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**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

AMENDMENT NO. 3

to

**FORM S-1**

**REGISTRATION STATEMENT**

UNDER

**THE SECURITIES ACT OF 1933**

**CORCEPT THERAPEUTICS INCORPORATED**

(Exact Name of Corporation as Specified in Its Charter)

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

**2834**  
(Primary Standard Industrial  
Classification Code Number)

**77-0487658**  
(I.R.S. Employer Identification No.)

**Corcept Therapeutics Incorporated**  
275 Middlefield Road, Suite A  
Menlo Park, CA 94025  
(650) 327-3270

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

**Joseph K. Belanoff, M.D.**  
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**Approximate date of commencement of proposed sale to the public:** As soon as practicable following the effectiveness of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act of 1933, please check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering:

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act of 1933, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering:

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act of 1933, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering:

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box:

**THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(A) OF THE SECURITIES ACT OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE SECURITIES AND EXCHANGE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(A), MAY DETERMINE.**

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[Table of Contents](#)

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

**PRELIMINARY PROSPECTUS**

**SUBJECT TO COMPLETION, DATED APRIL 14, 2004**



**5,000,000 Shares  
Common Stock**

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Corcept Therapeutics Incorporated is selling 5,000,000 shares of our common stock. The underwriters have a 30-day option to purchase up to an additional 750,000 shares from us, the selling stockholder, or both, to cover over-allotments, if any. We will not receive any proceeds from the sale of any shares sold by the selling stockholder.

This is an initial public offering of our common stock. We currently expect the initial public offering price to be \$12.00 per share. Our common stock has been approved for quotation on the Nasdaq National Market under the symbol "CORT".

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**INVESTING IN OUR COMMON STOCK INVOLVES RISKS. SEE "[RISK FACTORS](#)" BEGINNING ON PAGE 6.**

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	<b>Per Share</b>	<b>Total</b>
Public offering price	\$	\$
Underwriting discount	\$	\$
Proceeds, before expenses, to us	\$	\$

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

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**Thomas Weisel Partners LLC**

**Piper Jaffray**

**Legg Mason Wood Walker**  
Incorporated

The date of this prospectus is \_\_\_\_\_, 2004

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[Table of Contents](#)

TABLE OF CONTENTS

	<b>Page</b>
<a href="#">Prospectus Summary</a>	1
<a href="#">Risk Factors</a>	6
<a href="#">Special Note Regarding Forward-Looking Statements</a>	21
<a href="#">Use of Proceeds</a>	22
<a href="#">Dividend Policy</a>	22
<a href="#">Capitalization</a>	23
<a href="#">Dilution</a>	24
<a href="#">Selected Financial Data</a>	26
<a href="#">Management’s Discussion and Analysis of Financial Condition and Results of Operations</a>	27
<a href="#">Business</a>	34
<a href="#">Management</a>	48
<a href="#">Related Party Transactions</a>	57
<a href="#">Principal and Selling Stockholders</a>	59
<a href="#">Description of Capital Stock</a>	62
<a href="#">Shares Eligible for Future Sale</a>	65
<a href="#">Underwriting</a>	67
<a href="#">United States Federal Income Tax Consequences to Non-United States Holders</a>	70
<a href="#">Legal Matters</a>	73
<a href="#">Experts</a>	73
<a href="#">Where You Can Find Additional Information</a>	73
<a href="#">Index to Financial Statements</a>	F-1

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You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized any other person to provide you with different information. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any state where the offer or sale is not permitted. The information in this prospectus is complete and accurate as of the date on the front cover, but the information may have changed since that date.

In this prospectus, “Corcept,” “we,” “us” and “our” refer to Corcept Therapeutics Incorporated.

## PROSPECTUS SUMMARY

*The items in the following summary are described in more detail later in this prospectus. This summary provides an overview of the key aspects of this offering and does not contain all of the information you should consider. Therefore, you should also read the more detailed information set out in this prospectus, the financial statements and the other information contained in this prospectus.*

### Overview

We are a pharmaceutical company engaged in the development of drugs for the treatment of severe psychiatric and neurological diseases. Our lead product candidate, CORLUX™, is currently in Phase III clinical trials and has been granted “fast track” status by the FDA for the treatment of the psychotic features of psychotic major depression, a disorder that affects approximately three million people in the United States each year and for which there are no FDA-approved treatments. We have also initiated a clinical study to evaluate the tolerability and efficacy of CORLUX in improving cognition in patients with mild to moderate Alzheimer’s disease.

### Market Opportunity

Psychotic major depression, or PMD, is a serious psychiatric disorder that is more prevalent than either schizophrenia or manic depressive illness. The disorder is characterized by severe depression accompanied by psychosis. Psychosis is delusional thinking, hallucinations or both. 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. People with PMD are approximately 70 times more likely to commit suicide in their lifetime than the rest of the general population.

There is no treatment for PMD approved by the FDA. However, there are two treatment approaches currently used by psychiatrists: electroconvulsive therapy, or ECT, and combination drug therapy. Both of these approaches can have debilitating side effects. Even using these approaches, PMD patients often require lengthy and expensive hospital stays. Of the two approaches, ECT is generally considered more effective.

ECT involves passing an electrical current through the brain until the patient has a seizure. ECT 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 can reduce depressive and psychotic symptoms, the procedure can result in cognitive impairment including permanent memory loss, cardiovascular complications, headache, muscle ache and nausea. In addition, complications can arise from general anesthesia. 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.

Combination drug therapy involves the simultaneous administration of antidepressant and antipsychotic medications. Combination drug therapy is not as effective as ECT in relieving the symptoms of PMD and often requires three or more weeks before patients show improvement in their condition. In addition, combination drug therapy is associated with significant side effects, including weight gain, diabetes, sedation, permanent movement disorders and sexual dysfunction.

### CORLUX for the Treatment of PMD

CORLUX, also known as mifepristone, works by selectively blocking the binding of cortisol, a steroid hormone, to one of its two known receptors. Elevated levels and abnormal release patterns of cortisol have been implicated in a broad range of human disorders, including PMD. We have an exclusive license to a method of use patent covering the use of CORLUX for the treatment of the

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## [Table of Contents](#)

psychotic features of PMD. By modifying the level and release pattern of cortisol within the human body, we believe that CORLUX will be able to treat the psychotic features of PMD more quickly and effectively and with fewer side effects than is possible with currently available treatments. We have not submitted a New Drug Application, or NDA, to market CORLUX and we have no other commercially available products. We have no revenues and have incurred significant losses in each year of our operations.

In January 2001, we completed 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 a widely-used psychiatric rating scale, the BPRS. A clinically meaningful reduction in psychosis represents a reduction of symptoms that are readily recognizable by patients and physicians.

Based on the encouraging results from our dose finding trial, 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 the '02 study and '03 study, were double-blind, placebo-controlled safety and efficacy studies in which a total of 429 patients were enrolled. The '02 study 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. The '03 study demonstrated with statistical significance ( $p$  value = 0.01) 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. The '03 study 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 positive symptom subscale at day 7 sustained to day 28. 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.

In our fourth trial, we evaluated the safety of retreatment in patients with a favorable response to treatment in the '02 and '03 studies, and our analysis indicates that patients tolerated their retreatment well. Although the results of the '03 study were favorable, the FDA will determine, upon our filing of an NDA, whether CORLUX is sufficiently safe and effective to warrant marketing approval.

We do not expect that the results of the '02 and '03 studies will be sufficient for them to be considered as pivotal clinical trials by the FDA. We plan to initiate two pivotal clinical trials to support an NDA to market CORLUX in the United States. We expect these two pivotal trials to be completed in the first half of 2006. We submitted protocols for our two pivotal clinical studies to the FDA for a special protocol assessment in March 2004. These clinical trials may not, however, ultimately show that CORLUX is safe and effective.

### **Alzheimer's Program**

Alzheimer's disease is the most common form of dementia, accounting for approximately 50% of patients in the United States with progressive cognitive decline. More than 3.5 million people in the United States have Alzheimer's disease. With the aging of the population, this number continues to grow each year. Published studies have suggested that higher cortisol levels are associated with a more rapid decline in Alzheimer's patients.

We are conducting a clinical trial designed to demonstrate whether or not CORLUX will improve cognition in Alzheimer's patients. This is the first clinical trial conducted by us in Alzheimer's disease using CORLUX. The primary objective of this study is to assess the efficacy and tolerability of CORLUX in these patients. The study is a randomized, double-blind, parallel group comparison of the effects of CORLUX and placebo.

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[Table of Contents](#)

**GR-II Antagonist Platform**

We believe that CORLUX exerts its effects by blocking the action of cortisol at one of its two known receptors, known as the GR-II receptor. A receptor is a structure that accepts a chemical messenger and creates a signal for biologic action. We also believe that elevated levels and abnormal release patterns of cortisol are involved in several other psychiatric and neurological diseases. We have assembled a patent portfolio covering the treatment of psychiatric and neurological disorders that may benefit from drugs that block, or antagonize, 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 other disorders, including early dementia, mild cognitive impairment, psychosis associated with cocaine addiction and weight gain following treatment with antipsychotic medication. We also have patent applications filed for the use of GR-II antagonists in nine other diseases.

In addition, we have discovered, and filed patent applications for, two series of more selective GR-II antagonists that may eventually serve as follow-on compounds to CORLUX. These proprietary compounds bind to the GR-II receptor with a potency similar to that of CORLUX.

**Company Information**

We were incorporated in the State of Delaware on May 13, 1998. Our trademarks include Corcept™ and CORLUX. We have applied to register these trademarks with the U.S. Patent and Trademark Office. Other service marks, trademarks and tradenames referred to in this prospectus are the property of their respective owners.

Our principal executive offices are located at 275 Middlefield Road, Suite A, Menlo Park, California 94025, and our telephone number is (650) 327-3270.

**THE OFFERING**

Common stock offered	5,000,000 shares
Common stock to be outstanding after this offering	23,142,128 shares
Over-allotment option	750,000 shares
Use of proceeds	We intend to use the net proceeds of this offering to fund clinical trials, preclinical testing, manufacturing and other research and development activities; general and administrative expenses; and working capital and other general corporate purposes. We will not receive any proceeds from the shares of common stock sold by the selling stockholder, if any. See the discussion of "Use of Proceeds" for a more detailed description.
Proposed Nasdaq National Market symbol	CORT

The number of shares of our common stock outstanding after this offering is based on 18,142,128 shares outstanding on March 31, 2004 and does not take into account:

- 730,500 shares issuable upon exercise of outstanding options to purchase our common stock at a weighted average exercise price of \$6.62 per share;
- 3,000,000 shares available for future issuance under our equity incentive plan; and
- 43,640 shares of our common stock issuable upon conversion of a promissory note.

Unless otherwise indicated, all information in this prospectus:

- assumes no exercise of the underwriters' over-allotment option to purchase up to 750,000 shares;
- reflects the conversion of all outstanding shares of our preferred stock into 8,807,146 shares of our common stock upon the completion of this offering; and
- assumes the filing of our amended and restated certificate of incorporation.

[Table of Contents](#)

**SUMMARY FINANCIAL DATA**  
(in thousands, except per share data)

	Years Ended December 31,					Period from inception (May 13, 1998) to December 31, 2003
	1999	2000	2001	2002	2003	
<b>Statements of Operations Data:</b>						
Operating expenses:						
Research and development*	\$ 140	\$ 1,319	\$ 5,390	\$ 13,150	\$ 8,108	\$ 28,108
General and administrative*	174	577	2,616	5,653	1,887	10,917
<b>Total operating expenses</b>	<b>314</b>	<b>1,896</b>	<b>8,006</b>	<b>18,803</b>	<b>9,995</b>	<b>39,025</b>
Loss from operations	(314)	(1,896)	(8,006)	(18,803)	(9,995)	(39,025)
Interest and other income, net	4	50	552	299	182	1,087
<b>Net loss</b>	<b>\$ (310)</b>	<b>\$ (1,846)</b>	<b>\$ (7,454)</b>	<b>\$ (18,504)</b>	<b>\$ (9,813)</b>	<b>\$ (37,938)</b>
Net loss per share:						
Basic and diluted	\$ (0.09)	\$ (0.35)	\$ (1.25)	\$ (2.50)	\$ (1.13)	
<b>Weighted average shares—basic and diluted</b>	<b>3,569</b>	<b>5,305</b>	<b>5,981</b>	<b>7,392</b>	<b>8,650</b>	
Pro forma net loss per share:						
Basic and diluted					\$ (0.55)	
<b>Weighted average shares—basic and diluted</b>					<b>17,758</b>	
* Includes non-cash stock-based compensation of the following:						
Research and development	\$ 7	\$ 90	\$ 1,214	\$ 1,957	\$ 551	\$ 3,819
General and administrative	—	—	680	2,145	(308)	2,517
<b>Total stock-based compensation</b>	<b>\$ 7</b>	<b>\$ 90</b>	<b>\$ 1,894</b>	<b>\$ 4,102</b>	<b>\$ 243</b>	<b>\$ 6,336</b>

As of December 31, 2003

	Actual	As Adjusted
<b>Balance Sheet Data:</b>		
Cash, cash equivalents and short-term investments	\$ 11,577	\$ 66,277
Working capital	10,729	65,429
Total assets	11,781	66,481
Long-term liabilities	524	524
Convertible preferred stock	41,716	—
Deficit accumulated during the development stage	(37,937)	(37,937)
Total stockholders' equity (net capital deficiency)	(31,473)	64,943

The as adjusted balance sheet data above assumes the issuance of 5,000,000 shares of our common stock in this offering at an assumed initial public offering price of \$12.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, and the automatic conversion of all of the outstanding shares of our convertible preferred stock into 8,807,146 shares of common stock upon the completion of this offering.

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



## RISK FACTORS

*You should carefully consider the risks described below before making an investment decision. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this prospectus, including our financial statements and related notes.*

### Risks Related to Our Business

#### **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 future clinical trials support 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. Our net losses in 2001, 2002 and 2003 were approximately \$7.5 million, \$18.5 million and \$9.8 million, respectively. As of December 31, 2003, we had an accumulated deficit of approximately \$37.9 million. We do not know when or if we will generate product revenue. We expect our research and development expenses to increase in connection with the planned pivotal clinical trials and other development activities for other product candidates. We expect to incur significant sales and marketing expenses related to our market research activities for CORLUX and our development of a sales and marketing staff. 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.

#### **We depend heavily on the success of our lead product candidate, CORLUX, which is still in development. 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 successful development, approval and commercialization of CORLUX. We plan to conduct, in the United States, at least two pivotal clinical trials for CORLUX for the treatment of the psychotic features of PMD before submitting an application for FDA approval. While we expect that these trials will be completed before the end of the first half of 2006, we cannot assure you that this will occur. We may decide, or the FDA may require us, to pursue additional clinical trials or other studies on CORLUX. If we are unable to successfully conclude our clinical development program and obtain regulatory approval for CORLUX for the treatment of the psychotic features of PMD, we may be unable to generate revenue and our stock price may decline.

