have concluded the contract with the U.K.-based contract research organization and are currently evaluating which compound or compounds we intend to move toward an Investigational New Drug application (IND). We hope to initiate human clinical trials under an exploratory IND with the selected compound or compounds late in 2007.

Medical Education and Commercialization

We intend to develop our own medical education and commercialization infrastructure in the United States for CORLUX because we believe that the initial market for PMD in the United States is highly concentrated and accessible. We anticipate that this will include hiring a small, experienced field force of up to approximately 35 people. We intend to focus initially on patients who are candidates for ECT by marketing to hospitals and psychiatrists that perform ECT. We estimate that there are approximately 900 hospitals with more than 30 in-patient psychiatric beds. Of these, we estimate that approximately 300 offer ECT. We believe that approximately 1000 psychiatrists administer a majority of ECT procedures. Subsequently, we also intend to expand our commercialization efforts to address the larger set of PMD patients currently undergoing combination drug therapy, which would require an increase in the size of our initial sales force.

We believe that a significant opportunity exists to further expand the market for the treatment of the psychotic features of PMD beyond patients currently treated by ECT and combination drug therapy. A large portion of the people who suffer from PMD remain unrecognized and undertreated. We intend to develop medical educational programs to alert the medical community about early diagnosis of PMD and increase awareness regarding CORLUX.

We are planning for the commercialization of CORLUX. To achieve commercial success for any approved product, we must either develop a sales and marketing force or enter into arrangements with others to market and sell our products.

Manufacturing

As a drug development entity, we intend to continue to utilize our financial resources to complete the development of CORLUX and advance other product candidates rather than diverting resources to establishing our own manufacturing facilities.

We intend to continue to rely on experienced contract manufacturers to produce our product candidates. We have entered into manufacturing agreements with two contract manufacturers, Produits Chimiques Auxiliaires et de Synthese SA (PCAS) and ScinoPharm Taiwan (ScinoPharm), to produce the active pharmaceutical ingredient, or API, for CORLUX. The agreement with PCAS is for an initial period of five years with an automatic extension for one additional year unless either party gives twelve month s prior notice that it does not want the extension. There is no guaranteed minimum purchase commitment under this agreement. If PCAS is unable to manufacture the product for a consecutive six-month period, we have the right to terminate the agreement. The agreement with ScinoPharm obligates us to purchase at least $1,000,000 of bulk mifepristone per year following the commercial launch of CORLUX. This agreement is terminable by either party at any time. We have also entered into an agreement with another contract manufacturer, PharmaForm,L.L.C., for the production of CORLUX tablets for use in clinical activities In the event we are unable, for whatever reason, to obtain mifepristone or CORLUX from our contract manufacturers, we may not be able to identify alternate manufacturers able to meet our needs on commercially reasonable terms and in a timely manner, or at all. To date, our need for CORLUX tablets has been limited to the amounts required to support our clinical trials.

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Competition

If approved for commercial use as a treatment for the psychotic features of PMD, CORLUX will compete with established treatments, including ECT and combination drug therapy.

ECT has been shown to be the most effective treatment for PMD, despite the risks of anesthesia and the adverse effects and stigma associated with the procedure. Use of CORLUX does not require anesthesia and, in our clinical trials conducted to date, patients treated with CORLUX have not exhibited the adverse effects associated with ECT.

Other competitors will be companies that market antipsychotic drugs that are used off-label as part of combination drug therapy for PMD. To reduce the psychotic features of PMD, these drugs generally are taken in combination with antidepressant medication over a period of weeks to several months. Unlike the use of CORLUX, this extended course of treatment may put patients at risk of significant adverse side effects, including weight gain, diabetes, sedation, permanent movement disorders and sexual dysfunction. Antipsychotics include Bristol-Myers Squibb s Abilify, Novartis Clozaril, Pfizer s Geodon and Navane, Ortho-McNeil s Haldol, Janssen Pharmaceutica s Risperdal, AstraZeneca s Seroquel, GlaxoSmithKline s Stelazine and Thorazine, Mylan s thioridazine, Schering Corporation s Trilafon and Eli Lilly s Zyprexa.

We are aware of one clinical trial, conducted by the pharmaceutical division of Akzo Nobel, for a new chemical entity for the treatment of PMD. This new medicine is a GR-II antagonist, the commercial use of which would be covered by our patent. In 2004, Akzo Nobel filed an observation in our exclusively licensed European patent application with claims directed to PMD, in which Akzo Nobel challenged the claims of that patent application. In 2005, we filed a rebuttal to Akzo Nobel s observation. In February 2006, the European Patent Office, or EPO, allowed our patent application. We are not aware of any public disclosures by any company, other than Akzo Nobel, regarding the development of new medicinal products to treat PMD. However, other companies may be developing new drug products to treat PMD and the other conditions we are exploring. Our present and potential competitors include major pharmaceutical companies, as well as specialized pharmaceutical firms. Most of our competitors have considerably greater financial, technical and marketing resources than we do. We expect competition to intensify as technical advances are made.

Many colleges, universities and public and private research organizations are also active in the human health care field. While these entities focus on education, they may develop or acquire proprietary technology that we may require for the development of our product candidates. We may attempt to obtain licenses to this proprietary technology.

Our ability to compete successfully will be based on our ability to develop proprietary products, attract and retain scientific personnel, obtain patent or other protection for our product candidates, obtain required regulatory approvals and manufacture and successfully market our future products either alone or through outside parties.

Intellectual Property

Patents and other proprietary rights are important to our business. It is our policy to seek patent protection for our inventions, and to rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position.

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Under an agreement with Stanford University, we have licensed exclusive rights to the following issued U.S. patents and any corresponding foreign patents:

U.S. Patent Number	Subject Matter	Expiration Date
U.S. Pat. No. 6,150,349	Use of GR-II antagonists in the treatment of PMD	October 5, 2018
U.S. Pat. No. 6,362,173	Use of GR-II antagonists in the treatment of cocaine-induced psychosis	October 5, 2018
U.S. Pat. No. 6,369,046	Use of GR-II antagonists in the treatment of early dementia, including early Alzheimer s disease	February 4, 2019

We are required to make milestone payments and pay royalties to Stanford University on sales of products commercialized under any of the above patents. We are currently in compliance with our obligations under the agreement. If Stanford University were to terminate our CORLUX license or other exclusive licenses due to breach of the license on our part, we would not be able to commercialize CORLUX for the treatment of the psychotic features of PMD or develop mifepristone as a treatment for early dementia, including early Alzheimer s disease.

We also own issued U.S. patents for the use of GR-II antagonists in the treatment of mild cognitive impairment, for the treatment of weight gain following treatment with antipsychotic medication, for the prevention and treatment of stress disorders and for the treatment of delirium. In addition, we have three U.S. composition of matter patent applications covering specific GR-II antagonists and nine U.S. method of use patent applications covering certain GR-II antagonists for increasing the therapeutic response to ECT, preventing neurological damage in premature infants and for the treatment of:

migraine;

postpartum psychosis;

antidepressant induced weight gain;

catatonia;

psychosis associated with interferon-alpha therapy;

gastroesophageal reflux disease; and

Down s syndrome.

We are also considering, where appropriate, the filing of foreign patent applications corresponding to our U.S. patent applications.

However, we cannot assure you that any of our patent applications will result in the issuance of patents, that any issued patent will include claims of the breadth sought in these applications or that competitors will not successfully challenge or circumvent our patents if they are issued.

Although three of our patent applications have claims directed to the composition of compounds that are necessary to make our potential products, none of our issued patents have such claims. Specifically, we do not have a patent with claims directed to the composition of mifepristone. Our rights under our issued patents cover only the use of GR-II antagonists, including mifepristone, in the treatment of specific diseases.

The patent covering the product mifepristone has expired. The only FDA-approved use of mifepristone is to terminate pregnancy. The FDA has imposed significant restrictions on administering physicians for use of mifepristone to terminate pregnancy and may impose similar restrictions on CORLUX for the treatment of the

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psychotic features of PMD. We plan to rely on (1) the scope of our use patent, (2) the restrictions imposed by the FDA on the use of mifepristone to terminate pregnancy, (3) the different patient populations, administering physicians and treatment settings between the use of mifepristone to terminate pregnancy and to treat PMD and (4) the likely denial of reimbursement for off-label uses of mifepristone to provide us an exclusive market position for the term of our use patent for the treatment of the psychotic features of PMD.

The patent positions of companies in the pharmaceutical industry are highly uncertain, involve complex legal and factual questions and have been and continue to be the subject of much litigation. Our product candidates may give rise to claims that we infringe on the products or proprietary rights of others. If it is determined that our drug candidates infringe on others patent rights, we may be required to obtain licenses to those rights. If we fail to obtain licenses when necessary, we may experience delays in commercializing our product candidates while attempting to design around other patents, or determine that we are unable to commercialize our product candidates at all. If we do become involved in intellectual property litigation, we are likely to incur considerable costs in defending or prosecuting the litigation. We believe that we do not currently infringe any third party s patents or other proprietary rights, and we are not obligated to pay royalties to any third party other than Stanford University.

In November 2003, McLean Hospital had alleged that it also had rights to the technology that led to the patent for the use of GR-II antagonists to treat the psychotic features of PMD. McLean Hospital was a prior employer of one of our founders, Dr. Alan Schatzberg and it alleged that the invention of the technology underlying this patent was conceived by Dr. Schatzberg and/or Dr. Anthony Rothschild while the two were employed by McLean Hospital. We contended that the invention was actually conceived by Dr. Schatzberg and Dr. Joseph Belanoff while they were employed by Stanford University and that the patent was appropriately assigned by them to Stanford University. In October 2004, we announced a resolution of this issue in which we retained our exclusive rights under the patent and which required us to make no additional payments under the license, regardless of the resolution of the impending inventorship dispute. In January 2005, the inventorship issue was resolved in favor of Stanford University.

As discussed above under Competition, in 2004 Akzo Nobel filed an observation to the grant of our exclusively licensed European patent application with claims directed to PMD. In February 2006, the EPO allowed our patent application. We are not aware of any other disputes related to patent issues.

License Agreement

Under our exclusive license agreement with Stanford University to patents covering the use of CORLUX to treat the psychotic features of PMD and for the treatment of early dementia, we are required to pay Stanford $50,000 annually as a nonrefundable royalty payment. This payment is creditable against future royalties. We are also obligated to pay Stanford a $50,000 milestone upon the filing of the NDA for CORLUX for the treatment of PMD and a further $200,000 milestone payment upon FDA approval of CORLUX. The milestone payments are also creditable against future royalties. This license agreement expires upon expiration of the related patents or upon notification by us to Stanford.

Government Regulation

Prescription pharmaceutical products are subject to extensive pre- and post-market regulation, including regulations that govern the testing, manufacturing, safety, efficacy, labeling, storage, record keeping, advertising, and promotion of the products under the Federal Food, Drug and Cosmetic Act. All of our product candidates will require regulatory approval by government agencies prior to commercialization. The process required by the FDA before a new drug may be marketed in the United States generally involves the following: completion of preclinical laboratory and animal testing; submission of an investigational new drug application, or IND, which must become effective before clinical trials may begin; performance of adequate and well controlled human clinical trials to establish the safety and efficacy of the proposed drug or biologic s intended use; and, in the case

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of a new drug, approval by the FDA of an NDA. The process of complying with these and other federal and state statutes and regulations in order to obtain the necessary approvals and subsequently complying with federal and state statutes and regulations involves significant time and expense.