Many factors could harm our efforts to develop and commercialize CORLUX, including:

- negative, inconclusive or otherwise unfavorable results from our clinical development program;
- delays in our clinical development program;
- rapid technological change making CORLUX obsolete;
- 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;

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## [Table of Contents](#)

- 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 trials of CORLUX for the treatment of the psychotic features of PMD do not demonstrate safety and efficacy, or if the clinical trials are delayed or terminated, our business will be harmed.**

To gain regulatory approval from the FDA to market CORLUX, our planned pivotal clinical trials must demonstrate the safety and efficacy of CORLUX for the treatment of the psychotic features of PMD. Clinical development is a long, expensive and uncertain process and is subject to delays. 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 have obtained favorable results in some of our clinical trials, these results have not been sufficient to support an application for FDA approval. Our future clinical trials may not demonstrate that CORLUX is effective.

In addition, data obtained from pivotal clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. To obtain marketing approval, we may decide, or the FDA or other regulatory authorities may require us, to pursue additional pivotal clinical or other studies. These trials could significantly delay the approval and commercialization of CORLUX and would require us to commit significant additional financial resources. Even after we conduct these additional clinical trials, we may not receive regulatory approval to market CORLUX.

We intend to submit the protocol for our first pivotal clinical trial to the FDA for a special protocol assessment, or SPA, pursuant to which the FDA will assess whether the protocol is adequate to meet the scientific and regulatory requirements necessary to support marketing approval of CORLUX for the treatment of the psychotic features of PMD. In connection with the assessment, we may decide, or the FDA may require us, to modify the protocol by, for example, changing the proposed primary endpoint, the size of the study or otherwise, which may result in a delay in the completion of our clinical trials.

Many other factors could delay or result in termination of our clinical trials, including:

- negative or inconclusive results;
- slow patient enrollment or 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.

In addition to our pivotal trials, we plan to conduct carcinogenicity studies and toxicology tests in support of our planned NDA to market CORLUX for the treatment of the psychotic features of PMD. We cannot assure you that these studies and tests will produce results that support our planned NDA, or these studies and tests may delay commercialization of CORLUX.

**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 plan to enroll an aggregate of approximately 500 patients in two randomized, double-blind, placebo-controlled trials to further assess the safety and efficacy of CORLUX for the treatment of the psychotic features of PMD. If successful, we expect to use these trials as pivotal clinical trials in support of an NDA to market CORLUX in the United States. We rely on clinical investigators and clinical sites to enroll these patients and other third parties to manage the trial 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 pivotal clinical trials. If these clinical

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## [Table of Contents](#)

investigators and clinical sites fail to enroll a sufficient number of patients in our pivotal clinical trials, we will be unable to complete these trials, which could prevent us from obtaining regulatory approvals for CORLUX.

We have contracted with Scirex Corporation and PPD Development, LP, or PPD, to perform investigator supervision, data collection and analysis in our pivotal clinical trials. In addition, we have identified over 30 clinical sites for our pivotal clinical trials and are in the process of qualifying those sites and negotiating contracts with them to conduct clinical testing. We may not be able to maintain these relationships with Scirex and PPD or to establish relationships with qualified clinical sites without undue delays or excessive expenditures. Any delay in contracting with qualified clinical sites to conduct our clinical testing may delay the completion of our pivotal clinical trials or the commercialization of CORLUX.

Our agreements with clinical investigators and clinical sites for clinical testing and with Scirex and PPD for trial management services place substantial responsibilities on these parties, which could result in delays in, or termination of, our pivotal 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, our pivotal clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for, or successfully commercialize, CORLUX.

**If we are unable to obtain or maintain regulatory approval, we will be limited in our ability to commercialize our products, 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.

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 drug approval process. The FDA can deny, delay or limit approval of a product candidate for many reasons including:

- the failure to demonstrate 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 products.

Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the indicated uses for which the drug may be marketed or contain requirements for potentially costly post-marketing follow-up studies. In addition, if the FDA approves any of our product

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## [Table of Contents](#)

candidates, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping for the drug will be subject to extensive regulatory requirements. The subsequent discovery of previously unknown problems with the drug, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the drug, and could include withdrawal of the drug from the market.

### **Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products abroad.**

We intend to market our products in international markets. Outside the United States, we can market 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, and in some cases, additional risks, associated with the FDA approval process. 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 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 products in any market.

### **The “fast track” designation for development 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 drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA “fast track” designation for a particular indication. Marketing applications filed by sponsors of products 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 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 drugs 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 currently no FDA-approved treatment for PMD, there are two treatment approaches currently used by psychiatrists: ECT and combination drug 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;

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## Table of Contents

- 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 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. Additionally, even though appropriate measures will be required to avoid prescribing 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 have no manufacturing capabilities and we currently depend on third parties who are single source suppliers to manufacture CORLUX. 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, manufacturing any products. We have a contract with ScinoPharm Taiwan, Ltd., a manufacturer of the active pharmaceutical ingredient, or API, of mifepristone and a contract with KP Pharmaceutical Technology, Inc., a tablet manufacturer for CORLUX. If we are unable to reach an agreement acceptable to us with a second API manufacturer that we have identified, ScinoPharm will be a single source supplier. Our agreement with ScinoPharm is terminable by either party at any time. The possible second API manufacturer we have identified and ScinoPharm both obtain the raw material they use to manufacture mifepristone from the same single source supplier. KP Pharmaceutical is a single source supplier to us as well. Our agreement with KP Pharmaceutical is effective through February 2005, but may be extended by mutual agreement. We have not yet identified an alternative tablet manufacturer. 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 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.

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## [Table of Contents](#)

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 products, 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 requires 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 products are on the market, we may be required to perform lengthy additional clinical trials, change the labeling of our products or withdraw our 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 products are on the market:

- regulatory authorities may withdraw their approvals;
- we may be required to reformulate our products, conduct additional clinical trials, make changes in labeling of our 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.

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

**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 products.**

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 two 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 two 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. 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, a third party has alleged that it also has rights to the technology that led to the patent for the use of GR-II antagonists to treat the psychotic features of PMD. The third party is a prior employer of one of our founders, Dr. Alan Schatzberg and it alleges that the invention of the technology underlying this patent was conceived by Dr. Schatzberg and/or another employee of the employer while the two were employed by the third party. We believe that the invention was actually conceived by Drs. Schatzberg and Belanoff while they were employed by Stanford University and that the patent was

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## [Table of Contents](#)

appropriately assigned by them to Stanford University. We believe we will prevail if this matter is pursued against us. If, however, the third party's claims were successful, it would have rights to market GR-II antagonists to treat the psychotic features of PMD or to license those rights to others and our business could be materially harmed. In addition, Akzo Nobel has filed an observation in our exclusively licensed European patent application with claims directed to PMD, in which Akzo Nobel challenges the claims of that patent application. We plan to vigorously rebut the points raised by Akzo. During prosecution of the U.S. patent for the use of CORLUX to treat the psychotic features of PMD, the U.S. Patent and Trademark Office considered issues similar to those raised by Akzo and the U.S. patent was ultimately granted. We cannot assure you, however, that the European Patent Office will reach the same conclusion. Should Akzo's arguments persuade the European Patent Office that the claims should not issue, we will not have the benefit of patent protection in Europe for CORLUX to treat the psychotic features of PMD.

We have exclusively licensed three issued U.S. patents and one patent application from Stanford University for the use of GR-II antagonists in the treatment of PMD and early dementia, including early Alzheimer's disease, and for increasing blood-brain barrier permeability. 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 these agreements. 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 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 substantially 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.

### **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 products 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

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## [Table of Contents](#)

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, 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 one of our 10 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 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, early dementia, mild cognitive impairment, psychosis associated with cocaine addiction and weight gain following treatment with antipsychotic medication, in addition to nine U.S. method of use patent applications covering GR-II antagonists for the treatment of a number of other neurological and psychiatric disorders and two 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 that the use of GR-II antagonists in these patient populations has unacceptable side effects or is otherwise not safe.

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. Our ongoing discovery research program may fail to generate commercially viable product candidates in spite of the resources we are dedicating 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. 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.



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## [Table of Contents](#)

### **Failure to raise additional capital or generate the significant capital necessary to expand our operations and invest in new products could reduce our ability to compete.**

We anticipate that our existing capital resources and the net proceeds from this offering will enable us to maintain currently planned operations through at least the next two years. However, our expectations are based on our current operating plan, which may change as a result of many factors, including:

- the timing of commercialization of CORLUX and future product candidates;
- the results of our research efforts and clinical trials;
- developments or disputes concerning patents or proprietary rights, including announcements of claims of infringement, interference or litigation against us or our licensors;
- changes in the reimbursement policies of third-party insurance companies or government agencies;
- actual or anticipated fluctuations in our operating results; and
- changes in our growth rates.

Consequently, we may need additional funding sooner than anticipated. We currently have no credit facility or committed sources of capital. Our inability to raise capital would harm our business and product development efforts.

In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in dilution to our then-existing stockholders.

### **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 products are not effective, whether by participants in our clinical trials or by patients using our products. A product liability claim may damage our reputation by raising questions about our products' safety or efficacy and could limit our ability to sell a product by preventing or interfering with product commercialization. In addition, the active ingredient in CORLUX is used to terminate pregnancy. Therefore, necessary and strict precautions must be taken by clinicians using the drug in our clinical trials and, if approved by the FDA, physicians prescribing the drug to women with childbearing potential. 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 products 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 inhibit the commercialization of our products. 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 products, our liability could exceed our total assets.

### **We have no sales and marketing staff 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 and marketing staff. 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

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## [Table of Contents](#)

and sell our 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 will need to substantially increase the size of our organization, and we may experience difficulties in managing growth.**

As we expand our research and development efforts and develop a sales and marketing organization, we expect to experience substantial 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 capacity, scalability and performance 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 we are unable to obtain acceptable prices or adequate reimbursement for our products 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 drugs. The commercial success of our drugs in both domestic and international markets is substantially dependent on whether third-party coverage and reimbursement is available for the ordering of our drugs by the medical profession for use by their patients. 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 drugs, and, as a result, they may not cover or provide adequate payment for our drugs. The continuing efforts of 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 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

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## [Table of Contents](#)

influence the purchase of health care services and products and may result in lower prices for our products or the exclusion of our 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 drug therapy.

Combination drug therapy consists of the use of antipsychotic and antidepressant drugs, 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' Clozaryl, 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. While we are unaware of any other ongoing clinical trials for new drugs for the treatment of PMD, other companies may also be developing new drug 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 drug 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 substantially 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 drugs, 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 drug 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.

### **Rapid technological change could make our products obsolete.**

Pharmaceutical technologies have undergone rapid and significant change and we expect that they will continue to do so. 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 products obsolete or uneconomical.

### **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

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## [Table of Contents](#)

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, 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 currently have no commitments, agreements or plans for any acquisitions. The process of acquiring rights to another GR-II antagonist 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 GR-II antagonist. Future acquisitions could dilute your 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 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 products. 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.

### **Risks Related to this Offering**

#### **The market price of our common stock may experience extreme price and volume fluctuations.**

Prior to this offering, there has been no public market for our common stock. An active trading market for our common stock may not develop or be sustained following this offering. We have determined the initial public offering price with the representatives of the underwriters based on several factors. This price may vary after this offering. Our stock price is likely to be volatile. The stock market in general and securities of pharmaceutical companies in particular have been highly volatile and may continue to be highly volatile in the future. The following factors, in addition to other risk factors described in this section and general market and economic conditions, may have a significant impact on the market price of our common stock:

- the timing of commercialization of CORLUX and future product candidates;
- announcements of technological innovations or new products by us or our competitors;
- announcement of FDA approval or non-approval of our products or delays in the FDA review process;
- the results of our research and development efforts and clinical trials;
- developments or disputes concerning patents or proprietary rights, including announcements of claims of infringement, interference or litigation against us or our licensors;

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## Table of Contents

- announcements concerning our competitors, or the biotechnology, specialty pharmaceutical or pharmaceutical industry in general;
- public concerns as to the safety of CORLUX and future product candidates or our competitors' products;
- changes in the reimbursement policies of third-party insurance companies or government agencies;
- actual or anticipated fluctuations in our operating results;
- changes in our growth rates or our competitors' growth rates;
- changes in securities analysts recommendations regarding our common stock or our competitors' common stock;
- changes in financial estimates or recommendations by securities analysts;
- sales of large blocks of our common stock;
- political considerations relating to mifepristone;
- the absence of a public market for our securities prior to this offering;
- changes in accounting principles or practices; and
- the loss of any of our key scientific or management personnel.

Significant volatility may lead to securities class action litigation against us. Whether or not meritorious, litigation brought against us could result in substantial costs and a diversion of management's attention and resources. Our insurance to cover claims of this sort may not be adequate.

**Securities analysts may not 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 may elect not to provide research coverage of our common stock after the completion of this offering. If securities analysts do not cover our common stock after the completion of this offering, the 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 on 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, recently-adopted 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 will lead to a number of fundamental changes in how analysts are reviewed and compensated. In particular, many investment banking firms will be 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 following this offering could harm the market price of our common stock. As additional shares of our common stock become available for resale in the public market, the supply of our common stock will increase, which could decrease the price. Subject to applicable volume and other resale restrictions, there will be approximately 18,142,128 million additional shares of common stock eligible for sale beginning 180 days after the effective date of this prospectus upon the expiration of lock-up arrangements between our stockholders and the underwriters.

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[Table of Contents](#)

**Our officers, directors and principal stockholders will control 71% of our common stock after this offering and will be able to significantly influence corporate actions.**

After this offering, our officers, directors and principal stockholders will control approximately 71% 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, will 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 substantially 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.

**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 guidance from relevant accounting authorities, including the SEC. For example, we currently are not required to record stock-based compensation charges if an employee's stock option exercise price equals or exceeds the fair value of our common stock at the date of grant. The Financial Accounting Standards Board has announced its support for recording expense for the fair value of stock options granted. If we were to change our accounting policy to record expense for the fair value of stock options granted and retroactively restate all prior periods presented, then our operating expenses could increase. We rely heavily on stock options to compensate existing employees and attract new employees. If we are required to expense stock options, we may then 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 as in effect immediately after this offering 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

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[Table of Contents](#)

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.

**We may spend a substantial portion of the net proceeds of this offering in ways that do not yield a favorable return.**

We have broad discretion to spend the net proceeds from this offering. As a result, investors in this offering will be relying upon our judgment with only limited information about our specific intentions regarding the use of proceeds. We cannot assure you that the proceeds will be applied in a manner that yields a favorable return.

**New investors will experience immediate and substantial dilution in the value of their common stock following this offering.**

The assumed initial public offering price is substantially higher than the book value per share of our common stock. Investors purchasing common stock in this offering will, therefore, incur immediate dilution of \$9.19 in net tangible book value per share of common stock, based on an assumed initial public offering price of \$12.00 per share. Investors will incur additional dilution upon the exercise of outstanding stock options. As a result of this dilution, investors purchasing stock in this offering may receive significantly less than the full purchase price that they paid for the shares purchased in this offering in the event of a liquidation.

### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. The forward-looking statements are contained principally in the sections entitled “Summary,” “Risk Factors,” “Use of Proceeds,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business.” These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements 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 complete our clinical trials;
- our ability to market, commercialize and achieve market acceptance for CORLUX or other future product candidates;
- our estimated use of the proceeds of this offering;
- our estimates for future performance; and
- our estimates regarding our capital requirements and our needs for additional financing.

In some cases, you can identify forward-looking statements by terms such as “anticipates,” “believes,” “could,” “estimates,” “expects,” “may,” “plans,” “potential,” “predicts,” “projects,” “should,” “will,” “would,” and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. We discuss many of these risks in this prospectus in greater detail under the heading “Risk Factors.” Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our estimates and assumptions only as of the date of this prospectus. You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect.

Except as required by law, we assume no obligation to update such forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in such forward-looking statements, even if new information becomes available in the future.



### **USE OF PROCEEDS**

We estimate that the net proceeds from the sale of 5,000,000 shares of common stock that we are selling in this offering will be approximately \$54.7 million, based on an assumed initial public offering price of \$12.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters' over-allotment option is exercised in full and none of these shares are sold by the selling stockholder, we estimate that we will receive net proceeds of approximately \$63.1 million. We will not receive any proceeds from the sale of common stock by the selling stockholder.

We intend to use the net proceeds of this offering to fund our operations, including approximately \$34.5 million for clinical trials, preclinical testing, manufacturing and other research and development activities, and approximately \$9.0 million for general and administrative expenses, and the remainder for working capital and other general corporate purposes.

The amounts actually expended for these purposes may vary significantly and will depend on a number of factors, including the amount of our future revenues, expenses and the other factors described under "Risk Factors." While we have no present understandings, commitments or agreements to enter into any potential acquisitions, we may also use a portion of the proceeds for the acquisition of, or investment in, technologies or products that complement our business. In addition, we will retain broad discretion in the allocation of the net proceeds of this offering. Pending these uses, we intend to invest the net proceeds from this offering in interest-bearing, investment-grade securities.

### **DIVIDEND POLICY**

Since our incorporation, we have not declared or paid any cash dividends on our common stock and do not expect to do so in the foreseeable future. We currently intend to retain all available funds for use in the operation and expansion of our business.

[Table of Contents](#)**CAPITALIZATION**

The following table sets forth our cash, cash equivalents, and short-term investments, and capitalization as of December 31, 2003 on an actual and pro forma as adjusted basis. This table does not include:

- 470,500 shares issuable upon exercise of outstanding options to purchase our common stock at a weighted average exercise price of \$5.46 per share;
- 3,000,000 shares available for future issuance under our equity incentive plan; and
- 43,640 shares of our common stock issuable upon conversion of a promissory note.

This table should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operation” and the financial statements and related notes included elsewhere in this prospectus.

	As of December 31, 2003	
	Actual	Pro Forma As Adjusted
Cash, cash equivalents and short-term investments	\$ 11,577,283	\$ 66,277,283
Convertible note payable	\$ 523,689	\$ 523,689
Convertible preferred stock, \$0.001 par value, 10,000,000 shares authorized, and 6,768,558 shares issued and outstanding, actual (no shares authorized or outstanding pro forma as adjusted)	41,715,974	—
Stockholders’ equity (net capital deficiency):		
Preferred stock, \$0.001 par value, 10,000,000 shares authorized and no shares outstanding, pro forma		—
Common stock, \$0.001 par value, 30,000,000 and 140,000,000 shares authorized, actual and pro forma as adjusted, respectively; 9,334,982 shares issued and outstanding, actual; 23,142,128 shares issued and outstanding pro forma as adjusted	9,335	23,142
Additional paid-in capital	8,981,827	105,383,994
Stockholder notes receivable	(246,258)	(246,258)
Deferred compensation	(2,279,524)	(2,279,524)
Deficit accumulated during the development stage	(37,937,426)	(37,937,426)
Accumulated other comprehensive loss	(643)	(643)
Total stockholders’ equity (net capital deficiency)	(31,472,689)	64,943,285
Total capitalization	\$ 10,766,974	\$ 65,466,974

The pro forma as adjusted information gives effect to the sale in this offering of 5,000,000 shares of common stock at an assumed initial public offering price of \$12.00 per share, less underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information also assumes the conversion of all outstanding shares of preferred stock into 8,807,146 shares of common stock upon the completion of this offering.

## DILUTION

The actual net tangible book value as of December 31, 2003 was \$(31.5) million, or \$(3.37) per share, based on 9,334,982 shares of common stock outstanding. Actual net tangible book value per share represents our total tangible assets less total liabilities and convertible preferred stock by the actual number of outstanding shares of our common stock.

The pro forma net tangible book value of our common stock as of December 31, 2003 was \$10.2 million, or approximately \$0.56 per share, based on 18,142,128 shares of common stock outstanding pro forma. Pro forma net tangible book value per share represents our total tangible assets less our total liabilities divided by the number of shares of our common stock outstanding after giving effect to the conversion of all outstanding shares of our convertible preferred stock into common stock upon the completion of this offering.

After giving effect to the sale by us of 5,000,000 shares of our common stock in this offering at an assumed initial public offering price of \$12.00 per share, less the underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2003 would have been \$64.9 million, or approximately \$2.81 per share. This represents an immediate increase in pro forma net tangible book value of \$2.25 per share to existing stockholders and an immediate dilution of \$9.19 per share to new investors purchasing our common stock in this offering.

The following table illustrates the per share dilution to new investors:

Assumed initial public offering price per share	\$ 12.00
Actual net tangible book value per share as of December 31, 2003	\$ (3.37)
Pro forma increase in net tangible book value per share attributable to the conversion of convertible preferred stock	3.93
Pro forma net tangible book value per share as of December 31, 2003	\$ 0.56
Increase in pro forma net tangible book value per share attributable to this offering	2.25
Adjusted pro forma net tangible book value per share after this offering	2.81
Dilution in per share to new investors in this offering	\$ 9.19

The following table summarizes, on a pro forma as adjusted basis as of December 31, 2003, the differences between the number of shares of common stock purchased from us, the total price and the average price per share paid by existing stockholders and by the new investors, before deducting the underwriting discounts and commissions and estimated offering expenses payable by us, at an assumed initial public offering price of \$12.00 per share.

	Shares Purchased		Total Consideration		Average Price Per share
	Number	Percent	Amount	Percent	
Existing stockholders	18,142,128	78%	\$ 42,166,663	41%	\$ 2.32
New investors	5,000,000	22%	60,000,000	59%	\$ 12.00
<b>Total</b>	<b>23,142,128</b>	<b>100%</b>	<b>\$ 102,166,663</b>	<b>100%</b>	

If the underwriters' over-allotment option is exercised in full and none of these shares are sold by the selling stockholder, the number of shares held by the new investors will be increased to 5,750,000, or approximately 24% of the total numbers of shares of our common stock outstanding after this offering.

The existing stockholder amounts in the table above have been calculated on a pro forma basis, which includes shares outstanding as of December 31, 2003, including the conversion of all outstanding shares of preferred stock into 8,807,146 of common stock upon the completion of this offering, but excludes:

- 470,500 shares issuable upon exercise of outstanding options to purchase our common stock at a weighted average exercise price of \$5.46 per share;

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[Table of Contents](#)

- 3,000,000 shares available for future issuance under our equity incentive plan; and
- 43,640 shares of our common stock issuable upon conversion of a promissory note.

After this offering and assuming the exercise in full of all options outstanding, vested and exercisable as of December 31, 2003, our pro forma net tangible book value per share as of December 31, 2003 would be \$2.81 per share, representing an immediate increase in net tangible book value of \$2.24 per share to existing stockholders and an immediate dilution in net tangible book value of \$9.19 per share to new investors.

[Table of Contents](#)

**SELECTED FINANCIAL DATA**  
(in thousands, except per share data)

The selected financial data set forth below are derived from our financial statements. The statements of operations data for the years ended December 31, 2001, 2002, and 2003 and for the period from inception (May 13, 1998) to December 31, 2003 and the balance sheet data as of December 31, 2002 and 2003 are derived from our audited financial statements included in this prospectus. The statements of operations data for the years ended December 31, 1999 and 2000, and the balance sheet data as of December 31, 1999, 2000 and 2001 have been derived from our audited financial statements which are not included in this prospectus. 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 prospectus.

	Year Ended December 31,					Period from inception (May 13, 1998) to December 31, 2003
	1999	2000	2001	2002	2003	
<b>Statements of Operations Data:</b>						
Operating expenses:						
Research and development*	\$ 140	\$ 1,319	\$ 5,390	\$ 13,150	\$ 8,108	\$ 28,108
General and administrative*	174	577	2,616	5,653	1,887	10,917
<b>Total operating expenses</b>	<b>314</b>	<b>1,896</b>	<b>8,006</b>	<b>18,803</b>	<b>9,995</b>	<b>39,025</b>
Loss from operations	(314)	(1,896)	(8,006)	(18,803)	(9,995)	(39,025)
Interest and other income, net	4	50	552	299	182	1,087
<b>Net loss</b>	<b>\$ (310)</b>	<b>\$ (1,846)</b>	<b>\$ (7,454)</b>	<b>\$ (18,504)</b>	<b>\$ (9,813)</b>	<b>\$ (37,938)</b>
Net loss per share:						
Basic and diluted	\$ (0.09)	\$ (0.35)	\$ (1.25)	\$ (2.50)	\$ (1.13)	
<b>Weighted average shares – basic and diluted</b>	<b>3,569</b>	<b>5,305</b>	<b>5,981</b>	<b>7,392</b>	<b>8,650</b>	
Pro forma net loss per share:						
Basic and diluted					\$ (0.55)	
<b>Weighted average shares – basic and diluted</b>					<b>17,758</b>	
* Includes non-cash stock-based compensation of the following:						
Research and development	\$ 7	\$ 90	\$ 1,214	\$ 1,957	\$ 551	\$ 3,819
General and administrative	—	—	680	2,145	(308)	2,517
<b>Total non-cash stock-based compensation</b>	<b>\$ 7</b>	<b>\$ 90</b>	<b>\$ 1,894</b>	<b>\$ 4,102</b>	<b>\$ 243</b>	<b>\$ 6,336</b>

	As of December 31,					
	1999	2000	2001	2002	2003	
<b>Balance Sheet Data:</b>						
Cash, cash equivalents and short-term investments		\$ 416	\$ 1,000	\$ 22,980	\$ 21,543	\$ 11,577
Working capital		375	(227)	22,224	20,222	10,729
<b>Total assets</b>		<b>421</b>	<b>1,046</b>	<b>24,259</b>	<b>21,795</b>	<b>11,781</b>
Long-term liabilities		—	—	463	503	524
Convertible preferred stock		623	1,803	29,914	41,716	41,716
<b>Total stockholders’ equity (net capital deficiency)</b>		<b>(244)</b>	<b>(2,000)</b>	<b>(7,539)</b>	<b>(21,941)</b>	<b>(31,473)</b>

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

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion should be read in conjunction with our financial statements and related notes appearing elsewhere in this prospectus. This discussion may contain forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of selected factors, including those set forth under "Risk Factors" and elsewhere in this prospectus. We believe that the section entitled "Risk Factors" includes all material risks that could harm our business.*

### Overview

We are a pharmaceutical company engaged in the development of drugs for the treatment of severe psychiatric and neurological diseases. Since our inception in May 1998, our activities have primarily been associated with the development of our lead product, CORLUX™, for the treatment of the psychotic features of PMD under an exclusive patent license from Stanford University. We have been granted "fast track" status by the FDA with respect to CORLUX for the treatment of the psychotic features of PMD. We have completed the analysis of our first two large, double-blind trials, and plan to initiate additional clinical trials in 2004, including two pivotal clinical trials in the United States to support our NDA. We also initiated a clinical study in 2003 to explore the tolerability and efficacy of CORLUX in improving cognition in patients with mild to moderate Alzheimer's disease. Specifically, our activities have included:

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

Historically, we have financed our operations and internal growth primarily through private placements of our preferred stock rather than through collaborative or partnership agreements. Therefore, we have no research funding or collaborative payments payable to us and the funding we received from one research institution is repayable to that organization subject to the terms of our convertible note.

We are in the development stage and have incurred significant losses since our inception because we have not generated any revenue, and do not expect to generate any revenue for the foreseeable future. As of December 31, 2003 we had a deficit accumulated during the development stage of approximately \$37.9 million. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for CORLUX, drug discovery research, non-clinical activities such as toxicology and carcinogenicity studies, manufacturing process development and regulatory activities, as well as general and administrative expenses. We expect to continue to incur net losses over the next several years as we complete our CORLUX clinical trials, 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 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 develop, obtain regulatory approval for, manufacture and market our lead product.

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[Table of Contents](#)**Results of Operations****Years Ended December 31, 2003 and 2002**

*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 clinical trial preparations, enrollment and monitoring expenses, regulatory costs and the costs of manufacturing development.

Research and development expenses decreased 39% to \$8.1 million for the year ended December 31, 2003, from \$13.2 million for the year ended December 31, 2002. This decrease of \$5.1 million was primarily attributable to decreases in preclinical and clinical trial expenses of \$4.3 million due to the completion of one double-blind PMD clinical trial at the end of 2002 partially offset by the costs of the early-stage Alzheimer's disease trial commenced in 2003. The decrease was also attributable to a decrease in non-cash stock-based compensation of \$1.4 million due to the graded-vesting method used to determine non-cash employee stock-based compensation, which results in greater expense in earlier years. We also experienced decreased costs of \$1.3 million related to clinical supplies, as no purchases of clinical supplies were required in 2003, and to certain manufacturing capacity development projects that were completed in 2002. Those decreases were partially offset by an increase in GR-II antagonists drug discovery research activities in 2003 resulting in additional research and development expenses of \$1.9 million.

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

Project	Year ended December 31,	
	2003	2002
	(in thousands)	
CORLUX for the treatment of the psychotic features of PMD	\$ 4,659	\$ 11,073
CORLUX for the treatment of early-stage Alzheimer's disease	838	12
Drug discovery research	2,059	108
Total research and development expense (excluding non-cash stock-based compensation)	\$ 7,556	\$ 11,193

We expect that research and development expenditures will increase substantially during 2004 and subsequent years due to the continuation and expansion of clinical trials of CORLUX for PMD and early-stage Alzheimer's disease, the initiation of trials of CORLUX for other indications and additional study expenditures for new GR-II antagonists and other pharmaceutical candidates.

Many factors can affect the cost and timing of our trials including inconclusive results requiring additional clinical trials, slow patient enrollment, adverse side effects among patients, insufficient supplies for our clinical trials and real or perceived lack of effectiveness or safety of our trials. In addition, the development of all of our products 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 products.

*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 decreased 67% to \$1.9 million for the year ended December 31, 2003, from \$5.7 million for the year ended December 31, 2002. This decrease of \$3.8 million was primarily attributable to a decrease in non-cash stock-based compensation of \$2.5 million. Included in the total decrease is the reversal of \$1.4 million expense to reverse stock-based compensation expense as a result of using the graded vesting method for unvested options forfeited by terminated employees and by a director due to a reduction in service. In addition, there was a reduction of \$1.2 million in professional service fees, \$1.0 million of which related to the expenses of a proposed public offering withdrawn in October 2002. We expect that general and administrative expenditures will

## Table of Contents

increase during 2004 and subsequent years due to increasing payroll and non-cash stock-based compensation, commercialization efforts, business development costs associated with growth in our market research, and expanded operational infrastructure. An increase in general and administrative expenses is also expected to accompany our infrastructure growth associated with our public company reporting activities.