Preclinical studies are generally conducted in laboratory animals to evaluate the potential safety and the efficacy of a product. Drug developers submit the results of preclinical studies to the FDA as a part of an IND, which must be approved before beginning clinical trials in humans. Typically, human clinical trials are conducted in three sequential phases that may overlap.

Phase 1. Clinical trials are conducted with a small number of subjects to determine the early safety profile, maximum tolerated dose and pharmacokinetics of the product candidate in human volunteers.

Phase 2. Clinical trials are conducted with groups of patients afflicted with a specific disease to determine preliminary efficacy, optimal dosages and expanded evidence of safety.

Phase 3. Large-scale, multi-center, comparative trials are conducted with patients afflicted with a target disease to establish the overall risk/benefit ratio of the drug and to provide enough data to demonstrate with substantial evidence the efficacy and safety of the product, as required by the FDA.

The FDA and the Institutional Review Boards closely monitor the progress of each of the three phases of clinical trials that are conducted in the United States and may reevaluate, alter, suspend or terminate the testing at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable health risk. The FDA may also require that additional studies be conducted, such as studies demonstrating that the drug being tested does not cause cancer.

After Phase 3 trials are completed, drug developers submit the results of preclinical studies, clinical trials, formulation studies and data supporting manufacturing to the FDA in the form of a new drug application for approval to commence commercial sales. The FDA reviews all NDAs submitted before it accepts them for filing. The FDA may request additional information rather than accept an NDA for filing. If the FDA accepts an NDA for filing, they may grant marketing approval, request additional information or deny the application if it determines that the application does not meet regulatory approval criteria. FDA approvals may not be granted on a timely basis, or at all.

If the FDA approves an NDA, the subject drug becomes available for physicians to prescribe in the United States. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-market regulatory standards is not maintained. The drug developer must submit periodic reports to the FDA. Adverse experiences with the product must be reported to the FDA and could result in the imposition of marketing restrictions through labeling changes or product removal. Product approvals may be withdrawn if problems with safety or efficacy occur after the product reaches the marketplace. In addition, the FDA may require post-marketing studies, referred to as Phase 4 studies, to monitor the effect of approved products, and may limit further marketing of the product based on the results of these post-market studies.

Facilities used to manufacture drugs are subject to periodic inspection by the FDA and other authorities where applicable, and must comply with current Good Manufacturing Practices regulations, or cGMP. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product or voluntary recall of a product.

With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among others, standards and regulations for direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving the Internet. The FDA has very broad enforcement authority under the Federal Food, Drug and Cosmetic Act, and failure to abide by these regulations can result in penalties including the issuance of a warning letter directing a company to correct deviations from FDA standards, a

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requirement that future advertising and promotional materials be pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions.

In addition to studies requested by the FDA after approval, a drug developer may conduct other trials and studies to explore use of the approved compound for treatment of new indications. The purpose of these trials and studies and related publications is to broaden the application and use of the drug and its acceptance in the medical community. Data supporting the use of a drug for these new indications must be submitted to the FDA in a new or supplemental NDA that must be approved by the FDA before the drug can be marketed for the new indications.

Approvals outside the United States. We have not started the regulatory approval process in any jurisdiction other than the United States and we are unable to estimate when, if ever, we will commence the regulatory approval process in any foreign jurisdiction. We will have to complete an approval process similar to the U.S. approval process in foreign target markets for our product candidates before we can commercialize our product candidates in those countries. The approval procedure and the time required for approval vary from country to country and can involve additional testing. Foreign approvals may not be granted on a timely basis, or at all. Regulatory approval of prices is required in most countries other than the United States. The prices approved may be too low to generate an acceptable return to us.

Fast Track Designation. The FDA sometimes grants fast track status under the Food and Drug Administration Modernization Act of 1997. The fast track mechanism was created to facilitate the development and approval of new drugs intended for the treatment of life-threatening conditions for which there are no effective treatments and which demonstrate the potential to address unmet medical needs for the condition. The fast track process includes scheduling of meetings to seek FDA input into development plans, the option of submitting an NDA serially in sections rather than submitting all components simultaneously, the option to request evaluation of studies using surrogate endpoints, and the potential for a priority review.

We have been granted fast track status for CORLUX for the treatment of the psychotic features of PMD. However, the fast track designation may be withdrawn by the FDA at any time. The fast track designation does not guarantee that we will qualify for or be able to take advantage of the expedited review procedures and does not increase the likelihood that CORLUX will receive regulatory approval.

Employees

We are managed by a core group of experienced pharmaceutical executives with a track record of bringing new drugs to market. To facilitate advancement of development programs, we also enlist the expertise of associates and advisors with extensive pharmaceutical development experience.

As of December 31, 2006, we had 11 full-time employees, three part-time employees and six long-term contract staff. Three of our full-time employees and one of our long-term contract staff are M.D.s. We consider our employee relations to be good. None of our employees is covered by a collective bargaining agreement.

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ITEM 1A RISK FACTORS

An investment in our common stock involves significant risks. In addition to other information in this report, you should carefully consider the risks described below and the other information in this Form 10-K, including our financial statements and related notes, before you decide to invest in our common stock. If any of the following risks actually occur, our business, prospects, financial condition and results of operations could be materially harmed, the trading price of our common stock could decline and you could lose all or part of your investment. The risks and uncertainties described below are those that we currently believe may materially affect us. Additional risks and uncertainties of which we are unaware or that we currently deem immaterial may also become important factors that affect us. Except as required by law, we undertake no obligations to update any risk factors.

Risks Related to Our Business

Our current capital is not sufficient to fund operations beyond early 2008. We need additional capital in order to continue operations and capital may not be available to us at all or on favorable terms.

We expect that our existing cash resources will not be sufficient to fund our operations beyond early 2008. Our cash and marketable securities have enabled us to complete the third of our three Phase 3 clinical studies evaluating our lead product candidate, CORLUX, for treating the psychotic features of PMD. However, we do not have sufficient funds to maintain our current infrastructure beyond the completion and reporting of results of the proof-of-concept weight-gain mitigation study and to prepare for our next Phase 3 trial. We will require substantial additional funding in the form of public or private equity offerings, debt financings, strategic partnerships and/or licensing arrangements in order to continue our operations.

Additional financing may not be available on acceptable terms or at all. We believe that our ability to secure substantial additional funding will depend largely on investors acceptance of our business plan going forward, which includes the completion of a fourth Phase 3 clinical trial in PMD, opportunities that may be created by the results of the proof-of-concept mitigation of atypical antipsychotic induced weight gain trial and the development of our new chemical entities.

If we are unable to raise additional funds, we may, among other things, be required to delay, reduce the scope of or eliminate one or more of our research or development programs or to obtain funds through collaborations with others that are on unfavorable terms or that may require us to relinquish certain rights to our technologies or products, including potentially our lead product candidate, that we would otherwise seek to develop on our own; or we may be required to discontinue operations.

Even if we are successful in raising funds in the near term, we will need to raise substantial additional funds to complete the development of and the potential commercialization of CORLUX for PMD and for other development programs. We may choose to raise additional capital at any time based on market conditions or strategic considerations even if we believe we have raised sufficient funds for our current or future operating plans. Additional financing may be dilutive to stockholders, may involve the relinquishment of valuable rights, and may involve restrictive covenants.

We will depend heavily on the success of our lead product candidate, CORLUX for the treatment of the psychotic features of PMD, which is still in development. Our first three Phase 3 trials did not meet their primary and key secondary endpoints. If we are unable to commercialize CORLUX, or experience significant delays in doing so, we may be unable to generate revenues and our stock price may decline.

We have invested a significant portion of our time and financial resources since our inception in the development of CORLUX. We currently do not have any commercial products and we anticipate that for the foreseeable future our ability to generate revenues and achieve profitability will be solely dependent on the

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successful development, approval and commercialization of CORLUX. We have completed three Phase 3 clinical trials evaluating CORLUX for the treatment of the psychotic features of PMD. None of the first three trials met its primary or key secondary endpoints. The FDA generally requires at least two positive Phase 3 studies prior to the submission of an NDA. Many factors could harm our efforts to develop and commercialize CORLUX, including:

- insufficient funding;
- negative, inconclusive or otherwise unfavorable results from our pre-clinical or clinical development programs;
- side effects that may be identified in the course of our clinical trials;
- changes or delays in our clinical development program;
- rapid technological change making CORLUX obsolete;
- competition from companies with greater financial, technical and marketing resources than ours;
- increases in the costs of our clinical trials;
- an inability to obtain, or delay in obtaining, regulatory approval for the commercialization of CORLUX for the treatment of the psychotic features of PMD;
- an inability to manufacture CORLUX or the active ingredient in CORLUX in commercial quantities and at an acceptable cost; and
- political concerns relating to other uses of mifepristone that could limit the market acceptance of CORLUX.

Our clinical trials may not demonstrate that CORLUX is safe and effective. If our clinical program for CORLUX for the treatment of the psychotic features of PMD does not demonstrate safety and efficacy, our business will be harmed.

To gain regulatory approval from the FDA to market CORLUX for the treatment of the psychotic features of PMD, our Phase 3 clinical trials must demonstrate the safety and efficacy of CORLUX for this treatment. Our first three Phase 3 studies did not meet their primary or key secondary endpoints. In addition to the need for additional Phase 3 clinical trials, we are conducting, or plan to conduct, other studies in support of a potential NDA. Clinical development is a long, expensive and uncertain process and is subject to delays, and data obtained from clinical trials and supportive studies are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Favorable results of preclinical studies and initial clinical trials of CORLUX are not necessarily indicative of the results we will obtain in later clinical trials. While we obtained favorable results in our Phase 2 clinical trials program, these results were not replicated in a robust enough way in Studies 07, 09 or 06 and are not sufficient to support an application for FDA approval. In addition, we cannot assure you that supportive studies and tests will produce favorable results.

The development plan for CORLUX is not certain, and may require additional, expensive clinical and preclinical trials. We may not be able to finance the development program.

During the development of CORLUX, we have been engaged in dialogue with the FDA to determine an acceptable development plan which would enable the FDA to complete its review in a satisfactory manner. Because the results of our recently completed Phase 3 trials did not meet their primary endpoints, the FDA will require us to pursue additional clinical trials to demonstrate the safety and/or efficacy of CORLUX. The FDA generally requires at least two positive Phase 3 studies prior to the submission of an NDA. In addition, the FDA may require us to pursue additional supportive studies. Recently, the FDA recommended that we conduct a dose proportionality study and other studies to determine whether there are interactions between CORLUX and some commonly used drugs. We are continuing our dialogue with the FDA to define any additional data needed to

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complete an NDA. Although our cash and marketable securities have enabled us to complete our ongoing Phase 3 trials, we will need to raise additional funds for our research and development and general and administrative activities in 2007 and subsequent years. We believe that our ability to secure substantial additional funding in the near term will depend largely on investors acceptance of our business plan going forward, which includes a Phase 3 clinical trial in PMD and the development of our new chemical entities. We cannot be certain that additional funding will be available on acceptable terms or at all. Our inability to raise capital will result in a delay of the performance of these activities and harm our business and product development efforts. Without additional funding we will not be able to continue the company s operations beyond early 2008.