*Interest and other income, net.* Interest and other income, net, decreased to \$203,000 for the year ended December 31, 2003 from \$320,000 for the year ended December 31, 2002. The decrease was principally attributable to lower average cash, cash equivalents, and short-term investments balances during the year ended December 31, 2003 as compared to the year ended December 31, 2002.

*Interest Expense.* Interest expense of \$21,000 for the years ended December 31, 2003 and 2002 represents interest on our convertible note payable to the Institute for the Study of Aging.

### Years Ended December 31, 2002 and 2001

*Research and development expenses.* Research and development expenses increased 144% to \$13.2 million for the year ended December 31, 2002, from \$5.4 million for the year ended December 31, 2001. This increase of \$7.8 million was primarily attributable to preclinical and clinical trial expenses increasing by \$5.5 million as two double-blind PMD clinical trials were in progress throughout 2002. The increase was also attributable to increased costs of \$946,000 due to purchases of clinical supplies that were required in 2002 and certain manufacturing capacity development projects that were initiated in 2002. The increase was also attributable to increases in non-cash stock-based compensation expense of \$740,000 primarily due to the issuance of common stock options in late 2001 deemed to be below the fair value of common stock.

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

Project	Year ended December 31,	
	2002	2001
	(in thousands)	
CORLUX for the treatment of the psychotic features of PMD	\$ 11,073	\$ 4,177
CORLUX for the treatment of early-stage Alzheimer's disease	12	—
Drug discovery research	108	—
	<u>11,193</u>	<u>4,177</u>
Total research and development expense (excluding non-cash stock-based compensation)	\$ 11,193	\$ 4,177

*General and administrative expenses.* General and administrative expenses increased 116% to \$5.7 million for the year ended December 31, 2002, from \$2.6 million for the year ended December 31, 2001. This increase of \$3.0 million was primarily attributable to a non-cash stock-based compensation expense increase of \$1.5 million from the issuance of common stock options in late 2001 deemed to be below the fair value of common stock. The increase was also attributable to a \$1.0 million increase in professional service fees primarily related to the expenses of a proposed public offering withdrawn in October 2002 and increased staffing costs of \$553,000 due to the expansion of administrative activities to support our research and development. We also experienced an increase in general and administrative activities of \$289,000 primarily due to the increased filings of patent applications and prosecution fees in 2002.

*Interest and other income, net.* Interest and other income, net, decreased to \$320,000 for the year ended December 31, 2002 from \$600,000 for the year ended December 31, 2001. The decrease was primarily attributable to lower average cash, cash equivalents and short-term investments balances during the year ended December 31, 2002 as compared to the year ended December 31, 2001.

*Interest expense.* Interest expense of \$21,000 for the year ended December 31, 2002 represents interest on our convertible note payable to the Institute for the Study of Aging. Interest expense of \$48,000 for the year ended December 31, 2001 represents interest on convertible promissory notes



## Table of Contents

previously issued to investors and converted to preferred stock in May 2001, as well as interest on the convertible note payable to the Institute for the Study of Aging.

### Liquidity and Capital Resources

We have incurred annual operating losses since inception, and at December 31, 2003, we had a deficit accumulated during the development stage of \$37.9 million. Since our inception, we have relied primarily on the proceeds from private placements of our equity securities to fund our operations.

At December 31, 2003, we had cash, cash equivalents and short-term investments balances of \$11.6 million, compared to \$21.5 million at December 31, 2002 and cash and cash equivalents of \$23.0 million at December 31, 2001. Net cash used in operating activities for the years ended December 31, 2003, 2002 and 2001, was \$10.0 million, \$13.2 million and \$5.4 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. If this offering is significantly delayed or we do not complete it, we may need to curtail or delay our planned clinical trials and other product development activities.

We believe that the net proceeds from this offering, together with our current cash balances and interest thereon, will be sufficient to complete our ongoing and planned clinical trials reflected in the description of business, to conduct appropriate development studies and to satisfy our other anticipated cash needs for operating expenses for at least the next two years. However, we cannot be certain that additional funding will not be required and, if required, 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 rights to certain of our technologies or products, including potentially our lead product, that we would otherwise seek to develop on our own.

### Contractual Obligations and Commercial Commitments

Our contractual payment obligations that are fixed and determinable as of December 31, 2003 were as follows:

Payments Due by Period	2004	2005	2006	2007	2008	Beyond 2008
	(in thousands)					
Research and development studies <sup>(1)</sup>	\$ 249	\$ —	\$ —	\$ —	\$ —	\$ —
Drug discovery <sup>(2)</sup>	1,060	—	—	—	—	—
Operating lease <sup>(3)</sup>	104	—	—	—	—	—
Minimum royalty payments <sup>(4)</sup>	60	60	60	60	60	60 per year
<b>Total</b>	<b>\$ 1,473</b>	<b>\$ 60</b>	<b>\$ 60</b>	<b>\$ 60</b>	<b>\$ 60</b>	<b>\$60 per year</b>

<sup>(1)</sup> The first two double-blind trials for PMD have concluded, with payments of approximately \$249,000 remaining to be made in 2004.

<sup>(2)</sup> We may terminate our agreement with a third party for drug discovery research on or after June 30, 2004 upon 90 days' prior notice. Under the agreement, we may be obligated to make milestone payments upon the occurrence of certain events, including: (i) patent filings in connection with the project; (ii) entries into Phase I clinical trials; and (iii) national regulatory approval of each product arising from work performed under the agreement, provided that sales of the product by us or any future licensees reach \$5,000,000.

<sup>(3)</sup> Our operating lease commitment relates to the lease of our office facility. As of January 2004, the lease is a month-to-month lease terminable by either party upon 180 days' notice to the other party.

<sup>(4)</sup> Under our cancelable license agreements with Stanford University, we are obligated to make nonrefundable minimum royalty payments of \$60,000 annually for as long as we maintain our licenses from Stanford; however, these payments are creditable against future royalties.

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## [Table of Contents](#)

We also have other contractual payment obligations, the timing of which are 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. Under our license agreement with Stanford related to the patent application covering the use of GR-II antagonists for modulation of the blood-brain barrier, we are obligated to make milestone payments to Stanford of \$100,000 upon commencement of pivotal clinical trials related to the licensed product and \$250,000 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.

We enter into agreements with third-party service providers to conduct our clinical and preclinical trials and make payments to these providers based upon the number of patients enrolled in the trial as well as the completion of certain agreed-upon milestones. We are currently unable to estimate the amounts to be paid or the time period in which amounts will be paid pursuant to these agreements.

### **Net Operating Loss Carryforwards**

At December 31, 2003 we had approximately \$13.7 million of federal net operating loss carryforwards and approximately \$100,000 in federal research and development tax credit carryforwards, as well as approximately \$12.5 million of California net operating loss carryforwards and approximately \$200,000 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.

### **Quantitative and Qualitative Disclosures About Market Risk**

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk of loss. As of December 31, 2003, our cash and cash equivalents consisted primarily of money market funds maintained at one major U.S. financial institution, and the short-term investments consist of corporate debt securities and U.S. government obligations. To minimize our exposure to interest rate market risk, we have limited the maturities of our fixed rate investments to less than one year. Due to the short-term nature of these instruments, a 1% increase or decrease in market interest rates would not have a material adverse impact on the total value of our portfolio as of December 31, 2003 or 2002.

### **Critical Accounting Estimates**

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States. 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 of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

*Stock-based compensation.* Stock-based compensation arises from the granting of stock options to employees and directors as well as non-employees.

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## [Table of Contents](#)

Deferred stock-based compensation related to option grants to employees and directors represents the difference between the exercise price of an option and the deemed fair value of our common stock on the date of the grant. Given the absence of an active market for our common stock, management is required to estimate the fair value of our common stock based on a variety of company and industry-specific factors for the purpose of measuring the cost of the transaction and properly reflecting it in our financial statements. Deferred compensation is included as a reduction of stockholders' equity and is being amortized to expense over the vesting period of the underlying options, generally five years. Our policy is to use the graded-vesting method for recognizing compensation costs for fixed employee awards. We amortize the deferred stock-based compensation of employee options on the graded-vesting method over the vesting periods of the applicable stock options. The graded-vesting method provides for vesting of portions of the overall awards at interim dates and results in greater vesting in earlier years than the straight-line method. Upon termination of employment, the difference between the expense recorded under the graded-vesting method and the expense that would have been recorded based upon the vesting of the related option is required to be reversed upon such termination. We recognized non-cash stock-based compensation expense related to option grants to employees and directors of approximately \$86,000, \$4.0 million and \$1.5 million for the years ended December 31, 2003, 2002 and 2001, respectively. As of December 31, 2003, we had remaining employee deferred stock-based compensation of approximately \$2.0 million, of which approximately \$1.1 million will be amortized to expense in 2004.

Deferred stock-based compensation related to option grants to non-employees represents the difference between the exercise price of an option and the fair value of our common stock on the date that these options vest. We recognized stock-based compensation expense related to option grants to non-employees of approximately \$89,000, \$63,000 and \$316,000 for the years ended December 31, 2003, 2002 and 2001, respectively as the straight-line amortization of deferred compensation recorded related to non-employees.

*Clinical trials.* We recorded accruals for estimated preclinical and clinical study costs of approximately \$334,000 and \$530,000 as of December 31, 2003 and 2002, respectively. The related costs are a significant component of our research and development expenses. We make significant judgments and estimates in determining the accrual balance in each reporting period. Accrued clinical trial costs are based on estimates of the work completed under the service agreements, milestones achieved, patient enrollment and past experience with similar contracts. Our estimate of the work completed and associated costs to be accrued includes our assessment of the information received from our third-party contract research organizations and the overall status of our clinical trial activities. In the past, we have not experienced any material deviations between accrued clinical trial expenses and actual clinical trial expenses. However, actual services performed, number of patients enrolled and the rate of patient enrollment may vary from our estimates, resulting in adjustments to clinical trial expense in future periods.

### **Recently Issued Accounting Standards**

In January 2003, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation number 46, *Consolidation of Variable Interest Entities* ("FIN 46"). This interpretation requires existing unconsolidated variable interest entities to be consolidated by their primary beneficiaries if the entities do not effectively disperse risks among parties involved. It explains how to identify variable interest entities and how an enterprise assesses its interest in a variable interest entity to decide whether to consolidate that entity. This interpretation, as amended, applies in the first fiscal year or interim period beginning after December 15, 2003, to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. Because we do not currently have any unconsolidated variable interest entities, we do not expect the adoption of FIN 46 to have a material impact on our financial position or results of operations.

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[Table of Contents](#)

In May 2003, the FASB issued Statement of Financial Accounting Standards (“SFAS”) No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*. SFAS No. 150 requires that certain financial instruments, which under previous guidance were accounted for as equity, must now be accounted for as liabilities. The financial instruments affected include mandatorily redeemable stock, certain financial instruments that require or may require the issuer to buy back some of its shares in exchange for cash or other assets and certain obligations that can be settled with shares of stock. SFAS No. 150 is effective for all financial instruments entered into or modified after May 31, 2003 and otherwise is effective at the beginning of the first interim period after June 15, 2003. The adoption of SFAS No. 150 did not have a material impact on our financial position or results of operations.

## BUSINESS

### Overview

We are a pharmaceutical company engaged in the development of drugs for the treatment of severe psychiatric and neurological 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 neurological 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 FDA and are preparing to initiate pivotal clinical trials for CORLUX for the treatment of the psychotic features of PMD. We have also initiated a clinical study to evaluate the safety and efficacy of CORLUX in improving cognition in patients with mild to moderate Alzheimer's disease.

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 manic depressive illness. The disorder is characterized by severe depression accompanied by delusions, hallucinations or both. 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 psychosis manifested by PMD patients. 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 early dementia, such as early dementia associated with Alzheimer's disease, mild cognitive impairment, psychosis associated with cocaine addiction, and weight gain following treatment with antipsychotic medication. We have also filed patent applications for additional diseases that may benefit from treatment with a drug that blocks the GR-II receptor.

We initially intend to market and sell CORLUX in the United States directly to hospitals with in-patient psychiatric units, first focusing on those that use ECT. 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 sales and marketing 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 neurological conditions, such as mood changes, psychosis and cognitive impairment.

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## [Table of Contents](#)

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 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 in the bloodstream to the brain, where it directly influences neurological 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 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.

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## [Table of Contents](#)

Data from a congressionally mandated study, the National Co-Morbidity Survey published in 2003, indicate that each year approximately 7% of adults in the United States, or about 14 million people, experience a major depressive episode. Of these people, many published studies show that approximately 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.

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

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## [Table of Contents](#)

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, 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 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:* 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-21:* This is a 21-item 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 21 items.

*Clinical Trials.* We have completed the following four clinical trials with CORLUX for the treatment of psychotic features of PMD:

- Our first trial was an open-label dose finding study in which we concluded that patients receiving daily doses of 600 mg or 1200 mg of CORLUX were more likely than patients receiving 50 mg of CORLUX to experience a clinically meaningful reduction in the psychotic symptoms of PMD.
- Our second and third trials, which we call the '02 study and '03 study, tested a regimen of 600 mg of CORLUX dosed for 7 days. These were double-blind, placebo-controlled safety and efficacy studies in which a total of 429 patients were enrolled. The '02 study confirmed that CORLUX was well tolerated and that there were no discernable problems with drug interactions between CORLUX and commonly prescribed antipsychotic and antidepressant medications. The '03 study demonstrated with statistical significance ( $p$  value = 0.01) 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. 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 the '02 study 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. All p values for the '03 study 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 the '02 and '03 studies, and our analysis indicates that patients tolerated their retreatment well.



## Table of Contents

We plan to initiate two pivotal clinical trials in the United States by the end of 2004 to evaluate further the safety and efficacy of CORLUX and we expect that these studies will be concluded in the first half of 2006. These studies will be of a similar design to the '03 study.

*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, 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 the '02 study 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 the '02 study, patients received their usual treatment plus CORLUX or placebo. In the '03 study, 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.

*'02 Study.* The results of the '02 study 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 the '02 study 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

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## [Table of Contents](#)

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 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 the '02 study 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 very small, the difference between the usual treatment plus CORLUX group and the usual treatment plus placebo group was statistically significant (p value = 0.01).

*'03 Study.* The results of the '03 study 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. The '03 study 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. The '03 study 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 positive symptom subscale 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.

We do not intend to rely on the '03 study as one of our required pivotal clinical trials in support of an application to market CORLUX for the treatment of the psychotic features of PMD because 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 as measured by the BPRS, a differentiating characteristic that we had noted in post-hoc '02 study analysis. In the '03 study, as in the '02 study, only a very small number of patients became asymptomatic and, in the '03 study, there was no statistically significant difference between the CORLUX and placebo groups.

Of the approximately 480 patients who have been enrolled in our studies completed to date, over 240 individuals have been treated with CORLUX. The drug seemed to be well tolerated by these patients, with a low incidence of adverse events. In the '02 and '03 studies, 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 the '02 study, 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 the '03 study, 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 the '02 and '03 studies. Twenty-eight patients completed the study. Our analysis indicates that patients tolerated their retreatment well.

*Pivotal Clinical Trials.* We plan to initiate two randomized, double-blind, placebo-controlled studies in the United States to further assess the safety and efficacy of CORLUX for the treatment of the psychotic features of PMD. These studies will be of a similar design to the '03 study. In March 2004, we submitted protocols for our two pivotal clinical studies to the FDA for a special protocol assessment.