Further, we may decide, or the FDA or other regulatory authorities may require us, to pursue additional clinical, pre-clinical or manufacturing studies to satisfactorily complete our NDA. Additional trials or studies will require additional funding which is not assured. Also, it is possible that additional trials or studies that we decide are necessary or desirable will delay or prevent the completion of the development of CORLUX for treating PMD.

If adequate funds are not available for our currently contemplated trials and studies, or for any further ones that we may decide are necessary or desirable, we may be required to delay, reduce the scope of or eliminate some or all of our research or development programs or to obtain funds through collaborations with others that are on unfavorable terms or that may require us to relinquish certain rights to our technologies or product candidates, potentially including our lead product candidate, that we would otherwise seek to develop on our own. Even if funds are available, additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants. Even after we conduct all of the clinical trials and supportive studies that we consider appropriate for an optimal NDA, we may not receive regulatory approval to market CORLUX.

Many other factors could delay or result in termination of our clinical trials, including, but not limited to:

- negative or inconclusive results;
- slow patient enrollment;
- patient noncompliance with the protocol;
- adverse medical events or side effects among patients during the clinical trials;
- FDA inspections of our clinical operations; and
- real or perceived lack of effectiveness or safety of CORLUX.

We have incurred losses since inception and anticipate that we will incur continued losses for the foreseeable future.

We are a development stage company with no current source of product revenue. We have a limited history of operations and have focused primarily on clinical trials, and if the outcome of our clinical trials supports it, we plan to seek FDA regulatory clearance to market CORLUX for the treatment of the psychotic features of PMD. Historically, we have funded our operations primarily from the sale of our equity securities. We have incurred losses in each year since our inception in 1998. As of December 31, 2006, we had an accumulated deficit of approximately $98.4 million. We do not know when or if we will generate product revenue. Subject to our ability to raise additional funds, we expect our research and development expenses to increase in connection with the clinical trials and other development activities for CORLUX and for other product candidates. We expect to incur significant expenses related to the preparation for commercializing CORLUX and for the product s launch, if the FDA approves our NDA. As a result, we expect that our losses will increase for the foreseeable future. We are unable to predict the extent of any future losses or whether or when we will become profitable.

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We depend on clinical investigators and clinical sites to enroll patients in our clinical trials and other third parties to manage the trials and to perform related data collection and analysis, and, as a result, we may face costs and delays outside of our control.

We rely on clinical investigators and clinical sites to enroll patients and other third parties to manage our trials and to perform related data collection and analysis. However, we may not be able to control the amount and timing of resources that the clinical sites that conduct the clinical testing may devote to our clinical trials. If our clinical investigators and clinical sites fail to enroll a sufficient number of patients in our clinical trials or fail to enroll them on our planned schedules, we will be unable to complete our trials or to complete them as planned, which could delay or prevent us from completing the clinical development of CORLUX or other development programs.

We have contracted with Premier Research (formerly Scirex Corporation), PPD Development, LP, (PPD), and i3 Research, an Ingenix Company (i3), to monitor clinical site performance and to perform investigator supervision, data collection and analysis in Study 06. We may not be able to maintain these relationships with Premier Research, PPD or i3 or with the clinical sites without excessive expenditures. Our agreements with clinical investigators and clinical sites for clinical testing and with Premier Research, PPD and i3 for trial management services place substantial responsibilities on these parties, which could result in excessive expenditures for our clinical trials if these parties fail to perform as expected. For example, if any of our clinical trial sites fail to comply with FDA-approved good clinical practices, we may be unable to use the data gathered at those sites. If these clinical investigators, clinical sites or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, we may be unable to obtain regulatory approval for, or successfully commercialize, CORLUX.

The conduct of any future clinical trials will likely also be conducted through the use of clinical research organizations and investigative research sites. The conduct, timing and cost of these trials will be subject to the same kinds of risks as discussed above.

The contracts for our European trial activities are denominated in Euros and we bear the currency rate exposure for the cost of these trials.

We have engaged a contract research organization to assist in the conduct of our clinical trial activity in Europe. The costs of these trials are denominated in Euros, which the vendor converts into U.S. dollars for invoicing as costs are incurred on a monthly basis. Thus, we bear some currency rate exposure for the costs of these activities. European trial activity is expected to be conducted through the second quarter of 2007. The timing of payments will depend upon various factors including the timing of final reporting of trial results and the final payments of pass-through costs, such as grants to investigators and laboratory services. All European trial activities are being conducted under a master agreement that provides for termination by us with forty-five days notice.

If we are unable to obtain or maintain regulatory approval, we will be limited in our ability to commercialize our product candidates, including CORLUX, and our business will be harmed.

The research, testing, manufacturing, selling and marketing of product candidates are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. Obtaining and maintaining regulatory approval typically is an uncertain process, is costly and takes many years. In addition, failure to comply with the FDA and other applicable foreign and U.S. regulatory requirements may subject us to administrative or judicially imposed sanctions. These include warning letters, civil and criminal penalties, injunctions, product seizure or detention, product recalls, total or partial suspension of production, and refusal to approve pending NDAs, or supplements to approved NDAs.

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Regulatory approval of an NDA or NDA supplement is never guaranteed. Despite the time, resources and effort expended, failure can occur at any stage. The FDA has substantial discretion in the approval process for human medicines. The FDA can deny, delay or limit approval of a product candidate for many reasons including:

- the FDA may not find that the candidate is safe;
- the FDA may not find data from the clinical or preclinical testing to be sufficient; or
- the FDA may not approve our or our third party manufacturers processes or facilities.

Future governmental action or changes in FDA policy or personnel may also result in delays or rejection of an NDA in the United States. In addition, because the only currently FDA-approved use of mifepristone is the termination of pregnancy, we expect that the label for CORLUX will include some limitations, including a warning that it should not be used by pregnant women.

If we receive regulatory approval for our product candidates, including CORLUX, we will also be subject to ongoing FDA obligations and continued regulatory oversight and review, such as continued safety reporting requirements; and we may also be subject to additional FDA post-marketing obligations. If we are not able to maintain regulatory compliance, we may not be permitted to market our product candidates.

Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the indicated uses for which the medicine may be marketed or contain requirements for potentially costly post-marketing follow-up studies. In addition, if the FDA approves any of our product candidates, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping for the medicine will be subject to extensive regulatory requirements. The subsequent discovery of previously unknown problems with the medicine, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the medicine, and could include withdrawal of the medicine from the market.

Failure to obtain regulatory approval in foreign jurisdictions will prevent us from commercializing our product candidates abroad.

We intend to commercialize our product candidates in international markets. Outside the United States, we can commercialize a product only if we receive a marketing authorization and, in some cases, pricing approval, from the appropriate regulatory authorities. This foreign regulatory approval process includes all of the risks associated with the FDA approval process, and, in some cases, additional risks. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. We have not taken any actions to obtain foreign approvals. We may not develop our product candidates in the clinic in order to obtain foreign regulatory approvals on a timely basis, if at all.

Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our product candidates in any market.

The fast track designation for the development program of CORLUX for the treatment of the psychotic features of PMD may not lead to a faster development or regulatory review or approval process.

If a human medicine is intended for the treatment of a serious or life-threatening condition and the medicine demonstrates the potential to address unmet medical needs for this condition, the sponsor of an Investigational New Drug Application, or IND, may apply for FDA fast track designation for a particular indication. Marketing applications submitted by sponsors of product candidates in fast track development may qualify for expedited FDA review under the policies and procedures offered by the FDA, but the fast track designation does

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not assure any such qualification. Although we have obtained a fast track designation from the FDA for CORLUX for the treatment of the psychotic features of PMD, we may not experience a faster development process, review or approval compared to applications considered for approval under conventional FDA procedures. In addition, the FDA may withdraw our fast track designation at any time. If we lose our fast track designation, the approval process may be delayed. In addition, our fast track designation does not guarantee that we will qualify for or be able to take advantage of the expedited review procedures and does not increase the likelihood that CORLUX will receive regulatory approval for the treatment of the psychotic features of PMD.

Even if we receive approval for the marketing and sale of CORLUX for the treatment of the psychotic features of PMD, it may never be accepted as a treatment for PMD.

Many factors may affect the market acceptance and commercial success of CORLUX for the treatment of the psychotic features of PMD. Although there is no FDA-approved treatment for PMD, there are two treatment approaches currently used by psychiatrists: electroconvulsive therapy, or ECT, and combination medicinal therapy. Even if the FDA approves CORLUX for the treatment of the psychotic features of PMD, physicians may not adopt CORLUX. Physicians will recommend the use of CORLUX only if they determine, based on experience, clinical data, side effect profiles and other factors, that it is preferable to other products or treatments then in use. Acceptance of CORLUX among influential practitioners will be essential for market acceptance of CORLUX.

Other factors that may affect the market acceptance and commercial success of CORLUX for the treatment of the psychotic features of PMD include:

- the effectiveness of CORLUX, including any side effects, as compared to alternative treatment methods;
- the product labeling or product insert required by the FDA for CORLUX;
- the cost-effectiveness of CORLUX and the availability of insurance or other third-party reimbursement, in particular Medicare and Medicaid, for patients using CORLUX;
- the timing of market entry of CORLUX relative to competitive products;
- the intentional restriction of distribution of CORLUX to physicians treating the target patient population;
- the extent and success of our sales and marketing efforts;
- the rate of adoption of CORLUX by physicians and by target patient population; and
- negative publicity concerning CORLUX, RU-486 or mifepristone.

The failure of CORLUX to achieve market acceptance would prevent us from generating meaningful product revenue.

Public perception of the active ingredient in CORLUX, mifepristone or RU-486, may limit our ability to market and sell CORLUX.

The active ingredient in CORLUX, mifepristone or RU-486, is used to terminate pregnancy. As a result, mifepristone has been and continues to be the subject of considerable ethical and political debate in the United States and elsewhere. Public perception of mifepristone may limit our ability to engage alternative manufacturers and may limit the commercial acceptance of CORLUX by patients and physicians. Even though we intend to create measures to minimize the likelihood of the prescribing of CORLUX to a pregnant woman, physicians may decline to prescribe CORLUX to a woman simply to avoid altogether any risk of unintentionally terminating a pregnancy. We intend to create measures for

controlling the distribution of CORLUX to reduce the potential for diversion. However, controlled distribution may negatively impact sales of CORLUX.

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We have no manufacturing capabilities and we currently depend on third parties to manufacture the active ingredient and the tablets for CORLUX. The tablet manufacturer is a single source supplier. If these suppliers are unable to continue manufacturing CORLUX and we are unable to contract quickly with alternative sources, our business will be harmed.

We currently have no experience in, and we do not own facilities for, nor do we plan to develop facilities for, manufacturing any products. We have agreements with two manufacturers of the active pharmaceutical ingredient, or API, of mifepristone and an agreement with a tablet manufacturer for development quantities of CORLUX. The tablet manufacturer is a single source supplier to us. Our current arrangements with these manufacturers are terminable by either party at any time. Although we anticipate engaging our current tablet supplier to produce commercial quantities of CORLUX, we cannot guarantee that we will enter into an agreement with them on terms acceptable to us. If we are unable, for whatever reason, to obtain the active pharmaceutical ingredient or CORLUX tablets from our contract manufacturers, we may not be able to manufacture our required quantities of CORLUX in a timely manner, if at all**.**

If our third party manufacturers of CORLUX fail to comply with FDA regulations or otherwise fail to meet our requirements, our product development and commercialization efforts may be delayed.

We depend on third party manufacturers to supply the active pharmaceutical ingredient in CORLUX and to manufacture CORLUX tablets. These suppliers and manufacturers must comply with the FDA s current Good Manufacturing Practices, or cGMP, regulations and guidelines. Our suppliers and manufacturers may encounter difficulties in achieving quality control and quality assurance and may experience shortages of qualified personnel. Their failure to follow cGMP or other regulatory requirements and to document their compliance with cGMP may lead to significant delays in the availability of products for commercial use or clinical study or the termination or hold on a clinical study, or may delay or prevent filing or approval of marketing applications for CORLUX.

Failure of our third party suppliers and manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could harm our business. If the operations of any current or future supplier or manufacturer were to become unavailable for any reason, commercialization of CORLUX could be delayed and our revenue from product sales could be reduced.

We may use a different third-party manufacturer to produce commercial quantities of CORLUX than we are using in our clinical trials. The FDA may require us to conduct a study to demonstrate that the tablets used in our clinical trials are equivalent to the final commercial product. If we are unable to establish that the tablets are equivalent or if the FDA disagrees with the results of our study, commercial launch of CORLUX would be delayed.

If we or others identify side effects after our product candidates are on the market, we may be required to perform lengthy additional clinical trials, change the labeling of our future products or withdraw our future products from the market, any of which would hinder or preclude our ability to generate revenues.

If we or others identify side effects after any of our product candidates are on the market:

- regulatory authorities may withdraw their approvals;
- we may be required to reformulate our future products, conduct additional clinical trials, make changes in labeling of such products or implement changes to or obtain re-approvals of our manufacturing facilities;
- we may experience a significant drop in the sales of the affected products;
- our reputation in the marketplace may suffer; and

we may become the target of lawsuits, including class action lawsuits.

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Any of these events could harm or prevent sales of the affected products or could increase the costs and expenses of commercializing and marketing these product candidates.

If CORLUX or future product candidates conflict with the patents of others or if we become involved in other intellectual property disputes, we could have to engage in costly litigation or obtain a license and we may be unable to commercialize our product candidates.

Our success depends in part on our ability to obtain and maintain adequate patent protection for the use of CORLUX for the treatment of the psychotic features of PMD and other potential uses of GR-II antagonists. If we do not adequately protect our intellectual property, competitors may be able to use our intellectual property and erode our competitive advantage.

To date, we own four issued U.S. patents and have exclusively licensed three issued U.S. patents, in each case along with a number of corresponding foreign patents or patent applications. We also have nine U.S. method of use patent applications for GR-II antagonists and three composition of matter patent applications covering specific GR-II antagonists. We have applied, and will continue to apply, for patents covering our product candidates as we deem appropriate.

We have exclusively licensed three issued U.S. patents from Stanford University for the use of GR-II antagonists in the treatment of PMD, cocaine-induced psychosis and early dementia, including early Alzheimer s disease. We bear the costs of protecting and defending the rights to these patents. In order to maintain the exclusive license to these patents until their expiration, we are obligated to make milestone and royalty payments to Stanford University. We are currently in compliance with our obligations under this agreement. If we become noncompliant, we may lose the right to commercialize CORLUX for the treatment of PMD and Alzheimer s disease and our business would be materially harmed.

Our patent applications and patents licensed or issued to us may be challenged by third parties and our patent applications may not result in issued patents. For example, in 2004, Akzo Nobel filed an observation challenging the claims of our exclusively licensed European patent application with claims directed to PMD. In 2005, we filed a rebuttal to EPO that responded to the points raised by Akzo Nobel. In February 2006, the EPO allowed our patent application and in July 2006, this patent was issued.

Our presently pending and future patent applications may not issue as patents, and any patent issued to us may be challenged, invalidated, held unenforceable or circumvented. For example, the arguments presented by Akzo Nobel could be raised in the United States either before the U.S. Patent and Trademark Office or in a court of law. Furthermore, the claims in patents which have been issued to us, or which may be issued to us in the future, may not be sufficiently broad to prevent third parties from producing competing products. In addition, the laws of various foreign countries in which we compete may not protect our intellectual property to the same extent as do the laws of the United States. If we fail to obtain adequate patent protection for our proprietary technology, our competitors may produce competing products based on our technology, which would impair our ability to compete.

If a third party were successful in asserting an infringement claim against us, we could be forced to pay damages and prevented from developing, manufacturing or marketing our potential products. We do not have liability insurance for patent infringements. A third party could require us to obtain a license to continue to use their intellectual property, and we may not be able to do so on commercially acceptable terms, or at all. We believe that significant litigation will continue in our industry regarding patent and other intellectual property rights. If we become involved in litigation, it could consume a substantial portion of our resources. Regardless of the merit of any particular claim, defending a lawsuit takes significant time, is expensive and diverts management s attention from other business.

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If we are unable to protect our trade secrets and proprietary information, our ability to compete in the market could be diminished.

In addition to patents, we rely on a combination of confidentiality, nondisclosure and other contractual provisions, laws protecting trade secrets and security measures to protect our trade secrets and proprietary information. Nevertheless, these measures may not adequately protect our trade secrets or other proprietary information. If they do not adequately protect our rights, third parties could use our proprietary information, which could diminish our ability to compete in the market. In addition, employees, consultants and others who participate in the development of our product candidates may breach their agreements with us regarding our trade secrets and other proprietary information, and we may not have adequate remedies for the breach. We also realize that our trade secrets may become known through means not currently foreseen. Notwithstanding our efforts to protect our trade secrets and proprietary information, our competitors may independently develop similar or alternative products that are equal or superior to our product candidates without infringing on any of our proprietary information or trade secrets.

Our licensed patent covering the use of mifepristone to treat PMD is a method of use patent rather than a composition of matter patent, which increases the risk that physicians will prescribe another manufacturer s mifepristone for the treatment of PMD rather than CORLUX.

We have an exclusive license from Stanford University to a patent covering the use of GR-II antagonists, including mifepristone, targeted for the treatment of PMD. A method of use patent covers only a specified use of a particular compound, not a particular composition of matter. All of our issued patents and all but three of our 12 U.S. patent applications relate to use patents. Because none of our issued patents covers the composition of mifepristone or any other compound, we cannot prevent others from commercializing mifepristone or any other GR-II antagonist. If others receive approval to manufacture and market mifepristone or any other GR-II antagonist, physicians could prescribe mifepristone or any other GR-II antagonist for PMD patients instead of CORLUX. Although any such off-label use would violate our licensed patent, effectively monitoring compliance with our licensed patent may be difficult and costly. In addition, if others develop a treatment for PMD that works through a mechanism which does not involve the GR-II receptor, physicians could prescribe that treatment instead of CORLUX.

If Stanford University were to terminate our CORLUX license due to breach of the license on our part, we would not be able to commercialize CORLUX for the treatment of the psychotic features of PMD.

Our efforts to discover, develop and commercialize new product candidates beyond CORLUX are at a very early stage. If we fail to identify and develop additional uses for GR-II antagonists, we may be unable to market additional products.

To develop additional potential sources of revenue, we believe that we must identify and develop additional product candidates. We have only recently begun to expand our research and development efforts toward identifying and developing product candidates in addition to CORLUX for the treatment of the psychotic features of PMD. We own or have exclusively licensed issued U.S. patents covering the use of GR-II antagonists to treat PMD, weight gain following treatment with antipsychotic medication, early dementia, mild cognitive impairment, psychosis associated with cocaine addiction, and stress disorders, in addition to ten U.S. method of use patent applications covering GR-II antagonists for the treatment of a number of other metabolic and psychiatric disorders and three U.S. composition of matter patent applications covering specific GR-II antagonists.

We may not develop product candidates for any of the indications or compounds covered by our patents and patent applications. Typically, there is a high rate of attrition for product candidates in preclinical and clinical trials, so our product development efforts may not lead to commercially viable products. The use of GR-II antagonists may not be effective to treat these conditions or any other indications. In addition, we could discover

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that the use of GR-II antagonists in these patient populations has unacceptable side effects or is otherwise not safe.

We may elect to enter into collaboration arrangements with respect to one or more of our product candidates. If we do enter into such an arrangement, we would be dependent on a collaborative partner for the success of the product candidates developed under the arrangement. Any future collaborative partner may fail to successfully develop or commercialize a product candidate under a collaborative arrangement.

We only have experience with CORLUX and we may determine that CORLUX is not desirable for uses other than for the treatment of the psychotic features of PMD. In that event, we would have to identify and may need to secure rights to a different GR-II antagonist. For example, we do not intend to develop CORLUX for mitigation of the weight gain associated with the use of olanzapine, even though we have initiated the proof of concept study described earlier in this Form 10-K. We may pursue other GR-II antagonists for this use. The compounds developed pursuant to our discovery research program may fail to generate commercially viable product candidates in spite of the resources we have dedicated to the program. Even if product candidates are identified, we may abandon further development efforts before we reach clinical trials or after expending significant expense and time conducting clinical trials due to financial constraints, concerns over safety, efficacy of the product candidates or for other reasons. Moreover, governmental authorities may enact new legislation or regulations that could limit or restrict our development efforts. If we are unable to successfully discover and commercialize new uses for GR-II antagonists, we may be unable to generate sufficient revenue to support our operations.

We may not be able to pursue all of our product research and development opportunities if we are unable to secure adequate funding for these programs.

The costs required to start or continue many of the programs that our intellectual property allow us to consider for further development are collectively greater that the funds currently available to us. For example, we announced in 2004 that we had successfully discovered three series of compounds that are specific GR-II antagonists but, unlike CORLUX, do not block the progesterone receptor. Further development of these programs and others, such as the use of GR-II antagonists for the mitigation of weight gain associated with olanzapine, may be delayed or cancelled if we determine that such development may jeopardize our ability to complete the clinical development of CORLUX for the treatment of PMD.

We may have substantial exposure to product liability claims and may not have adequate insurance to cover those claims.

We may be subject to product liability or other claims based on allegations that the use of our products has resulted in adverse effects or that our product candidates are not effective, whether by participants in our clinical trials for CORLUX or other product candidates, or by patients using our future products. A product liability claim may damage our reputation by raising questions about our product candidates safety or efficacy and could limit our ability to sell a product by preventing or interfering with product commercialization. In some cases, less common adverse effects of a pharmaceutical product are not known until long after the FDA approves the product for marketing. The active ingredient in CORLUX is used to terminate pregnancy. Therefore, necessary and strict precautions must be taken by clinicians using the medicine in our clinical trials and, if approved by the FDA, physicians prescribing the medicine to women with childbearing potential, to insure that the medicine is not administered to pregnant women. The failure to observe these precautions could result in significant product claims.

We have only limited product liability insurance coverage, with limits customary for a development stage company. We intend to expand our product liability insurance coverage to any product candidates for which we obtain marketing approval. However, this insurance may be prohibitively expensive or may not fully cover our potential liabilities. Our inability to obtain adequate insurance coverage at an acceptable cost could prevent or

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inhibit the commercialization of our product candidates. Defending a lawsuit could be costly and significantly divert management s attention from conducting our business. If a third party successfully sues us for any injury caused by our product candidates, our liability could exceed our total assets.

We have no sales staff and limited marketing activities and will need to develop sales and marketing capabilities to successfully commercialize CORLUX and any future uses of GR-II antagonists.