Under the FDA's special protocol assessment procedures, the FDA will evaluate within 45 days certain protocols to assess whether they are adequate to meet scientific and regulatory requirements necessary to support an approval. We believe that obtaining the FDA's input on the details of the protocol design before starting this study will provide valuable guidance for the efficacy demonstration needed for our CORLUX NDA filing.

Given the serious nature of PMD, the lack of 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

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## [Table of Contents](#)

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 NDA.

*Additional Trials and Studies.* In support of our NDA submission, concurrently with our pivotal clinical trials, we plan to conduct a retreatment trial to assess the retreatment of patients with CORLUX, an open label safety trial that will include 300 to 500 patients and several small trials to evaluate how the human body processes CORLUX. We also plan to conduct a large, double-blind, placebo-controlled clinical trial outside the United States which we may also use as a pivotal clinical trial. In addition to our clinical trials, we plan to conduct a standard 12-month toxicology study and two carcinogenicity studies 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 Agreements.* We have clinical development agreements with Scirex Corporation and PPD Development, LP, under which Scirex and PPD, at our request, oversee clinical trials at various institutions to test the safety and efficacy of CORLUX for the psychotic features of PMD. These agreements may be terminated by us at any time upon thirty days' written notice. We expect that these organizations will work with us to conduct our pivotal clinical trials of CORLUX.

### **Overview of Alzheimer's Disease**

In addition to our development program for CORLUX for the psychotic features of PMD, we have initiated a clinical study to evaluate the safety and efficacy of CORLUX in patients with mild to moderate Alzheimer's disease because we believe that CORLUX may improve cognition in these patients.

No current treatment can change the ultimate course of Alzheimer's disease, a disease that affects more than 3.5 million people in the United States. For some people in the early and middle stages of the disease, medications that inhibit acetylcholinesterase, an enzyme that breaks down a particular neurotransmitter, may help slow the decline in cognition for a limited time. In clinical trials with acetylcholinesterase inhibitors, the reduction in the rate of decline as measured by standard scales was modest, with many patients showing no improvement at all.

In addition to the acetylcholinesterase inhibitors, the compound memantine has also been approved for the treatment of Alzheimer's disease. Memantine studies have shown small but statistically significant benefits in patients with more severe or advanced Alzheimer's disease. However, reports of recent studies indicate that memantine may not be of benefit in patients with milder forms of the illness who are also taking acetylcholinesterase inhibitors.

Also, a variety of medications are used to help control behavioral symptoms associated with Alzheimer's disease, such as agitation. Antipsychotics are frequently used for treating agitation. Anticonvulsants or mood stabilizers are often prescribed for hostility or aggression and anxiolytics are prescribed for anxiety, restlessness and verbally disruptive behavior.

Current treatments have a modest effect and only slow the decline in cognition for a short period of time. Therefore, there is a need for new therapies that could enhance cognition and improve behavioral problems in Alzheimer's patients.

Published studies have suggested that higher cortisol levels are associated with more rapid decline in Alzheimer's patients. For example, several studies suggest that among individuals with early-stage Alzheimer's disease, higher baseline cortisol was associated with a significantly greater rate of decline in cognitive function based on standardized measurements of cognition. Also, a small clinical study evaluated the use of mifepristone in patients with mild to moderate Alzheimer's disease and indicated that patients treated with mifepristone for six weeks had improved scores on a standard cognition scale, whereas patients taking placebo worsened.

*CORLUX Clinical Trial.* We are conducting a clinical trial designed to demonstrate the safety of CORLUX and whether or not CORLUX will improve cognition in Alzheimer's patients.

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## [Table of Contents](#)

The study is a randomized, double-blind, parallel group comparison of the effects of CORLUX and placebo. The trial assesses the effects of CORLUX on cognition and behavior when administered daily over a period of 16 weeks. Because a diagnosis of Alzheimer's disease is required for participation in the trial and acetylcholinesterase inhibitors are currently standard treatment for this condition, patients in the trial are required to be on a stable regimen of an acetylcholinesterase inhibitor for at least 12 weeks before enrolling in the trial.

The trial's primary efficacy measure will be the ADAS-Cog, which assesses a patient's cognitive capabilities. The ADAS-Cog is a battery of individual tests relating to recall, naming, commands, orientation, word recognition, spoken language and comprehension and word finding, among other cognitive functions. In clinical trials, the ADAS-Cog has been used to measure the cognitive and neuropsychological effects of treatment.

The study is designed to enroll up to 160 patients. As of March 31, 2004, 34 patients have been entered into the study.

### **GR-II Antagonist Platform**

We have assembled a patent portfolio covering the treatment of psychiatric and neurological 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:

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

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

### **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 use in our growing number of proprietary uses. Our discovery chemistry is being conducted on our behalf at a contract research organization in the United Kingdom. Through the research program, we have identified, and filed patent applications for, two series of GR-II antagonists that, unlike CORLUX, do not block the progesterone receptor and only block the GR-II receptor. These compounds bind to the GR-II receptor with a potency similar to that of CORLUX.

### **Our Business Strategy**

Our objective is to develop and commercialize drugs that address severe psychiatric and neurological diseases for which there is a significant unmet clinical need. We are pursuing the following strategies to achieve this objective:

- *Rapidly develop and commercialize CORLUX for the psychotic features of PMD.* We are conducting a clinical program to enable an NDA submission as quickly as possible. The FDA has granted a fast track designation for CORLUX for the treatment of the psychotic features of PMD because of the lack of approved drugs for this serious disorder and our favorable preliminary clinical data. The FDA has also indicated that CORLUX will receive a priority review if no other treatment has been approved for PMD at the time we submit our NDA.
- *Directly market CORLUX in the United States.* We initially intend to market and sell CORLUX in the United States directly to hospitals with large in-patient psychiatric units, first focusing on

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## [Table of Contents](#)

those approximately 300 centers that use ECT. 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 sales and marketing team.

- *Determine whether CORLUX improves cognition in Alzheimer's patients.* We are conducting a clinical trial to test our hypothesis that CORLUX improves cognition in patients with mild to moderate Alzheimer's disease. If the results of the trial are favorable, we intend to expand our Alzheimer's development program with CORLUX or another GR-II antagonist.
- *Build a portfolio of GR-II receptor antagonists.* We have identified, and filed patent applications relating to, additional GR-II antagonist compounds that are selective for GR-II and as potent as CORLUX. We intend to develop these for the treatment of diseases for which therapy is unavailable or substandard and the market opportunity is large.
- *Acquire or in-license additional products.* In addition to our in-house development efforts, we plan to acquire or in-license hospital-based products to more fully utilize our internal product development and sales and marketing organizations.
- *Employ an experienced team with a proven track record in developing and commercializing pharmaceuticals.* We expect to continue managing the company through product commercialization with a relatively small group of executives with an extensive history of success in the development and commercialization of new drugs. We believe that our expert consultants and third-party relationships in research, clinical trial management and manufacturing, along with the relatively small sales force we intend to form to support our initial sales and marketing effort, will help us minimize costs and accelerate the timing of our product development and commercialization efforts.

### **Sales and Marketing**

We intend to develop our own sales and marketing infrastructure in the United States to commercialize CORLUX because we believe that the initial market for PMD in the United States is highly concentrated and accessible. We anticipate hiring a small, experienced sales force of approximately 25 to 35. 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 sales 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 currently have no sales and marketing staff. 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 accelerate the development of CORLUX and other products rather than diverting resources to establishing our own manufacturing facilities.

We intend to continue to rely on experienced contract manufacturers to produce our products. We have entered into a manufacturing agreement with a contract manufacturer, ScinoPharm Taiwan, to

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## [Table of Contents](#)

produce the active pharmaceutical ingredient, or API, for CORLUX. This agreement 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. Although we do not currently have a second supplier of API, we have completed feasibility studies with a second contract manufacturer. Our existing API manufacturer and the second possible API manufacturer we have identified both obtain the raw material they use to produce mifepristone from the same single source supplier. We have entered into a separate agreement with another contract manufacturer, KP Pharmaceutical Technology, Inc., to produce CORLUX tablets for us. This agreement also requires us to invest in start-up costs and is terminable by the contract manufacturer only upon a breach of any of our material obligations. This agreement is effective through February 2005, unless terminated earlier for cause, but may be extended by mutual agreement of the parties. The tablet manufacturer is a single source supplier to us. 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. Our need for CORLUX tablets has been limited to the amounts required to support our clinical trials. KP Pharmaceutical has met our small quantity requirements to date. As we prepare for commercialization, we plan to develop a relationship with a second tablet manufacturer and will include both manufacturers in our NDA. We believe there are numerous qualified contract pharmaceutical manufacturing organizations in North America.

### **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.

While we are unaware of any other ongoing clinical trials, 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 products. 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 products, obtain required regulatory approvals and manufacture and successfully market our products either alone or through outside parties.

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[Table of Contents](#)

**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.

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. 6,369,046	Use of GR-II antagonists in the treatment of early dementia, including early Alzheimer's disease	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

We have also licensed exclusive rights from Stanford University to a pending U.S. patent application and any corresponding foreign patents for the use of GR-II antagonists in the modulation of the blood-brain barrier.

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 these agreements. 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 and for the treatment of weight gain following treatment with antipsychotic medication. In addition, we have two 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:

- delirium;
- migraine;
- postpartum psychosis;
- catatonia;
- gastrointestinal reflux disease;
- Down's syndrome; and
- post-traumatic stress disorder.

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 two 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 or any other GR-II antagonist. Our rights under our issued patents cover only the use of GR-II antagonists, including mifepristone, in the treatment of specific diseases.

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## [Table of Contents](#)

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 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 products while attempting to design around other patents, or determine that we are unable to commercialize our products 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. A third party has alleged that it also has rights to the technology that led to the patent for the use of GR-II antagonists to treat psychotic features of PMD. The third party is a prior employer of one of our founders, Dr. Schatzberg, and it alleges that the invention of the technology underlying this patent was conceived by Dr. Schatzberg and/or another employee of the employer while the two were employed by the third party. We believe that the invention was actually conceived by Drs. Schatzberg and Belanoff while they were employed by Stanford University and that the patent was appropriately assigned to Stanford University by them. We believe we will prevail if this matter is pursued against us. If, however, the third party's claims were successful, it would have the rights to market GR-II antagonists to treat the psychotic features of PMD or to license those rights to others and our business could be materially harmed. In addition, Akzo Nobel has filed an observation to the grant of our exclusively licensed European patent application with claims directed to PMD, in which Akzo Nobel challenges the grant of that patent. We plan to vigorously rebut the points raised by Akzo. During prosecution of the U.S. patent for the use of CORLUX to treat the psychotic features of PMD, the U.S. Patent and Trademark Office considered issues similar to those raised by Akzo and the U.S. patent was ultimately granted. We cannot assure you, however, that the European Patent Office will reach the same conclusion. Should Akzo's arguments persuade the European Patent Office that the claims should not issue, we will not have the benefit of patent protection in Europe for CORLUX to treat the psychotic features of PMD. 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 products will require regulatory approval by government agencies prior to commercialization. The



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## [Table of Contents](#)

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 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 I.* Clinical trials are conducted with a small number of subjects to determine the early safety profile, maximum tolerated dose and pharmacokinetics of the product in human volunteers.
- *Phase II.* 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 III.* 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 III 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 agency may request additional information rather than accept an NDA for filing. If the agency accepts an NDA for filing, the FDA 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 IV 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 cGMP regulations. 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

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## [Table of Contents](#)

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 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 products 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.

### **Facilities**

We have a month-to-month lease covering approximately 3,200 square feet of office space in Menlo Park, California for our corporate facilities. We or our landlord may terminate the lease on six months’ notice. We believe that our existing facility is adequate for our current needs and that suitable additional or alternative space will be available at such time as it becomes needed on commercially reasonable terms.

### **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 March 31, 2004, we have eight full-time employees, six part-time employees and five long-term contract staff. Three of our full-time employees and two of our part-time employees are M.D.s. We consider our employee relations to be good. None of our employees is covered by a collective bargaining agreement.

### **Legal Proceedings**

We are not currently involved in any material legal proceedings.

## MANAGEMENT

### Executive Officers and Directors

The following table sets forth, as of March 31, 2004, information about our executive officers and directors:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Joseph K. Belanoff, M.D.	46	Chief Executive Officer and Director
Robert L. Roe, M.D.	63	President and Secretary
Fred Kurland	54	Chief Financial Officer
James N. Wilson	60	Chairman of the Board
Alan F. Schatzberg, M.D.	59	Director
David B. Singer <sup>(1)(3)(4)</sup>	41	Director
G. Leonard Baker, Jr. <sup>(2)</sup>	61	Director
Steven Kapp <sup>(1)(4)</sup>	44	Director
Alix Marduel, M.D. <sup>(2)(3)</sup>	46	Director
Joseph C. Cook, Jr. <sup>(1)(3)</sup>	62	Director

<sup>(1)</sup> Member of the audit committee

<sup>(2)</sup> Member of the compensation committee

<sup>(3)</sup> Member of the nominating and corporate governance committee

<sup>(4)</sup> Mr. Singer is married to Mr. Kapp's sister. There are no other family relationships between directors or executive officers.

*Joseph K. Belanoff, M.D.* is a co-founder and has served as a member of our board of directors and as our Chief Executive Officer since 1999. Dr. Belanoff is currently a faculty member and has held various positions in the Department of Psychiatry and Behavioral Sciences at Stanford University since 1992. From 1997 to 2001, he served as the Director of Psychopharmacology at the outpatient division of the Palo Alto Veterans Affairs Hospital. Dr. Belanoff received his B.A. from Amherst College and his M.D. from Columbia University's College of Physicians & Surgeons.

*Robert L. Roe, M.D.* joined us as President in October 2001. He has spent more than 25 years in the pharmaceutical and biotechnology industries. From 1999 to 2001, Dr. Roe served as President and Chief Executive Officer of Allergenic, Inc. From 1996 to 1999, he was Executive Vice President, Chief Operating Officer and a director of Cytel Corporation. From 1995 to 1996, he was Executive Vice President, Chief Operating Officer and a director of Chugai Biopharmaceuticals, Inc. From 1992 to 1995, Dr. Roe served as President of the Development Research Division and Senior Vice President of Syntex Corporation. Dr. Roe received his B.A. from Stanford University and his M.D. from the University of California, San Francisco.

*Fred Kurland* joined us as Chief Financial Officer in February 2004. Mr. Kurland served as Vice President and Chief Financial Officer of Genitope Corporation from 2002 until February 2004. From 1998 to 2002 he served as Senior Vice President and Chief Financial Officer of Aviron, Inc. Mr. Kurland served as Vice President and Chief Financial Officer of Protein Design Labs, Inc. from 1996 to 1998. From 1995 to 1996, Mr. Kurland served as Vice President, Chief Financial Officer and Secretary of Applied Immune Sciences, Inc. From 1991 to 1995, Mr. Kurland served as Vice President and Controller of Syntex Corporation. Mr. Kurland received his B.S. from Lehigh University and his J.D. and M.B.A. degrees from the University of Chicago.