Our employees have limited experience in marketing or selling pharmaceutical products and we currently have no sales staff and limited marketing activities. To achieve commercial success for any approved product, we must either develop a sales and marketing force or enter into arrangements with others to market and sell our future products. We currently plan to establish a small, specialty sales force to market and sell CORLUX in the United States for the treatment of the psychotic features of PMD. However, our sales and marketing efforts may not be successful or cost-effective. In the event that the commercial launch of CORLUX is delayed due to FDA requirements or other reasons, we may establish a sales and marketing force too early relative to the launch of CORLUX. This may be expensive, and our investment would be lost if the sales and marketing force could not be retained. If our efforts to develop a sales and marketing force are not successful, cost-effective and timely, we may not achieve profitability.

We may need to increase the size of our organization, and we may experience difficulties in managing growth.

If resources are made available to continue operations beyond early 2008, we plan to use those resources to expand our research and development efforts and develop a sales and marketing organization when appropriate. In that event, we expect to experience growth, which may strain our operations, product development and other managerial and operating resources. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. To date, we have relied on a small management team, including a number of part-time contributors. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to manage any future growth effectively.

To that end, we must be able to:

- manage our research and development efforts effectively;
- manage our clinical trials effectively;
- integrate additional management, administrative and sales and marketing personnel;
- expand the size and composition of our management team;
- develop our administrative, accounting and management information systems and controls; and
- hire and train additional qualified personnel.

We may not be able to accomplish these tasks, and our failure to accomplish any of them could harm our business.

If CORLUX is approved and we are unable to obtain acceptable prices or adequate reimbursement for it from third-party payors, we will be unable to generate significant revenues.

There is significant uncertainty related to the availability of insurance coverage and reimbursement for newly approved medications. The commercial success of our potential medications in both domestic and international markets is dependent on whether third-party coverage and reimbursement is available for them. Medicare, Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new medicines, and, as a result, they may not

cover or provide adequate payment for our medications. The continuing efforts of

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government and third-party payors to contain or reduce the costs of health care may limit our revenues. Our dependence on the commercial success of CORLUX alone makes us particularly susceptible to any cost containment or reduction efforts. Accordingly, even if CORLUX or future product candidates are approved for commercial sale, unless government and other third-party payors provide adequate coverage and reimbursement for our future products, physicians may not prescribe them. We intend to sell CORLUX directly to hospitals if we receive FDA approval. As a result, we will need to obtain approval from hospital formularies to receive wide-spread third-party reimbursement. If we fail to obtain that approval, we will be unable to generate significant revenues.

In some foreign markets, pricing and profitability of prescription pharmaceuticals are subject to government control. In the United States, we expect that there will continue to be federal and state proposals for similar controls. Also, the trends toward managed health care in the United States and proposed legislation intended to reduce the cost of government insurance programs could significantly influence the purchase of health care services and products and may result in lower prices for our future products or the exclusion of such products from reimbursement programs.

We face competition from companies with substantial financial, technical and marketing resources, which could limit our future revenues from the commercialization of CORLUX for the treatment of the psychotic features of PMD.

If approved for commercial use, CORLUX as a treatment for PMD will compete with established treatments, including ECT and combination medicinal therapy.

Combination medicinal therapy consists of the use of antipsychotic and antidepressant medicines, not currently approved for the treatment of PMD. The antipsychotics are prescribed for off-label use by physicians to treat the psychotic features of PMD, which is the clinical target of CORLUX. Antipsychotics include Bristol-Myers Squibb s Abilify, Novartis Clozaril, Pfizer s Geodon and Navane, Ortho-McNeil s Haldol, Janssen Pharmaceutica s Risperdal, AstraZeneca s Seroquel, GlaxoSmithKline s Stelazine and Thorazine, Mylan s thioridazine, Schering Corporation s Trilafon and Eli Lilly s Zyprexa. CORLUX may not compete effectively with these established treatments. We are aware of one clinical trial conducted by the pharmaceutical division of Akzo Nobel, for a new chemical entity for the treatment of PMD. This new chemical entity is a GR-II antagonist, the commercial use of which would be covered by our patent. As discussed above, in 2004, Akzo Nobel filed an observation in our exclusively licensed European patent application with claims directed to PMD, in which Akzo Nobel challenged the claims of that patent application. In 2005, we filed a rebuttal to the EPO that responded to the points raised by Akzo Nobel. In February 2006, the EPO allowed our patent application. In July 2006, the patent was issued. We are not aware of any public disclosures by any company, other than Akzo Nobel, regarding the development of new products to treat PMD. Our present and potential competitors include major pharmaceutical companies, as well as specialized pharmaceutical firms, universities and public and private research institutions. Moreover, we expect competition to intensify as technical advances are made. These competitors, either alone or with collaborative parties, may succeed with the development and commercialization of medicinal products that are superior to and more cost-effective than CORLUX. Many of our competitors and related private and public research and academic institutions have greater experience, more financial resources and larger research and development staffs than we do. In addition, many of these competitors, either alone or together with their collaborative partners, have significantly greater experience than we do in developing human medicines, obtaining regulatory approvals, manufacturing and commercializing products.

Accordingly, CORLUX may not be an effective competitor against established treatments and our present or potential competitors may succeed in developing medicinal products that are superior to CORLUX or render CORLUX obsolete or non-competitive. If we are unable to establish CORLUX as a superior and cost-effective treatment for PMD, or any future use, we may be unable to generate the revenues necessary to support our business.

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Rapid technological change could make our product candidates obsolete.

Pharmaceutical technologies have undergone rapid and significant change and we expect that they will continue to do so. Our future will depend in large part on our ability to maintain a competitive position with respect to these technologies. Any products and processes that we develop may become obsolete or uneconomical before we recover any or all expenses incurred in connection with their development. Rapid technological change could make our product candidates obsolete or uneconomical, which could materially adversely affect our business, financial condition and results of operations.

If we lose our key personnel or are unable to attract and retain additional skilled personnel, we may be unable to pursue our product development and commercialization efforts.

We depend substantially on the principal members of our management and scientific staff, including Joseph K. Belanoff, M.D., our Chief Executive Officer, and Robert L. Roe, M.D., our President. We do not have agreements with any of our executive officers that provide for their continued employment with us or employment insurance covering any of our key personnel. Any officer or employee can terminate his or her relationship with us at any time and work for one of our competitors. The loss of these key individuals could result in competitive harm because we could experience delays in our product research, development and commercialization efforts without their expertise.

Our ability to operate successfully and manage our potential future growth depends significantly upon retaining key research, technical, sales, marketing, managerial and financial personnel, and attracting and retaining additional highly qualified personnel in these areas. We face intense competition for such personnel from numerous companies, as well as universities and nonprofit research organizations in the highly competitive northern California business area. Although we believe that we have been successful in attracting and retaining qualified personnel to date, we may not be able to attract and retain sufficient qualified personnel in the future. The inability to attract and retain these personnel could result in delays in the research, development and commercialization of our potential products.

If we acquire other GR-II antagonists or other technologies or potential products, we will incur a variety of costs and may never realize the anticipated benefits of the acquisition.

If appropriate opportunities become available, we may attempt to acquire other GR-II antagonists, particularly GR-II antagonists that do not terminate pregnancy. We may also be able to acquire other technologies or potential products that are complementary to our operating plan. We currently have no commitments, agreements or plans for any acquisitions. The process of acquiring rights to another GR-II antagonist or any other potential product or technology may result in unforeseen difficulties and expenditures and may absorb significant management attention that would otherwise be available for ongoing development of our business. In addition, we may fail to realize the anticipated benefits of any acquired potential product or technology. Future acquisitions could dilute our stockholders ownership interest in us and could cause us to incur debt, expose us to future liabilities and result in amortization or other expenses related to goodwill and other intangible assets.

The occurrence of a catastrophic disaster or other similar events could cause damage to our or our manufacturers facilities and equipment, which could require us to cease or curtail operations.

Because our executive offices are located in the San Francisco Bay Area and some of our current manufacturers are located in earthquake-prone areas, our business is vulnerable to damage from various types of disasters or other similarly disruptive events, including earthquake, fire, flood, power loss and communications failures. In addition, political considerations relating to mifepristone may put us and our manufacturers at increased risk for terrorist attacks, protests or other disruptive events. If any disaster or other similar event were to occur, we may not be able to operate our business and our manufacturers may not be able to produce our product candidates. Our insurance may not be adequate to cover, and our insurance policies may exclude coverage for, our losses resulting from disasters or other business interruptions.

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Risks Related to Our Stock

The market price of our common stock may be highly volatile.

We cannot assure you that an active trading market for our common stock will exist at any time. Holders of our common stock may not be able to sell shares quickly or at the market price if trading in our common stock is not active. During the 52-week period ended March 30, 2007 our average daily trading volume has been approximately 143,000 shares and the intra-day sales prices per share of our common stock ranged from $0.68 to $6.15. The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

- our cash and short-term investment position;
- actual or anticipated timing and results of our clinical trials;
- actual or anticipated regulatory approvals of our product candidates or of competing products;
- changes in laws or regulations applicable to our product candidates or our competitors products;
- changes in the expected or actual timing of our development programs or our competitors potential development programs;
- actual or anticipated variations in quarterly operating results;
- announcements of technological innovations by us, our collaborators or our competitors;
- new products or services introduced or announced by us or our competitors;
- changes in financial estimates or recommendations by securities analysts;
- conditions or trends in the biotechnology and pharmaceutical industries;
- changes in the market valuations of similar companies;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- additions or departures of key personnel;

disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;

developments concerning our collaborations;

trading volume of our common stock;

maintaining compliance with the listing requirements of the stock exchange on which we are listed;

announcement of, or expectation of, additional financing efforts; and

sales of our common stock by us or our stockholders.

In addition, the stock market in general, the Nasdaq Stock Market and the market for technology companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Further, there has been particular volatility in the market prices of securities of biotechnology and life sciences companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management s attention and resources.

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If we fail to continue to meet all applicable Nasdaq Global Market requirements, our stock could be delisted by the Nasdaq Global Market. If delisting occurs, it would adversely affect the market liquidity of our common stock and harm our business.

Our common stock is listed on the Nasdaq Global Market. In order to maintain that listing, we must satisfy minimum financial and other requirements. On November 16, 2006 we received notice from the Nasdaq Global Market that we were not in compliance with two listing requirements.

First, the Nasdaq Stock Market staff notified us that the closing bid price of our common stock had not met the $1.00 per share minimum requirement for 30 consecutive business days. The closing price of our common stock on the Nasdaq Global Market had been less than $1.00 for a period of at least 30 business days starting September 29, 2006. On January 11, 2007 the Nasdaq Stock Market staff informed us that we were no longer out of compliance with the minimum closing bid price requirement and that the staff considered the matter closed. Since regaining compliance, the closing bid price of our common stock has remained above $1.00 in compliance with the minimum bid price requirement.

Second, the Nasdaq Stock Market staff notified us that we were not in compliance with the requirement that stockholders equity for companies listed on the Nasdaq Global Market should be no less than $10,000,000. Our third quarter report showed that our stockholder s equity on September 30, 2006 was $6,978,000. On December 4, 2006, we submitted a plan to regain compliance with the minimum equity requirement which was rejected by the Nasdaq Stock Market staff on December 20, 2006. We appealed the staff s determination of non-compliance on December 27, 2006 and were granted a hearing before the Nasdaq Listings Qualifications Panel on February, 15, 2007. We had submitted a revised Plan of Compliance with the minimum stockholders equity requirement prior to the hearing and discussed this revised plan at the hearing.

In the event the Nasdaq Stock Market staff determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease. Such delisting could also adversely affect our ability to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees.

Securities analysts may not continue to provide or initiate coverage of our common stock or may issue negative reports, and this may have a negative impact on our common stock s market price.

Securities analysts currently covering our common stock may discontinue research coverage. Additional securities analysts may elect not to provide research coverage of our common stock. A lack of research coverage may adversely affect our common stock s market price. The trading market for our common stock may be affected in part by the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts who elects to cover us downgrades our stock, our stock price would likely decline rapidly. If one or more of these analysts ceases coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline. In addition, rules mandated by the Sarbanes-Oxley Act of 2002, and a global settlement reached in 2003 between the SEC, other regulatory analysts and a number of investment banks have led to a number of fundamental changes in how analysts are reviewed and compensated. In particular, many investment banking firms are required to contract with independent financial analysts for their stock research. It may be difficult for companies such as ours with smaller market capitalizations to attract independent financial analysts that will cover our common stock. This could have a negative effect on our market price.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

Sales of a substantial number of shares of our common stock in the public market could harm the market price of our common stock. As additional shares of our common stock become available for resale in the public

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market, the supply of our common stock will increase, which could decrease the price. Substantially all of the shares of our common stock are eligible for sale, subject to applicable volume and other resale restrictions.

Our officers, directors and principal stockholders control a majority of our common stock and will be able to significantly influence corporate actions.

As of March 30, 2007, our officers, directors and principal stockholders control a majority of our common stock. As a result, these stockholders, acting together, will be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders and may prevent or delay a change in control. This concentration of ownership may have the effect of delaying or preventing a change in control and might adversely affect the market price of our common stock. In addition, this significant concentration of share ownership may adversely affect the trading price of our common stock because investors often perceive disadvantages to owning stock in companies with controlling stockholders.

We may incur increased costs as a result of recently enacted and proposed changes in laws and regulations.

Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and regulations of the SEC and the Nasdaq Stock Market, have and will continue to result in increased costs to us. The new rules could make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, or our board committees, or as executive officers. At present, we cannot predict or estimate the amount of the additional costs related to these new rules and regulations or the timing of such costs.

Because we have been a public company for a short time, we have limited experience complying with public company obligations, including recently enacted changes in securities laws and regulations. Compliance with these requirements will increase our costs and require additional management resources, and we still may fail to comply.

We are a small company with limited resources. Until April 2004, we operated as a private company, not subject to many of the requirements applicable to public companies.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the company s internal controls over financial reporting in their annual reports on Form 10-K. In addition, the independent registered public accounting firm auditing the company s financial statements must attest to and report on management s assessment of the effectiveness of the company s internal controls over financial reporting, as well as the effectiveness of the company s internal controls over financial reporting. This requirement will first apply to our annual report on Form 10-K for our fiscal year ending December 31, 2007. Uncertainty exists regarding our ability to comply with these requirements by applicable deadlines. If we are unable to complete the required assessment as to the adequacy of our internal control reporting or if our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal controls over financial reporting as the required deadline and future year ends, investors could lose confidence in the reliability of our financial reporting.

Changes in or interpretations of accounting rules and regulations, such as expensing of stock options, could result in unfavorable accounting charges or require us to change our compensation policies.

Accounting methods and policies for business and marketing practices of pharmaceutical companies, including policies regarding expensing employee stock options, are subject to further review, interpretation and

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guidance from relevant accounting authorities, including the SEC. For example, in December 2004, the Financial Accounting Standards Board adopted Financial Accounting Standard 123R, Share Based Payment. This statement, which we adopted in the first quarter of 2006, requires the recording of expense for the fair value of stock options granted. As a result, our operating expenses have increased and are likely to continue to increase. We rely heavily on stock options to compensate existing employees and attract new employees. Because we are now required to expense stock options on a fair-value basis, we may choose to reduce our reliance on stock options as a compensation tool. If we reduce our use of stock options, it may be more difficult for us to attract and retain qualified employees. If we did not reduce our reliance on stock options, our reported losses would increase. Although we believe that our accounting practices are consistent with current accounting pronouncements, changes to or interpretations of accounting methods or policies in the future may require us to reclassify, restate or otherwise change or revise our financial statements.

Anti-takeover provisions in our charter and bylaws and under Delaware law may make an acquisition of us or a change in our management more difficult, even if an acquisition or a management change would be beneficial to our stockholders.

Provisions in our charter and bylaws may delay or prevent an acquisition of us or a change in our management. Some of these provisions divide our board into three classes with only a portion of our directors subject to election at each annual meeting, allow us to issue preferred stock without any vote or further action by the stockholders, require advance notification of stockholder proposals and nominations of candidates for election as directors and prohibit stockholders from acting by written consent. In addition, a supermajority vote of stockholders is required to amend our bylaws. Our bylaws provide that special meetings of the stockholders may be called only by our Chairman, President or the board of directors and that the authorized number of directors may be changed only by resolution of the board of directors. These provisions may prevent or delay a change in our board of directors or our management, which is appointed by our board of directors. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law. Section 203 may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us. These provisions in our charter, bylaws and under Delaware law could reduce the price that investors might be willing to pay for shares of our common stock in the future and result in the market price being lower than it would be without these provisions.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We lease approximately 7,700 square feet of office space in Menlo Park, California for our corporate facilities. The lease has an initial term of 30 months with a commencement date of July 1, 2005 and, provides us with an option to extend for an additional year. We expect that these facilities will accommodate our operations for the next year.

ITEM 3. LEGAL PROCEEDINGS

We are not currently involved in any material legal proceedings.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of security holders during the fourth quarter of fiscal 2006.

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PART II

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

Market Information

Our common stock is traded on The Nasdaq Global Market under the symbol CORT . The following table sets forth the high and low intra-day sale prices per share of our common stock on The Nasdaq Global Market for the periods indicated. These prices represent quotations among dealers without adjustments for retail mark-ups, markdowns or commissions, and may not represent prices of actual transactions.

	High	Low
2006		
First Quarter	$ 5.59	$ 3.45
Second Quarter	$ 6.15	$ 4.04
Third Quarter	$ 4.54	$ 0.75
Fourth Quarter	$ 1.70	$ 0.68

	High	Low
2005		
First Quarter	$ 6.29	$ 4.25
Second Quarter	$ 6.58	$ 3.41
Third Quarter	$ 7.00	$ 4.84
Fourth Quarter	$ 5.30	$ 3.63

Stockholders of Record and Dividends

As of March 30, 2007, we had 34,731,766 shares of common stock outstanding held by 94 stockholders of record. We have not paid cash dividends on our common stock since our inception and we do not anticipate paying any in the foreseeable future.

Use of Proceeds from Sale of Registered Securities

On April 19, 2004, we completed an initial public offering of 4,500,000 shares of our common stock. The shares of common stock sold in the offering were registered under the Securities Act of 1933, as amended, on a Registration Statement on Form S-1 (Reg. No. 333-112676) that was declared effective by the Securities and Exchange Commission on April 14, 2004. After deducting the underwriting discounts and commissions and the estimated offering expenses, we received net proceeds from the offering of approximately $49.0 million. Between the effective date of the Registration Statement and December 31, 2006, approximately $39.6 million of the net proceeds was used for research and development activities and approximately $9.4 million was used for general and administrative activities. The remaining proceeds from the offering have been invested in marketable securities for future use as needed.

Sale of Unregistered Securities

On December 15, 2006, the Company sold 3,000,000 shares of Common Stock of Corcept, par value $0.001, at a price of $1.00 per share, for aggregate proceeds of $3,000,000. The investor group was comprised of Paperboy Ventures LLC and Sutter Hill Ventures, both venture capital firms that are currently significant shareholders of the Company, and members of the Company s board of directors, Joseph C. Cook, Jr., David L. Mahoney and James N. Wilson. G. Leonard Baker, Jr., a member of the Company s board of directors, is a also managing director of the general partner of Sutter Hill Ventures.

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On March 30, 2007, the Company sold 9,000,000 shares of Common Stock of Corcept, par value $0.001, at a price of $1.00 per share, for aggregate proceeds of $9,000,000. The investor group included Paperboy Ventures LLC, Sutter Hill Ventures and Alta Partners LLP, all venture capital firms that are currently significant shareholders of the Company, members of the Company s board of directors, Joseph C. Cook, Jr., David L. Mahoney, Alan F. Schatzberg, M.D. and James N. Wilson, and other qualified investors. G. Leonard Baker, Jr., a member of the Company s board of directors, is also managing director of the general partner of Sutter Hill Ventures.

The December 2006 and March 2007 financings are exempt from registration pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(2) the Securities Act of 1933, as amended. The securities sold and issued in connection with the private placement have not been registered under the Securities Act of 1933, as amended, or any state securities laws and may not be offered or sold in the United States absent registration with the Securities and Exchange Commission or an applicable exemption from the registration requirements. As part of the transaction, the Company agreed to file a registration statement with the Securities and Exchange Commission for purposes of registering the resale of certain of the common stock issued in these transactions within two business days following the filing of this Annual Report on Form 10-K.

Market Performance Graph

The rules of the SEC require that the Company include in a line-graph presentation comparing cumulative stockholder returns on the Company s common stock with the NASDAQ Composite Index (which tracks the aggregate price performance of equity securities of companies traded on NASDAQ) and either a published industry or line-of-business standard index or an index of peer companies selected by the Company. The Company has elected to use the NASDAQ Biotechnology Index (consisting of a group of approximately 130 companies in the biotechnology sector, including the Company) for purposes of the performance comparison that appears below.

The graph shows the cumulative total stockholder return assuming the investment of $100.00 and the reinvestment of dividends and is based on the returns of the component companies weighted according to their market capitalizations as of the end of the period for which returns are indicated. No dividends have been declared on the Company s common stock.

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The stockholder return shown on the graph below is not necessarily indicative of future performance, and the Company does not make or endorse any predictions as to future stockholder returns.

COMPARISON OF 32-MONTH CUMULATIVE TOTAL RETURN* AMONG

CORCEPT THERAPEUTICS, THE NASDAQ STOCK MARKET (U.S.) INDEX

AND THE NASDAQ BIOTECHNOLOGY INDEX

* $100 invested on 4/14/04 including reinvestment of dividends. Fiscal year ending December 31.

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ITEM 6. SELECTED FINANCIAL DATA

SELECTED FINANCIAL DATA

(in thousands, except per share data)

The selected financial data set forth below are derived from our financial statements. The statement of operations data for the years ended December 31, 2004, 2005, and 2006 and for the period from inception (May 13, 1998) to December 31, 2006 and the balance sheet data as of December 31, 2005 and 2006 are derived from our audited financial statements included in this Annual Report on Form 10-K, or Form 10-K. The statements of operations data for the years ended December 31, 2002 and 2003, and the balance sheet data as of December 31, 2002, 2003 and 2004 have been derived from our audited financial statements, which are not included in this Form 10-K. The selected financial data set forth below should be read in conjunction with our financial statements, the related notes and Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Form 10-K.