*James N. Wilson* has served as a director and as Chairman of our board of directors since 1999. Since 2002, Mr. Wilson has served as a director of Amylin Pharmaceuticals, Inc. From 1996 to 2001, Mr. Wilson was Chairman of the board of Amira Medical, Inc. From 1991 to 1994, Mr. Wilson was Chief Operating Officer of Syntex Corporation. From 1989 to 1990, Mr. Wilson was Chairman and Chief Executive Officer of Neurex Corporation and from 1982 to 1988, Mr. Wilson was Chief Executive Officer of LifeScan, Inc. Mr. Wilson received his B.A. and M.B.A. from the University of Arizona.

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## [Table of Contents](#)

*Alan F. Schatzberg, M.D.* is a co-founder and has served as a member of our board of directors and as chairman of our Scientific Advisory Board since 1998. Since 1991, Dr. Schatzberg has been a Professor and the Chairman of the Department of Psychiatry and Behavioral Sciences at Stanford University's School of Medicine and is Past President of the American College of Neuropsychopharmacology. He received his B.S. from New York University and his M.D. from New York University, School of Medicine.

*David B. Singer* has served as a member of our board of directors since 1998. Since February 2004, Mr. Singer has served as Chairman of the Board of Directors of Genome Therapeutics Corporation. From September 1998 to February 2004, Mr. Singer was Chairman and Chief Executive Officer of GeneSoft Pharmaceuticals, Inc. From 1996 to 1998, Mr. Singer was Senior Vice President and Chief Financial Officer of Heartport, Inc. From 1992 to 1996, he was President and Chief Executive Office of Affymetrix, Inc. He currently serves on the board of Affymetrix, Inc. Mr. Singer received his B.A. from Yale University, and his M.B.A. from Stanford University.

*G. Leonard Baker, Jr.* has served as a member of our board of directors since 1999. Since 1973, Mr. Baker has been a Managing Director of the General Partner of Sutter Hill Ventures, a venture capital firm. Mr. Baker currently serves on the board of Praecis Pharmaceuticals Incorporated and the board of Thermo-Wave, Inc., each of which is a publicly traded company, and a number of private companies. Mr. Baker received his B.A. from Yale University and his M.B.A. from Stanford University.

*Steven Kapp* has served as a member of our board of directors since 2001. Since 1996, he has been a limited partner at Maverick Capital, Ltd., an investment adviser to private investment funds. From 1993 to 1996, he was founder and a General Partner of Longwood Partners, a private investment partnership. He received his B.A. and his M.B.A. from the University of North Carolina.

*Alix Marduel, M.D.* has served as a member of our board of directors since 2001. Since April 1997, she has been a managing director of Alta Partners, a venture capital firm. From 1990 to 1997, Dr. Marduel was a general partner at Sofinnova, Inc., a venture capital firm. She currently serves as director of a number of private companies. Dr. Marduel received her M.D. from the University of Paris.

*Joseph C. Cook, Jr.* has served as a member of our board of directors since 2002. Mr. Cook is chairman of the board of directors of Amylin Pharmaceuticals, Inc. Mr. Cook served as Chief Executive Officer of Amylin Pharmaceuticals from 1998 to 2003. Mr. Cook is a founder and currently serves as chairman of the board of Microbia, Inc. Mr. Cook is an officer of Mountain Ventures, Inc., and a founder of Clinical Products, Inc. and Mountain Group Capital, LLC. Mr. Cook retired as Group Vice President of Eli Lilly & Company in 1993 after more than 28 years of service. Mr. Cook received his B.S. from the University of Tennessee.

### **Scientific Advisory Board**

In 1998, we convened a scientific advisory board of individuals with expertise in psychiatry, psychopharmacology and neuroendocrinology. The chairman of our scientific advisory board is Dr. Schatzberg, who is also a member of our board of directors.

As of March 31, 2004, the following persons are members of our scientific advisory board:

<u>Member</u>	<u>University Affiliation</u>	<u>Professional Concentration</u>
Alan F. Schatzberg, M.D.	Stanford University	Psychiatry
Charles B. Nemeroff, M.D., Ph.D.	Emory University	Psychiatry
Bruce S. McEwen, Ph.D.	Rockefeller University	Neuroendocrinology
K. Ranga Rama Krishnan, M.D.	Duke University	Psychiatry
Edo Ronald de Kloet, M.D.	Leiden University (the Netherlands)	Neurobiology
Florian Holsboer, M.D., Ph.D.	Max Planck Institute of Psychiatry (Germany)	Psychiatry
Ned H. Kalin, M.D.	University of Wisconsin	Psychiatry

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[Table of Contents](#)

**Scientific Advisory Board Compensation**

We reimburse each member of our scientific advisory board for out-of-pocket expenses incurred in connection with attending board meetings, but do not, except as described below, compensate them for their services as scientific advisory board members. In the past, with the exception of Dr. Schatzberg, we have granted options to purchase our common stock to each member of our scientific advisory board. In August 1998, we granted to each of Dr. Nemeroff, Dr. McEwen, Dr. Krishnan, Dr. de Kloet and Dr. Holsboer an option to purchase 60,000 shares of our common stock at an exercise price of \$0.00033 per share. In April 2002, we granted to Dr. Kalin an option to purchase 25,000 shares of our common stock at an exercise price of \$7.00 per share. Pursuant to a consulting agreement with us, Dr. Schatzberg received compensation of \$60,000 as chair of the scientific advisory board in 2002 and \$60,000 for his services as chair in 2003. We can terminate this agreement for any reason upon 30 days' notice to Dr. Schatzberg.

**Board of Directors**

We currently have eight directors.

The directors will be elected at each annual meeting of stockholders, or special meeting in lieu thereof. The authorized number of directors may be changed only by resolution adopted by a majority of the board of directors.

**Board Committees**

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee.

*Audit Committee.* Our audit committee consists of Messrs. Cook, Kapp and Singer. Our audit committee oversees our corporate accounting and financial reporting process. Our audit committee evaluates the independent auditors qualifications, independence and performance; determines the engagement of the independent auditors; approves the retention of the independent auditors to perform any proposed permissible non-audit services; monitors the rotation of partners of the independent auditors on the engagement team as required by law; reviews our financial statements; reviews our critical accounting policies and estimates; and discusses with management and the independent auditors the results of the annual audit and the review of our quarterly financial statements. Mr. Singer will be our audit committee financial expert under the SEC rules implementing Section 407 of the Sarbanes-Oxley Act of 2002. We believe that the composition of our audit committee meets the requirements for independence under the current requirements of the Sarbanes-Oxley Act of 2002, the Nasdaq National Market and SEC rules and regulations. We believe that the functioning of our audit committee complies with the applicable requirements of the Sarbanes-Oxley Act of 2002, the Nasdaq National Market and SEC rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

*Compensation Committee.* Our compensation committee consists of Dr. Marduel and Mr. Baker. Our compensation committee reviews and recommends policy relating to compensation and benefits of our officers and employees, including reviewing and approving corporate goals and objectives relevant to compensation of the Chief Executive Officer and other executive officers, evaluating the performance of these officers in light of those goals and objectives, and setting compensation of these officers based on such evaluations. The compensation committee also administers the issuance of stock options and other awards under our equity incentive plan. We believe that the composition of our compensation committee meets the requirements for independence under, and the functioning of our compensation committee complies with, any applicable requirements of the Sarbanes-Oxley Act of 2002, the Nasdaq National Market and SEC rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

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## [Table of Contents](#)

*Nominating and Corporate Governance Committee.* Our nominating and corporate governance committee consists of Dr. Marduel, Mr. Cook and Mr. Singer, each of whom is a non-management member of our board of directors. The nominating and corporate governance committee will identify and evaluate nominees for election as directors, and review and assess our code of ethics.

### **Compensation Committee Interlocks and Insider Participation**

Prior to establishing the compensation committee, the board of directors as a whole made decisions relating to compensation of our executive officers. No member of the board of directors or the compensation committee serves as a member of the board of directors or compensation committee of any other entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

### **Director Compensation**

Except as described below, our non-executive directors do not receive any cash compensation for their service as members of the board or for their attendance at committee meetings, but they are entitled to reimbursement for all reasonable out-of-pocket expenses incurred in connection with attendance at board and committee meetings.

Pursuant to a consulting agreement, Mr. Wilson received compensation of \$60,000 during 2002 for his service as chairman of the board. Mr. Wilson became an employee in September 2002 and received a salary of \$40,000 in 2002 and \$103,500 in 2003. Mr. Wilson also received a bonus of \$10,350 in 2003.

In June 1998, Dr. Schatzberg purchased 3,000,000 shares of our common stock at \$0.00033 per share. In May 1999, Mr. Wilson purchased 1,770,939 shares of our common stock at \$0.033 per share. We have the right to repurchase a portion of those shares at cost if Mr. Wilson ceases to serve on our board of directors. This right of repurchase lapses monthly over five years. In April 2002 and November 2003, we granted stock options to Mr. Cook to purchase 50,000 shares and 25,000 shares, respectively, of our common stock at \$7.00 per share. Upon issuance, these shares will be subject to a right of repurchase that lapses as to 20% of the shares after one year and in equal monthly installments over the four year period thereafter.

### **Indemnification**

Our amended and restated certificate of incorporation limits the liability of directors to the maximum extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except liability for:

- any breach of their duty of loyalty to the corporation or its stockholders;
- acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

Our bylaws provide that we will indemnify our directors, officers, employees and other agents to the fullest extent permitted by law. We believe that indemnification under our bylaws covers at least negligence and gross negligence on the part of indemnified parties. Our bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in connection with their services to us, regardless of whether our bylaws permit such indemnification.

We have entered into separate indemnification agreements with our directors and executive officers, in addition to the indemnification provided for in our bylaws. These agreements, among other things,

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[Table of Contents](#)

provide that we will indemnify our directors and executive officers for certain expenses (including attorneys' fees), judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of such person's services as one of our directors or executive officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request. We believe that these provisions and agreements are necessary to attract and retain qualified persons as directors and executive officers.

There is no pending litigation or proceeding involving a director or executive officer of Corcept as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

**Executive Compensation**

The following table sets forth information regarding the compensation for the fiscal year ended December 31, 2003 paid by us to our Chief Executive Officer and to our other executive officer who received salary and bonus compensation in 2003 of more than \$100,000. These persons are collectively referred to as the "Named Executive Officers."

**Summary Compensation Table**

Name and Principal Position	Year	Annual Compensation		Long-Term Compensation Awards	All Other Compensation (\$)
		Salary (\$)	Bonus (\$)	Securities Underlying Options (#)	
Joseph K. Belanoff, M.D. Chief Executive Officer	2003	310,500	31,050	—	—
Robert L. Roe, M.D. President	2003	310,500	31,050	100,000	—

[Table of Contents](#)

**Options Grants in Last Fiscal Year**

The following table sets forth information with respect to stock options granted during the fiscal year ended December 31, 2003 to each of the Named Executive Officers. All options were granted under our 2000 Stock Option Plan at an exercise price equal to the fair market value of our common stock, as determined by our board of directors, on the date of grant. Shares purchased under the options granted to Dr. Roe will be subject to a right of repurchase that lapses as to 20% of the shares after one year and in equal monthly installments over the four year period thereafter. The percentage of options granted is based on an aggregate of options to purchase a total of 207,500 shares of common stock granted by us during the fiscal year ended December 31, 2003 to our employees, including the Named Executive Officers.

The potential realizable value amounts in the last two columns of the following chart represents hypothetical gains that could be achieved for the respective options if exercised at the end of the option term, are net of the exercise prices and before taxes associated with the exercise, and we have based them on an assumed initial public offering price of \$12.00 per share. The assumed 5% and 10% annual rates of stock price appreciation from the date of grant to the end of the option terms are provided in accordance with rules of the SEC and do not represent our estimate or projection of the future common stock price. Actual gains, if any, on stock option exercises are dependent on the future performance of the common stock, overall market conditions and the option holder's continued employment through the vesting period. This table does not take into account any actual appreciation in the price of the common stock from the date of grant to the present.

Name	Individual Grants				Potential Realizable Value at assumed Annual Rates of Stock Price Appreciation for Option Terms (\$)	
	Number of Securities Underlying Options Granted (#)	% of Total Options Granted to Employees in Fiscal Year	Exercise Price/Share (\$)	Expiration Date	5%	10%
Joseph K. Belanoff, M.D.	—	—	—	—	—	—
Robert L. Roe, M.D.	100,000	48%	\$ 7.00	11/23/13	1,254,668	2,412,488

**Aggregate Fiscal Year-End Option Values**

The following table sets forth certain information regarding stock options during the fiscal year ended December 31, 2003 and unexercised options held as of December 31, 2003 by each of the Named Executive Officers. All options were granted under our 2000 Stock Option Plan.

The value of unexercised in-the-money options at December 31, 2003 are based on an assumed initial public offering price of \$12.00 per share, minus the per share exercise price, multiplied by the number of shares underlying the option.

Name	Number of Securities Underlying Unexercised Options at Fiscal December 31, 2003 (#)		Value of Unexercised In-the-Money Options at December 31, 2003 (\$)	
	Exercisable	Unexercisable	Exercisable	Unexercisable
Joseph K. Belanoff, M.D.	—	—	—	—
Robert L. Roe, M.D.	106,346	3,654	575,517	43,483

**Employment and Change of Control Arrangements**

Our 2000 Stock Option Plan provides that, upon the sale of all or substantially all of our assets or upon our acquisition by another corporation pursuant to a merger or consolidation, each outstanding option will generally become fully vested, or the right of repurchase held by us will lapse, unless the surviving corporation assumes the option or replaces it with a comparable option.

Our 2004 Equity Incentive Plan provides, generally, that in the event of (a) a merger or consolidation in which we are not the surviving corporation, (b) a merger in which we are the surviving



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## [Table of Contents](#)

corporation but after which our stockholders immediately prior to such merger cease to own their shares or other equity interest in us, (c) the sale of all or substantially all of our assets, or (d) the acquisition, sale, or transfer of more than 50% of our outstanding shares by tender offer or similar transaction, any or all outstanding awards under the plan may be assumed, converted, replaced or substituted. In the event such successor corporation (if any) does not assume or substitute awards under the plan, the vesting with respect to awards will accelerate so that the awards may be exercised before the closing or completion of the transaction but then terminate. If the options, SARs, or stock awards are assumed or substituted under a change in control or other transaction, then vesting or termination of repurchase rights may occur upon the subsequent involuntary termination (which includes certain constructive termination events) of an awardee's service within 12 months following the transaction or change in control.

We have entered into a letter agreement with Robert L. Roe, M.D., our President. Pursuant to this letter agreement, Dr. Roe received a base salary of \$300,000 in 2002, which was increased to \$310,500 in 2003, and received a one-time hiring bonus equal to \$100,000 paid in lump sum and earned over the first year of Dr. Roe's employment with Corcept. In addition, in accordance with this letter agreement, Dr. Roe received an option to purchase 250,000 shares of our common stock with an exercise price of \$0.75 per share and a \$187,250 loan evidenced by a full-recourse promissory note to Corcept to finance the exercise of the option. Shares purchased by Dr. Roe pursuant to the option are subject to our right of repurchase. In the event of an acquisition of more than 50% of the voting control of Corcept, the right of repurchase will lapse as to an additional 20% of the shares subject to the option. If we terminate Dr. Roe's employment for any reason other than for cause, Dr. Roe will receive a lump sum severance payment equal to his annual salary in effect at the time of his termination.