	Year Ended December 31,					Period from inception (May 13, 1998) to December 31,
	2006	2005	2004	2003	2002	2006
	(In thousands, except per share data)					
Statement of Operations Data:						
Collaboration Revenue	$ 294	$	$	$	$	$ 294
Operating expenses:						
Research and development*	20,834	17,074	11,551	8,223	13,264	77,797
General and administrative*	5,042	4,084	4,494	1,746	5,531	24,273
Total operating expenses	25,876	21,158	16,045	9,969	18,795	102,070
Loss from operations	(25,582)	(21,158)	(16,045)	(9,969)	(18,795)	(101,776)
Non-operating income, net	709	1,065	510	157	291	3,338
Net loss	$ (24,873)	$ (20,093)	$ (15,535)	$ (9,812)	$ (18,504)	$ (98,438)
Net loss per share:						
Basic and diluted	$ (1.09)	$ (0.89)	$ (0.84)	$ (1.22)	$ (2.75)	
Weighted average shares basic and diluted	22,841	22,608	18,440	8,069	6,720	
* Includes non-cash stock-based compensation (recovery) of the following:						
Research and development	$ 535	$ (26)	$ 202	$ 551	$ 1,957	$ 4,531
General and administrative	1,013	799	1,475	(308)	2,145	5,804
Total non-cash stock-based compensation	$ 1,548	$ 773	$ 1,677	$ 243	$ 4,102	$ 10,335

	As of December 31,				
	2006	2005	2004	2003	2002
	(In thousands)				

Balance Sheet Data:					
Cash, cash equivalents and investments	$ 9,456	$ 29,619	$ 46,887	$ 11,577	$ 21,543
Working capital	6,286	25,984	36,415	10,729	20,222
Total assets	9,902	30,156	47,772	11,781	21,795
Long-term liabilities	29	42		524	503
Convertible preferred stock				41,716	41,716
Total stockholders equity (net capital deficiency)	6,360	26,593	45,948	(31,473)	(21,940)

See our financial statements and related notes for a description of the calculation of the net loss per share and the weighted-average number of shares used in computing the per share amounts.

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

Forward-Looking Statements

This Management s Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended and should be read in conjunction with the Risk Factors section of Part I of this Form 10-K. All statements contained in this Form 10-K other than statements of historical fact are forward-looking statements. When used in this report or elsewhere by management from time to time, the words believe, anticipate, intend, plan, estimate, expect, and similar expressions are forward-looking statements. Such forward-looking stateme based on current expectations, but the absence of these words does not necessarily mean that a statement is not forward-looking.
Forward-looking statements may include, but are not limited to, statements about:

- *the progress of our research, development and clinical programs and timing of the introduction of CORLUX® and future product candidates;*
- *estimates of the dates by which we expect to report results of our clinical trials;*
- *our ability to market, commercialize and achieve market acceptance for CORLUX or other future product candidates;*
- *uncertainties associated with obtaining and enforcing patents;*
- *our estimates for future performance; and*
- *our estimates regarding our capital requirements and our needs for additional financing.*

Our current capital is not sufficient to fund operations beyond early 2008. We need additional capital in order to continue operations and capital may not be available to us at all or on favorable terms.

Forward-looking statements are not guarantees of future performance and involve risks and uncertainties. Actual events or results may differ materially from those discussed in the forward-looking statements as a result of various factors. For a more detailed discussion of such forward-looking statements and the potential risks and uncertainties that may impact upon their accuracy, see Risk Factors included in Part I of this Form 10-K and the Overview and Liquidity and Capital Resources sections of this Management s Discussion and Analysis of Financial Condition and Results of Operations. These forward-looking statements reflect our view only as of the date of this report. Except as required by law, we undertake no obligations to update any forward looking statements. Accordingly, you should also carefully consider the factors set forth in other reports or documents that we file from time to time with the Securities and Exchange Commission.

Overview

We are a pharmaceutical company engaged in the development of medications for the treatment of severe psychiatric and metabolic diseases. Since our inception in May 1998, we have been developing our lead product, CORLUX, targeted for the treatment of the psychotic features of psychotic major depression, or PMD, under an exclusive patent license from Stanford University. The United States Food and Drug Administration, or FDA, has granted fast track status to evaluate the safety and efficacy of CORLUX for the treatment of the psychotic features of PMD. Between August 2006 and March 2007 we announced the top line results of our initial three Phase 3 trials in which CORLUX was evaluated for treating the psychotic features of PMD.

We reported the initial results of Study 06, the last of the three Phase 3 trials, in March 2007. These results indicated that this study did not achieve statistical significance with respect to the primary endpoint. However, there was a statistically significant correlation between plasma levels and clinical outcome achieved during treatment. Patients whose plasma levels rose above a predetermined threshold statistically separated from both

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those patients whose plasma levels were below the threshold and those patients who received placebo. In particular, those patients in Study 06 who achieved a predetermined level of 1661 nanograms of CORLUX per milliliter of plasma separated from the placebo group with statistical significance. Conversely, at substantially lower plasma levels, there was no distinguishable response rate between patients who received CORLUX and those receiving placebo. This study confirms a similar finding in Study 07 that at higher plasma levels the drug candidate is able to demonstrate desired clinical effects. Further, the incidence of serious adverse events did not differ between placebo and any of the three CORLUX dose groups.

We believe that the confirmation of a drug concentration threshold for efficacy, as well as other observations from Study 06 and the company s other two recently completed Phase 3 clinical trials, will serve as a strong basis for our next Phase 3 study, which is planned to commence later in 2007. The protocol for this trial will incorporate the learnings from the three completed trials that address the sensitivity of the model and decrease the random variability observed in the results of the psychometric instruments used to measure efficacy. We intend to meet with the FDA to discuss and seek input concerning the design of this trial. In this trial we expect to use a dose level of 1200 mg once per day for seven days because, as expected, at successively higher dosages, more patients achieved the predetermined plasma threshold concentration. In Study 06, 80% of the patients achieved a drug plasma level sufficient for a strong clinical response at that dose. In our initial review of a summary of the safety data, we have seen no difference between any of the dose levels used in Study 06. We believe that this change in dose as well as other modifications to the protocol should allow us to definitively demonstrate the efficacy of CORLUX in the treatment of the psychotic symptoms of PMD.

In addition, we initiated two additional Phase 3 clinical trials to evaluate the safety and tolerability of retreatment with CORLUX. The first, Study 10, commenced in the United States in December 2004. The second, Study 13, commenced in Europe in August 2005. We terminated the patient activity related to these clinical trials in the fourth quarter of 2006.

In October 2005, we announced that we had signed an agreement with Eli Lilly and Company, or Lilly, in which Lilly agreed to support our proof-of-concept clinical study evaluating the ability of CORLUX to mitigate weight gain associated with the use of olanzapine. This study in healthy male volunteers was initiated during the first quarter of 2006. We have relocated this study to a new site in India and have made minor changes in the protocol. We began screening patients in March 2007 and to report the results of this study at the end of the second quarter of 2007.

Our activities to date have included:

- product development;
- designing, funding and overseeing clinical trials;
- regulatory affairs; and
- intellectual property prosecution and expansion.

Historically, we have financed our operations and internal growth primarily through private placements of our preferred stock and the public sale of common stock rather than through collaborative or partnership agreements. Therefore, we have no research funding or collaborative payments payable to us, except for the revenue under the agreement with Lilly discussed above.

We are in the development stage and have incurred significant losses since our inception because we had not generated any revenue through 2005, and do not expect to generate significant revenue for the foreseeable future. As of December 31, 2006, we had an accumulated deficit of approximately $98.4 million. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for CORLUX, discovery research, non-clinical activities such as toxicology and carcinogenicity studies, manufacturing process development and regulatory activities, as well as general and administrative

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expenses. We expect to continue to incur net losses over at least the next several years as we continue our CORLUX clinical development program, apply for regulatory approvals, expand development of GR-II antagonists for new indications, acquire and develop treatments in other therapeutic areas, establish sales and marketing capabilities and expand our operations.

Our business is subject to significant risks, including the risks inherent in our research and development efforts, the results of our CORLUX clinical trials, uncertainties associated with securing financing, uncertainties associated with obtaining and enforcing patents, our investment in manufacturing set-up, the lengthy and expensive regulatory approval process and competition from other products. Our ability to successfully generate revenues in the foreseeable future is dependent upon our ability, alone or with others, to finance our operations and develop, obtain regulatory approval for, manufacture and market our lead product.

Our common stock is listed on the Nasdaq Global Market. In order to maintain that listing, we must satisfy minimum financial and other requirements. On November 16, 2006 we received notice from the Nasdaq Stock Market staff that we were not in compliance with two listing requirements.

First, the Nasdaq Stock Market staff notified us that the closing bid price of our common stock had not met the $1.00 per share minimum requirement for 30 consecutive business days. The closing price of our common stock on the Global Market had been less than $1.00 for a period of at least 30 business days starting September 29, 2006. On January 11, 2007, Nasdaq Stock Market staff informed us that we were no longer out of compliance with the minimum closing bid price requirement and that Nasdaq considered the matter closed. Since regaining compliance, the closing bid price of our common stock has remained above $1.00 in compliance with the minimum bid price requirement.

Second, the Nasdaq Stock Market staff notified us that we were not in compliance with the requirement that stockholders equity for companies listed on the Nasdaq Global Market should be no less than $10,000,000. Our third quarter report showed that our stockholder s equity on September 30, 2006 was $6,978,000. On December 4, 2006, we submitted a plan to regain compliance with the minimum equity requirement which was rejected by the Nasdaq Stock Market staff on December 20, 2006. We appealed the staff s determination of non-compliance on December 27, 2006 and were granted a hearing before the Nasdaq Listings Qualifications Panel on February, 15, 2007. We had submitted a revised Plan of Compliance with the minimum stockholders equity requirement prior to the hearing and discussed this revised plan at the hearing.

Results of Operations

Collaboration revenue Collaboration revenue relates to services rendered in connection with our agreement with Lilly discussed above. Under the agreement, Lilly will supply olanzapine and pay for the budgeted costs of the study. Under the agreement, we are required to perform specified development activities and the fee paid to us by Lilly is based on the costs associated with the conduct of that trial and the preparation and packaging of clinical trial materials. Revenue is recognized as services are rendered in accordance with the agreement. The cost of providing these research services approximates the revenue recognized. If the costs of the study exceed budgeted amounts, Lilly may not pay for the excess. As of December 31, 2006, the costs incurred have not exceeded the budgeted amounts.

During the year ended December 31, 2006, we recognized approximately $294,000 of revenue under this agreement. No such revenue was recorded during 2005 as the study did not commence until early 2006. Total revenues from this collaboration are expected to be approximately $775,000 over the course of this study.

Research and development expenses. Research and development expenses include the personnel costs related to our development activities, including non-cash stock-based compensation, as well as the costs of discovery research, pre-clinical studies, clinical trial preparations, enrolment and monitoring expenses, regulatory costs and the costs of manufacturing development.

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Research and development expenses increased 22% to $20.8 million for the year ended December 31, 2006 from $17.1 million for 2005 which had increased 48% from $11.6 million for 2004. The increase in expenses between years reflect clinical trial cost increases of approximately $4.7 million for 2006 as compared to 2005, which had increased $7.3 million from 2004 primarily related to clinical trial expenses for PMD. This increase was partially offset by a reduction in 2006 of approximately $450,000 and a decrease in 2005 of approximately $1.9 million in expenses for our discovery research program due to the successful conclusion of a program focusing on the discovery of new chemical entities that will be available for future development.

During 2006 as compared to 2005, the costs of our clinical program also reflected a decrease of approximately $695,000 from the conclusion of our study in mild to moderate Alzheimer s disease in 2005 and an increase of approximately $275,000 related to the commencement of the olanzapine induced weight gain mitigation clinical trial in collaboration with Lilly. In addition, during 2006, as compared to 2005 there were decreases in pre-clinical studies and manufacturing development of approximately $365,000 and $205,000, respectively, decreases in travel, consulting and other expenses of $435,000 and increases in staffing expenses of approximately $545,000. The increases in staffing expenses were primarily due to higher non-cash stock-based compensation expense.

In addition, during 2005 as compared to 2004, decreases in production and testing of clinical supplies and manufacturing development of approximately $370,000 and stock-based compensation of approximately $228,000 were offset by increases in pre-clinical studies, clinical consulting and infrastructure costs of approximately $285,000, $250,000 and $90,000, respectively.

Research and development expenses discussed above included stock based compensation charges related to option grants to individuals performing these functions of approximately $575,000, $224,000 and $442,000, respectively, for the years ended December 31, 2006, 2005 and 2004. In addition, during the years ended December 31, 2006, 2005 and 2004 upon the termination of employees or the change in status of employees who worked in a development function to consultants, we recorded reversals of approximately $40,000, $250,000 and $240,000, respectively, of previously reported stock-based compensation expense, which represents the difference between the expense recorded and the expense that would have been recorded based upon the rights to options that vested during the service of these individuals as employees. See the discussion below under the caption Stock-based compensation for options to employees impact of adopting SFAS 123R regarding the impact of adoption in January 2006.

Below is a summary of our research and development expenses by major project:

Project	Year Ended December 31, 2006	2005	2004
		(in thousands)	
CORLUX for the treatment of the psychotic features of PMD	$ 19,759	$ 15,391	$ 8,108
CORLUX for other clinical programs	276	954	641
Drug discovery research	264	755	2,600
Stock-based compensation	535	(26)	202
Total research and development expense	$ 20,834	$ 17,074	$ 11,551

We expect that research and development expenditures will decrease during 2007 because substantially all patient activities related to clinical trials for PMD that we have been conducting were completed during 2006 and remaining reporting activities should be completed by the second quarter of 2007. Research and development expenses in 2007 and future years will be largely dependent on the availability of additional funds to finance clinical development plans based on our experience from prior trials. See also, the Liquidity and Capital Resources section in this Form 10-K.

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Many factors can affect the cost and timing of our trials including inconclusive results requiring additional clinical trials, slow patient enrollment, adverse side effects in study patients, insufficient supplies for our clinical trials and real or perceived lack of effectiveness or safety of the drug in our trials. In addition, the development of all of our product candidates will be subject to extensive governmental regulation. These factors make it difficult for us to predict the timing and costs of the further development and approval of our product candidates.

General and administrative expenses. General and administrative expenses consist primarily of the costs of administrative personnel and related facility costs along with legal, accounting and other professional fees.

General and administrative expenses increased 23% to $5.0 million for the year ended December 31, 2006, from $4.1 million for the year ended December 31, 2005, which had decreased 9% from $4.5 million for the year ended December 31, 2004. The increase in 2006 as compared to 2005 was primarily due to increases in professional fees of approximately $560,000 and increases in staffing costs of approximately $455,000. The increases in staffing expenses were primarily due to higher non-cash stock-based compensation expense. During 2005 as compared to 2004 decreases in stock based compensation of approximately $680,000 and legal expenses of $70,000 were partially offset by increases in professional fees, insurance, market research and staffing of approximately $120,000, $80,000, $55,000 and $50,000, respectively.

General and administrative expenses included stock-based compensation expense related to option grants to individuals performing these functions of approximately $1.0 million, $799,000 and $1.5 million, respectively, for the years ended December 31, 2006, 2005 and 2004. See discussion below under the caption Stock-based compensation for options to employees impact of adopting SFAS 123R regarding the impact of adoption in January 2006. The decrease between 2005 and 2004 was due to the decelerating scale of expense recognition under the graded-vesting method.

The amount of general and administrative expenses in 2007 and future years will be largely dependent on our assessment of the staff necessary to support our continued clinical development activities and the availability of additional funds. See also, the Liquidity and Capital Resources section in this Form 10-K.

Interest and other income, net. Interest and other income, net of investment management fees, decreased to approximately $720,000 for the year ended December 31, 2006 from $1.1 million for the same period in 2005 after having increased from approximately $578,000 for the year ended December 31, 2004. The change during 2006 as compared to 2005 was principally attributable to decreased earnings due to lower average balance of invested funds that were partially offset by higher yields on the investment portfolios during the 2006 period as compared to the 2005 period. The increase during 2005 as compared to 2004 was principally attributable to higher balance with the investment of funds from the initial public offering of our common stock, or IPO, in April 2004 and to higher yields on the investment portfolios.

Other expense. Other expense was $10,000 for the year ended December 31, 2006, compared to $52,000 for the same period in 2005 and $68,000 for 2004. Other expense during 2006 and 2005 included state tax and interest expense on capitalized leases entered into during the second quarter of 2005. The expense in 2004 also included interest expense on our convertible note payable to the Institute for the Study of Aging. The note was converted into common stock in June 2004.

Liquidity and Capital Resources

We have incurred operating losses since inception, and at December 31, 2006, we had a deficit accumulated during the development stage of $98.4 million. Since our inception, we have relied primarily on the proceeds from public and private sales of our equity securities to fund our operations. In December 2006, we completed a private placement of 3 million shares of common stock at a price of $1.00 per share. Net proceeds of this financing were approximately $2.9 million after deducting expenses.

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At December 31, 2006, we had cash, cash equivalents and investments balances of $9.5 million, compared to $29.6 million at December 31, 2005. Net cash used in operating activities for the years ended December 31, 2006, 2005 and 2004, were $23.2 million, $17.2 million and $13.7 million, respectively. The use of cash in each period was primarily a result of net losses associated with our research and development activities and amounts incurred to develop our administrative infrastructure. On March 30, 2007, we sold 9 million shares of common stock at a price of $1.00 per share in a private placement. The net proceeds were approximately $8.8 million after deducting issuance costs.

We have sufficient funds to maintain our current operations through the completion and reporting of results of the proof-of-concept weight-gain mitigation study, expected in June 2007, to prepare for the next Phase 3 trial and to continue development of our new chemical entities. If we are not able to raise additional funds, we will not be able to continue operations beyond early 2008.

We will have to perform additional efficacy trials prior to submission of an NDA for CORLUX for the treatment of the psychotic features of PMD. We will need to raise additional funds to complete the development of CORLUX for the treatment of PMD and other indications, to prepare for its commercialization and to conduct other research activities. The additional funds will be used to fund increases in our research and development and general and administrative activities in 2008 and subsequent years.

We believe that funds should be available for these purposes assuming investors acceptance of our business plan going forward, which includes a fourth Phase 3 clinical trial in PMD, opportunities that may be created by the results of the proof-of-concept trial evaluating mitigation of atypical antipsychotic induced weight gain and the development of our new chemical entities. We cannot be certain that additional funding will be available on acceptable terms or at all. Further, any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or to obtain funds through collaborations with others that are on unfavorable terms or that may require us to relinquish certain rights to our technologies or product candidates, including potentially our lead product candidate, that we would otherwise seek to develop on our own; or we may be required to discontinue operations.

Contractual Obligations

The following table presents our estimates of obligations under contractual agreements as of December 31, 2006:

Payments Due by Period	Less than 1 year	1-3 Years	3-5 Years	More than 5 Years
		(in thousands)		
Research and development studies [1] [2] [3] [4]	$ 1,550	$	$	$
Operating lease [5]	171			
Capital leases [6]	13	29		
Minimum royalty payments [7]	50	100	100	50 per year
Total	$ 1,784	$ 129	$ 100	$ 50 per year

(1) Amounts reflected for research and development studies exclude amounts included in accounts payable and accrued clinical costs reflected on the balance sheet as of December 31, 2006.

(2) During 2004, 2005 and 2006, we executed a number of agreements to conduct clinical trials and pre-clinical studies for further development of our lead product, CORLUX, targeted for the treatment of the psychotic features of PMD. The agreements provide for termination by us upon forty-five days written notice or less. The exact amounts and timing of these obligations are dependent on the pace of activities of the various trials and studies. As of December 31, 2006, substantially all patient activities had been completed and remaining reporting activities are expected to be completed by the second quarter of 2007.

(3) Certain of the agreements discussed in footnotes (2) above relate to trials to be conducted in Europe. The contractual agreements for these trials are denominated in Euros, which are converted to U.S. Dollars at the time of invoicing. The remaining obligations under these agreements are subject to fluctuation based on the changes in the currency rates. See discussion under Item 7A Quantitative and Qualitative Disclosures about Market Risk.

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(4) In November 2006, we signed an agreement with a contract research organization to assist in the conduct of a weight-gain mitigation study to be performed in 2007. The total commitment remaining outstanding as of December 31, 2006 is approximately $336,000. The costs of this study will be reimbursed to us under a collaboration agreement with Lilly that was signed in October 2005.
(5) Our operating lease commitment relates to the lease of our office facility.
(6) During 2005, we entered into capital leases for the acquisition of certain pieces of office furniture and equipment.
(7) Under our cancelable license agreement with Stanford University, we are obligated to make nonrefundable minimum royalty payments of $50,000 annually for as long as we maintain our licenses from Stanford; however, these payments are creditable against future royalties.

We also have other contractual payment obligations, the timing of which is contingent on future events. Under our license agreement with Stanford University related to the patent covering the use of GR-II antagonists to treat the psychosis associated with PMD and early dementia, including early Alzheimer s disease, we are obligated to make milestone payments to Stanford of $50,000 upon filing of an NDA covering the licensed product and $200,000 upon FDA approval of the licensed product. The milestone payments payable to Stanford under these licenses are creditable against future royalties. In addition, our agreement with ScinoPharm Taiwan that provides for the manufacture and supply of the active pharmaceutical ingredient for CORLUX includes a minimum purchase commitment of $1,000,000 per year following the commercial launch of CORLUX. This agreement may be terminated by us at any time without penalty. On November 8, 2006, we signed an agreement with Produits Chimiques Auxiliaires et de Synthese SA ("PCAS") for the manufacture of mifepristone, the active pharmaceutical ingredient in CORLUX, for its development and commercial needs for an initial period of five years. The agreement provides for an automatic extension for one additional year unless either party gives twelve month s prior notice that it does not want the extension. There is no guaranteed minimum purchase commitment under this agreement. If PCAS is unable to manufacture the product for a consecutive six-month period, we have the right to terminate the agreement without penalty.

Net Operating Loss Carryforwards

At December 31, 2006 we had approximately $37.8 million of federal net operating loss carryforwards and approximately $640,000 in federal research and development tax credit carryforwards, as well as approximately $37.5 million of California net operating loss carryforwards and approximately $740,000 in California research and development tax credit carryforwards, available to offset any future taxable income we may generate. The federal and California net operating loss and tax credit carryforwards will expire beginning in 2019 and 2009, respectively. Our deferred tax assets have been offset by a full valuation allowance as the realization of such assets is uncertain. The Internal Revenue Code of 1986, as amended, places certain limitations on the annual amount of net operating loss and tax credit carryforwards that can be utilized in any particular year if certain changes in our ownership occur.

Critical Accounting Policies and Estimates

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results