We have entered into a letter agreement with Fred Kurland, our Chief Financial Officer. Pursuant to this letter agreement, Mr. Kurland receives a base salary of \$240,000. In addition, in accordance with this letter agreement, Mr. Kurland received an option to purchase 200,000 shares of our common stock with an exercise price of \$7.00 per share. This option will vest with respect to 20% of the shares after one year and with respect to the remaining shares in equal monthly installments over the four-year period thereafter.

### **Benefit Plans**

#### **2000 Stock Option Plan**

Our 2000 Stock Option Plan was adopted by our board of directors and stockholders in October 2000. Our 2000 Stock Option Plan provides for the grant of incentive stock options, which may provide for preferential tax treatment to our employees, and for the grant of nonstatutory stock options to our employees, directors and consultants. As of March 31, 2004, we had reserved an aggregate of 2,000,000 shares of our common stock for issuance under this plan. As of March 31, 2004, 590,536 of our outstanding shares have been issued pursuant to the exercise of options, options to purchase 730,500 shares of common stock were outstanding, and 678,964 shares are available for future grant. The 2000 Stock Option Plan provides that in the event of a change in control, each outstanding option will generally become fully vested, or the right of repurchase held by us will lapse, unless the surviving corporation assumes the option or replaces it with a comparable option. Upon the closing of this offering, no additional stock options may be granted under the 2000 Stock Option Plan.

#### **2004 Equity Incentive Plan**

In March 2004, our board of directors and stockholders approved the 2004 Equity Incentive Plan, or 2004 Plan, which will become effective upon the completion of this offering.

The purpose of the 2004 Plan is to enhance the long-term stockholders' value of our company by offering opportunities to eligible individuals to participate in the growth in value of the equity of our company. Stock options, stock appreciation rights, or SARs, stock awards and cash awards may be

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## [Table of Contents](#)

granted under the 2004 Plan. Each is referred to as an award in the 2004 Plan. Options granted under the 2004 Plan may be either “incentive stock options”, as defined under Section 422 of the Internal Revenue Code of 1986, as amended, or non-statutory stock options.

*Share Reserve.* We have reserved a total of 3,000,000 shares of our common stock, subject to adjustment, for issuance under the 2004 Plan, all of which are available for future grant.

*Automatic Annual Increase of Share Reserve.* The 2004 Plan provides that the share reserve will be cumulatively increased on January 1 of each year, beginning January 1, 2005 and for nine years thereafter, by a number of shares that is equal to the least of (a) 2% of the number of our company’s shares issued and outstanding prior to the preceding December 31, (b) 1,000,000 shares and (c) a number of shares set by the board.

*Administration.* The 2004 Plan is administered by our board of directors or the compensation committee of the board. The board or compensation committee is referred to in the 2004 Plan as the administrator.

*Eligibility.* Awards under the 2004 Plan may be granted to our employees, directors and consultants. Incentive stock options may be granted only to employees. The administrator, in its discretion, approves awards granted under the 2004 Plan.

*Termination of Awards.* Generally, if an awardee’s service to us as terminates other than by reason of death, disability, retirement or for cause, vested options and SARs will remain exercisable for a period of three months following the awardee’s termination. Unless otherwise provided for by the administrator in the award agreement, if an awardee dies or becomes totally and permanently disabled while an employee or consultant or director, the awardee’s vested options and SARs will be exercisable for one year following the awardee’s death or disability, or if earlier, the expiration of the term of such award.

*Nontransferability of Awards.* Unless otherwise determined by the administrator, awards granted under the 2004 Plan are not transferable other than by will, a domestic relations order, or the laws of descent and distribution and may be exercised during the awardee’s lifetime only by the awardee.

### *Stock Options*

*Exercise Price.* The administrator determines the exercise price of options at the time the options are granted. The exercise price of an incentive stock option may not be less than 100% of the fair market value of the our common stock on the date of grant. The exercise price of a non-statutory stock option may not be less than 85% of the fair market value of our common stock on the date of grant. The fair market value of our common stock will generally be the closing sales price as quoted on the Nasdaq National Market.

*Exercise of Option; Form of Consideration.* The administrator determines when options become exercisable. The means of payment for shares issued on exercise of an option are specified in each award agreement. The 2004 Plan permits payment to be made by cash, check, wire transfer, other shares of our common stock (with some restrictions), or broker-assisted same day sales.

*Term of Option.* The term of an option may be no more than ten years from the date of grant. No option may be exercised after the expiration of its term.

*Stock Appreciation Rights.* The administrator may grant SARs alone, in addition to, or in tandem with, any other awards. An SAR entitles the participant to receive the amount by which the fair market value of a specified number of shares on the exercise date exceeds an exercise price established by the administrator. The excess amount will be payable in ordinary shares, in cash or in a combination thereof, as determined by the administrator. The terms and conditions of an SAR will be contained in an award agreement. The grant of an SAR may be made contingent upon the achievement of objective performance conditions.

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## [Table of Contents](#)

*Stock Awards.* The administrator may grant stock awards (restricted shares) as payment of a bonus, as payment of any other compensation obligation, upon the occurrence of a special event or as otherwise determined by the administrator. The terms and conditions of a stock award will be contained in an award agreement. Vesting and the lapse of restrictions on such stock awards may be conditioned upon the achievement of performance goals determined by the administrator. Recipients of restricted shares may have voting rights and may receive dividends on the granted shares prior to the time the restrictions lapse.

*Cash Awards.* The administrator may grant cash awards, which entitle the recipient to a cash payment on the satisfaction of performance goals described in the award. The administrator determines the terms, conditions and restrictions related to cash awards.

*Adjustments on Changes in Capitalization.* In the event of any stock dividend, stock split, reverse stock split, recapitalization, combination, reclassification, spin-off or similar change to our capital structure, appropriate adjustments will be made to:

- the number and class of securities subject to the 2004 Plan;
- the number and class of securities that may be awarded to any individual under the 2004 Plan; and
- the exercise price and number and class of securities under each outstanding Award.

Any such adjustments will be made by our board in its absolute discretion.

*Merger or Change in Control.* Generally, in the event of (a) a merger or consolidation in which we are not the surviving corporation, (b) a merger in which we are the surviving corporation but after which our stockholders immediately prior to such merger cease to own their shares or other equity interest in us, (c) the sale of all or substantially all of our assets, or (d) the acquisition, sale, or transfer of more than 50% of our outstanding shares by tender offer or similar transaction, any or all outstanding awards may be assumed, converted, replaced or substituted. In the event such successor corporation (if any) does not assume or substitute awards, the vesting with respect to such awards will accelerate so that the awards may be exercised before the closing or completion of the transaction but then terminate.

In addition, our board may also specify that other transactions or events constitute a “change in control” and may provide for the accelerated vesting of shares which are the subject of awards and take any one or more the actions described for a merger transaction. Our board need not adopt the same rules for each award under the 2004 Plan or for each holder of such awards.

If the options, SARs, or stock awards are assumed or substituted under a change in control or other transaction, then vesting or termination of repurchase rights may occur upon the subsequent involuntary termination (which includes certain constructive termination events) of an awardee’s service within 12 months following the transaction or change in control.

In the event of a proposed dissolution or liquidation of our company, our board may cause awards to be fully vested and exercisable (but not after their expiration date) before the dissolution is completed but contingent on its completion.

*Amendment and Termination of the Plan.* Our board may amend, alter, suspend or terminate the 2004 Plan, or any part thereof, at any time and for any reason. However, we will solicit stockholder approval for any amendment to the 2004 Plan to the extent necessary to comply with applicable laws. Generally, no such action by our board or stockholders may alter or impair any award previously granted under the 2004 Plan without the written consent of the awardee. The 2004 Plan has a term of ten years.

## RELATED PARTY TRANSACTIONS

The following is a description of transactions:

- to which we have been a party during the last three years;
- in which the amount involved exceeds \$60,000; and
- in which any director, executive officer or holder of more than 5% of our capital stock had or will have a direct or indirect material interest.

You should also review certain arrangements with our executive officers that are described under “Management”.

### Preferred Stock Issuances

The following directors and holders of more than 5% of our securities purchased securities in our preferred stock financings in the amounts and as of the dates shown below.

Purchaser	Shares of Convertible Preferred Stock				
	Series A*	Series B*	Series BB	Series C	Series C
Sutter Hill Ventures and affiliates <sup>(1)</sup>	1,383,687	986,253	213,702	1,123,337	343,400
Alta BioPharma Partners II, LLC and affiliates <sup>(2)</sup>	—	—	—	1,132,182	566,092
Maverick Capital, Ltd. <sup>(3)</sup>	—	—	—	1,415,227	707,614
James N. Wilson and affiliates <sup>(4)</sup>	405,336	144,999	38,149	—	—
David B. Singer <sup>(5)</sup>	29,055	30,000	12,761	—	—
Price per common share equivalent	\$ 0.36	\$ 1.00	\$ 4.033	\$ 7.066	\$ 7.066
Dates of purchase	May 1999	January 2000	May 2001	June 2001	December 2002

\* The number of shares and per share purchase price of the Series A and Series B convertible preferred stock have been adjusted to reflect the number of shares of common stock issuable upon conversion of such preferred stock and the related conversion price.

<sup>(1)</sup> G. Leonard Baker, Jr., one of our directors, is a managing director of the general partner of Sutter Hill Ventures.

<sup>(2)</sup> Alix Marduel, one of our directors, is a managing director of Alta Partners, LLP.

<sup>(3)</sup> Steven Kapp, one of our directors, is a limited partner of Maverick Capital, Ltd.

<sup>(4)</sup> James N. Wilson, the chairman of our board of directors, is a partner of the James and Pamela Wilson Family Partners, a California limited partnership, and is a trustee for certain of the trusts that hold Corcept securities.

<sup>(5)</sup> David B. Singer is a director of Corcept.

Shares held by all affiliated persons and entities have been aggregated. For additional details on the shares held by each of these purchasers, please refer to the information in this prospectus under the heading “Principal and Selling Stockholders.” Each share of preferred stock will convert automatically into common stock upon the closing of this offering. The purchasers of these shares are entitled to certain registration rights. See “Description of Capital Stock—Registration Rights.”

### Loans to Officers and Directors

On October 22, 2001, we made a loan in the amount of \$187,250 to Dr. Roe. Dr. Roe exercised an option to purchase 250,000 shares of our common stock with this loan. In connection with this loan, we received a full-recourse promissory note in the amount of the loan, bearing interest at 6.5%. Principal and interest are due no later than October 1, 2011, subject to acceleration upon certain events.

### Royalty Arrangements

Drs. Belanoff and Schatzberg were named inventors on certain patents issued to Stanford University. Under two separate agreements with Stanford University, we have obtained exclusive rights, under these patents, for the treatment of diseases such as PMD. Pursuant to arrangements between Dr. Belanoff,

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[Table of Contents](#)

Dr. Schatzberg and Stanford University, Drs. Belanoff and Schatzberg will each receive approximately 14.2% of any royalty payments made by us under the licenses Stanford University has granted to us. These amounts will be paid by Stanford University.

**Business Relationship**

We lease office space pursuant to a sublease from Heller Ehrman White & McAuliffe LLP, our legal counsel since inception. In connection with this sublease, we paid Heller Ehrman approximately \$205,000 in 2003. Sarah A. O’Dowd, one of our directors until January 2004, is a shareholder of a professional corporation that is the general partner of the law firm of Heller Ehrman.

We believe that we have executed all of the transactions set forth above on terms no less favorable to us than terms we could have obtained from unaffiliated third parties. We have adopted a policy that all future transactions, including loans, between us and our officers, directors, principal stockholders and their affiliates, must be approved by a majority of the board of directors, including a majority of the independent and disinterested members of the board of directors, and are on terms no less favorable to us than those that we could obtain from unaffiliated third parties.

**Indemnification Agreements**

Our amended and restated certificate of incorporation and bylaws provide that we will indemnify each of our directors and officers to the fullest extent permitted by Delaware Law. Further, we have entered into separate indemnification agreements with each of our directors and executive officers. For further information, see “Management—Indemnification.”

## PRINCIPAL AND SELLING STOCKHOLDERS

The following table presents the beneficial ownership of our common stock as of March 31, 2004, and as adjusted to reflect the sale of shares of our common stock offered by this prospectus, by:

- each person, or group of affiliated persons, who is known by us to own beneficially 5% or more of our common stock;
- each of our directors;
- each of our named executive officers; and
- all directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission. All shares of our common stock subject to options currently exercisable or exercisable within 60 days of March 31, 2004 are deemed to be outstanding for the purpose of computing the percentage ownership of the person holding options, but are not deemed to be outstanding for computing the percentage of ownership of any other person.

Unless otherwise indicated by the footnotes below, we believe, based on the information furnished to us, that each stockholder named in the table has sole or shared voting and investment power with respect to all shares beneficially owned, subject to applicable community property laws. Percentage of ownership is based on 18,142,128 shares of common stock outstanding as of March 31, 2004 and 23,142,128 shares outstanding after this offering, assuming no exercise of the underwriters' over-allotment option.

*Selling Stockholder.* Dr. Alan Schatzberg is the selling stockholder referred to in this prospectus. If Dr. Schatzberg sells 750,000 shares pursuant to the exercise of the underwriters' over-allotment options, Dr. Schatzberg will beneficially own 2,229,346 shares, or 9.7%, of our common stock after this offering and our executive officers and directors as a group will beneficially own 15,627,342 shares, or 67.5%, of our common stock.

### *Principal Stockholders*

Unless otherwise indicated in the footnotes to the table, the address of each individual listed in the table is: c/o Corcept Therapeutics Incorporated, 275 Middlefield Road, Suite A, Menlo Park, California 94025.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
<b>5% Stockholders</b>			
Sutter Hill Ventures <sup>(1)</sup>	4,036,317	22.3%	17.5%
Maverick Capital, Ltd. <sup>(2)</sup>	2,122,841	11.7%	9.2%
Entities affiliated with Alta Partners, LLP <sup>(3)</sup>	1,698,274	9.4%	7.3%
<b>Directors and Named Executive Officers</b>			
Joseph K. Belanoff <sup>(4)</sup>	3,004,345	16.6%	13.0%
Alan Schatzberg <sup>(5)</sup>	3,004,346	16.6%	13.0%
G. Leonard Baker, Jr. <sup>(6)</sup>	2,775,169	15.3%	12.0%
James N. Wilson <sup>(7)</sup>	2,368,377	13.1%	10.2%
Steven Kapp <sup>(8)</sup>	0	*	*
Alix Marduel <sup>(9)</sup>	1,698,274	9.4%	7.3%
David B. Singer <sup>(10)</sup>	821,816	4.5%	3.6%
Robert L. Roe <sup>(11)</sup>	389,188	1.6%	1.2%
Joseph C. Cook <sup>(12)</sup>	75,000	*	*
All directors and executive officers as a group (10 persons) <sup>(13)</sup>	14,136,515	77.6%	60.9%

\* Less than 1% of Corcept's outstanding common stock.

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## Table of Contents

- (1) Includes 22,422 shares held of record by Sutter Hill Entrepreneurs Fund (AI), LP, 56,768 shares held of record by Sutter Hill Entrepreneurs Fund (QP), LP and 2,216,188 shares held of record by Sutter Hill Ventures, a California limited partnership over which Mr. Baker, a member of our board of directors and a managing director of the general partner of the Sutter Hill Ventures, shares voting and investment power with seven other managing directors of the general partner of the partnerships mentioned herein. Also includes 1,261,148 shares held of record by seven other managing directors, one retired managing director and their related family entities and 479,791 shares held of record by Mr. Baker and a related family entity. The address of Sutter Hill Ventures is 755 Page Mill Road, Suite A-200, Palo Alto, California 94304-5600. The natural persons who have voting or investment power over the shares held of record by Sutter Hill Ventures are David L. Anderson, G. Leonard Baker, Jr., William H. Younger, Jr., Tench Coxe, Gregory P. Sands, James C. Gaither, James N. White and Jeffrey W. Bird. Each of the managing directors disclaims beneficial ownership of the shares listed above except to the extent of his individual pecuniary interest therein.
- (2) Includes 194,999 shares held of record by Maverick Fund II, Ltd., 607,398 shares held of record by Maverick Fund USA, Ltd., and 1,320,444 shares held of record by Maverick Fund, L.D.C. Maverick Capital, Ltd. is an investment adviser registered under Section 203 of the Investment Advisers Act of 1940 and, as such, has beneficial ownership of the shares held by Maverick Fund USA, Ltd., Maverick Fund II, Ltd. and Maverick Fund, L.D.C. through the investment discretion it exercises over these accounts. Maverick Capital Management, LLC is the General Partner of Maverick Capital, Ltd. Lee S. Ainslie III is a manager of Maverick Capital Management, LLC, and is granted sole investment discretion pursuant to Maverick Capital Management, LLC's Regulations. The address of Maverick Capital, Ltd. is 300 Crescent Court, 18th Floor, Dallas, TX 75201.
- (3) Includes 1,632,012 shares held of record by Alta BioPharma Partners II, LP and 66,262 shares held of record by Alta Embarcadero BioPharma Partners II, LLC. The address of Alta Partners, LLP is One Embarcadero Center, Suite 4050, San Francisco, California 94111. The natural persons affiliated with Alta Partners LLP who have voting or investment power over these shares are Jean Deleage, Alix Marduel, Farah Champsy and Hilary Strain.
- (4) Includes 300,000 shares held as custodian for Edward G. Belanoff and 300,000 shares held as custodian for Julia E. Belanoff under the California Uniform Transfers to Minors Act over which Dr. Belanoff has voting control.
- (5) Includes 300,000 shares held of record by Lindsey D. Schatzberg and 300,000 shares held of record by Melissa A. Schatzberg, over which Dr. Schatzberg has voting control.
- (6) Includes 22,422 shares held of record by Sutter Hill Entrepreneurs Fund (AI), LP, 56,768 shares held of record by Sutter Hill Entrepreneurs Fund (QP), LP and 2,216,188 shares held of record by Sutter Hill Ventures, a California limited partnership over which Mr. Baker, a member of our board of directors and a managing director of the general partner of the partnerships mentioned herein, shares voting and investment power with seven other managing directors of the general partner of the partnerships mentioned herein. Also includes 479,791 shares held of record by Mr. Baker and a related family entity. Mr. Baker disclaims beneficial ownership of the shares listed above, except to the extent of his individual pecuniary interest therein. The address of G. Leonard Baker, Jr. is 755 Page Mill Road, Suite A-200, Palo Alto, California 94304-1005.
- (7) Includes 606,060 shares held of record by the James and Pamela Wilson Family Partners, 1,588,094 shares held of record by the James N. Wilson and Pamela D. Wilson Trust, 25,243 shares held of record by David Wilson, 6,358 shares held of record by the Norman and Ann Wilson Family Trust, 37,776 shares held of record by David K. Arterbum and Edith A. Watters, as trustees of the Arterbum/Watters Trust, 37,776 shares held of record by Edward M. West and Beth Ann Wilson West, and 67,070 shares held of record by Edward M. West and Beth Ann Wilson as trustees of the West Revocable Trust, over all of which Mr. Wilson has voting control pursuant to voting agreements. Mr. Wilson disclaims beneficial ownership of such shares, except to the extent of his pecuniary interests in the entities holding such shares.

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[Table of Contents](#)

- <sup>(8)</sup> Mr. Kapp is a limited partner of Maverick Capital, Ltd. The address of Steven Kapp is c/o MCL Corporation, 610 W. Germantown Pike, Suite 170, Plymouth Meeting, PA 19462.
- <sup>(9)</sup> Includes 1,632,012 shares held of record by Alta BioPharma Partners II, LP and 66,262 shares held of record by Alta Embarcadero BioPharma Partners II, LLC. Dr. Marduel and certain principals of Alta Partners LLP are Managing Directors of the funds mentioned herein, and as such, they may be deemed to share voting and investment powers for the shares held by the funds. The principals of Alta Partners LLP disclaim beneficial ownership of all such shares held by the foregoing funds, except to the extent of their pecuniary interests in such funds. The address of Alix Marduel is One Embarcadero Center, Suite 4050, San Francisco, California 94111.
- <sup>(10)</sup> Includes 40,000 shares held of record by the Singer-Kapp Family Trust FBO Kapp S. Singer.
- <sup>(11)</sup> Includes 7,181 shares issuable pursuant to options exercisable within 60 days of March 31, 2004 and includes 229,325 shares which we have the right to repurchase within 60 days of March 31, 2004.
- <sup>(12)</sup> Includes 75,000 shares issuable pursuant to options exercisable within 60 days of March 31, 2004, of which our right to repurchase will have elapsed with respect to 20,855 shares.
- <sup>(13)</sup> Total number of shares includes common stock held by entities affiliated with directors and executive officers. See footnotes 1 through 12 above.



## DESCRIPTION OF CAPITAL STOCK

Upon the closing of this offering, our authorized capital stock, after giving effect to the amendment and restatement of our certificate of incorporation, will consist of 140,000,000 shares of common stock, \$0.001 par value, and 10,000,000 shares of preferred stock, \$0.001 par value.

### Common Stock

As of March 31, 2004, there were 18,142,128 shares of common stock that were held of record by approximately 100 stockholders after giving effect to the conversion of our preferred stock into common stock. There will be 23,142,128 shares of common stock outstanding, assuming no exercise of the underwriters' over-allotment option and no exercise of outstanding options, after giving effect to the sale of the shares of common stock offered by this prospectus.

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors, and each holder does not have cumulative voting rights. Accordingly, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they so choose.

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the board of directors out of legally available funds. In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

Holders of common stock have no preemptive or conversion rights or other subscription rights, and there are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are, and the shares of common stock offered by us in this offering, when issued and paid for, will be fully paid and nonassessable. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock which we may designate in the future.

### Preferred Stock

Upon the closing of this offering, the board of directors will be authorized, subject to any limitations prescribed by law, without stockholder approval, to issue up to an aggregate of 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions granted to or imposed upon the preferred stock, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences. The rights of the holders of common stock will be subject to, and may be adversely affected by, the rights of holders of any preferred stock that may be issued in the future. Issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could have the effect of delaying, deferring or preventing a change in control of Corcept. We have no present plans to issue any shares of preferred stock.

### Convertible Promissory Note

In January 2001, we issued a convertible promissory note to the Institute for the Study of Aging, Inc., the principal amount of which is \$462,929 and which accrues interest at 4.5% per annum. The note and accrued interest may be converted once, upon the first to occur of our initial public offering, a merger or acquisition of our company or FDA approval to market mifepristone for the treatment of Alzheimer's disease. The method for determining the conversion price differs with respect to each of the foregoing events. In the case of our initial public offering, the conversion price will be the initial public offering price. Within 60 days of the closing of the offering, we must provide notice of the offering to the noteholder and the noteholder will then have 60 days from the date of the notice to exercise its option

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## [Table of Contents](#)

convert the note into shares of our common stock. If the noteholder declines to convert the note in connection with this offering, the note will no longer be convertible and will be payable on demand any time after January 4, 2006.

### **Registration Rights**

After this offering, the holders of preferred stock convertible into 8,807,146 shares of common stock will be entitled to rights to cause us to register the sale of such shares under the Securities Act. These shares are referred to as registrable securities. Specifically, commencing 180 days after the effective date of the registration statement of which this prospectus is a part, holders of at least 50% of the registrable securities may require us to prepare and file a registration statement under the Securities Act at our expense covering at least 50% of the registrable securities then outstanding, or any lesser amount if the shares to be included in such registration will generate anticipated aggregate net proceeds to Corcept of at least \$10,000,000.

Under these demand registration rights, we are required to use our best efforts to cause the shares requested to be included in the registration statement, subject to customary conditions and limitations. We are not obligated to effect more than one of these stockholder-initiated registrations. Once we become eligible to file a registration statement on Form S-3, the holders of at least one-third of the registrable securities may require us to register for a public offering of shares of registrable securities on a registration statement on Form S-3 and may participate in certain registrations by us, subject to specific conditions and limitations. Registration rights terminate no later than four years after this offering. Registration of these shares under the Securities Act would result in these shares, other than shares purchased by our affiliates, becoming freely tradable without restriction under the Securities Act.

### **Effect of Certain Provisions of our Amended and Restated Certificate of Incorporation and Bylaws and the Delaware Anti-Takeover Statute**

#### *Amended and Restated Certificate of Incorporation and Bylaws*

Some provisions of Delaware law and our amended and restated certificate of incorporation and bylaws contain provisions that could make the following transactions more difficult:

- acquisition of us by means of a tender offer;
- acquisition of us by means of a proxy contest or otherwise; or
- removal of our incumbent officers and directors.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids and to promote stability in our management. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors.

- *Undesignated Preferred Stock.* The ability to authorize undesignated preferred stock makes it possible for our board of directors to issue one or more series of preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of Corcept. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.
- *Stockholder Meetings.* Our charter documents provide that a special meeting of stockholders may be called only by the chairman of the board or by our president, or by a resolution adopted by a majority of our board of directors.
- *Requirements for Advance Notification of Stockholder Nominations and Proposals.* Our bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

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## Table of Contents

- *Elimination of Stockholder Action by Written Consent.* Our amended and restated certificate of incorporation eliminates the right of stockholders to act by written consent without a meeting.
- *Amendment of Bylaws.* Any amendment of our bylaws by our stockholders requires approval by holders of at least 66 2/3% of our then outstanding common stock, voting together as a single class.

### *Delaware Anti-Takeover Statute*

We are subject to Section 203 of the Delaware General Corporation Law. This law prohibits a publicly-held Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned by persons who are directors and also officers and by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the date of the transaction, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines “business combination” to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of our assets involving the interested stockholder;
- in general, any transaction that results in the issuance or transfer by us of any of our stock to the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an “interested stockholder” as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company.

## SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of our common stock in the public market could adversely affect prevailing market prices. Furthermore, a large number of our shares of common stock outstanding will not be available for sale shortly after this offering because of contractual and legal restrictions on resale as described below. Sales of substantial amounts of our common stock in the public market after these restrictions lapse, or the perception that such sales may occur, could depress the prevailing market price and limit our ability to raise equity capital in the future.

Upon completion of this offering, we will have outstanding an aggregate of 23,142,128 shares of common stock, based upon the shares outstanding as of March 31, 2004, assuming no exercise of the underwriters' over-allotment option and no exercise of outstanding options prior to completion of this offering. Of the total outstanding shares, the 5,000,000 shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except that any shares held by our affiliates, as that term is defined under the Securities Act, may generally only be sold in accordance with Rule 144 of the Securities Act.

### **Sales of Restricted Shares**

The remaining 18,142,128 shares of common stock held by existing stockholders were issued and sold by us in reliance on exemptions from the registration requirements of the Securities Act. All of these shares will be subject to "lock-up" agreements under which the holders have agreed not to offer, sell or otherwise dispose of any of the shares of common stock owned by them for a period of 180 days after the completion of this offering. Thomas Weisel Partners, however, may in its sole discretion, at any time without notice, release all or any portion of the shares subject to lock-up agreements. Upon expiration of the lock-up agreements, 2,257,694 shares will become eligible for sale pursuant to Rule 144(k), 15,750,141 shares will become eligible for sale under Rule 144 and 134,293 shares will become eligible for sale under Rule 701. In addition, of the 730,500 shares issuable upon exercise of options to purchase our common stock outstanding as of March 31, 2004, approximately 163,275 shares will be vested and eligible for sale 180 days after the date of this prospectus.

### **Stock Options**

After the completion of this offering, we intend to file a registration statement on Form S-8 under the Securities Act to register all of the shares of common stock subject to issuance of options outstanding or reserved for future issuance under our 2000 Stock Option Plan and 2004 Equity Incentive Plan. Based upon the number of shares subject to outstanding options as of March 31, 2004 and the shares reserved for issuance under our 2000 Stock Option Plan and 2004 Equity Incentive Plan, the registration statement on Form S-8 would cover approximately 3,730,500 shares. Shares registered under that registration statement will generally be available for sale in the open market immediately after the 180 day lock-up agreements expire.

### **Registration Rights**

After this offering, the holders of an aggregate of approximately 8.8 million shares of our common stock will have the right to require us to register these shares under the Securities Act under certain circumstances. After registration, the shares will be freely tradable without restriction under the Securities Act. For more information regarding these registration rights, see "Description of Capital Stock—Registration Rights."

### **Rule 144**

In general, under Rule 144 as currently in effect, beginning 180 days after the date of this prospectus, a person who has beneficially owned restricted securities for at least one year and is not an

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## [Table of Contents](#)

affiliate would be entitled to sell in “broker’s transactions” or to market makers, within any three-month period, a number of shares that does not exceed the greater of:

- 1% of the number of shares of common stock then outstanding (which will equal approximately shares immediately after this offering); or
- the average weekly trading volume in the common stock on the Nasdaq National Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales under Rule 144 are generally subject to the availability of current public information about Corcept.

### **Rule 144(k)**

Under Rule 144(k), a person who is not deemed to have been our affiliate at any time during the 90 days preceding a sale, and who has beneficially owned the shares proposed to be sold for at least two years, is entitled to sell these shares without having to comply with the manner of sale, public information, volume limitation or notice filing provisions of Rule 144. Therefore, unless otherwise restricted, “144(k) shares” may be sold immediately upon the completion of this offering. Affiliates must always sell pursuant to Rule 144, even after the applicable holding periods have been satisfied.

### **Rule 701**

In general, under Rule 701, any of our employees, directors, officers, consultants or advisors who purchase shares from us in connection with a compensatory stock or option plan or other written agreement before the effective date of this offering is entitled to sell his or her shares 90 days after the effective date of this offering, unless otherwise restricted, in reliance on Rule 144, without having to comply with the holding period of Rule 144 and, in the case of non-affiliates, without having to comply with the public information, volume limitation or notice filing provisions of Rule 144.

## UNDERWRITING

### General

Subject to the terms and conditions contained in an agreement among the underwriters and us, each of the underwriters named below, through their representatives, Thomas Weisel Partners LLC, Piper Jaffray & Co. and Legg Mason Wood Walker, Incorporated have severally agreed to purchase the aggregate number of shares of common stock listed opposite its name below:

Underwriters	Number of Shares
Thomas Weisel Partners LLC	
Piper Jaffray & Co.	
Legg Mason Wood Walker, Incorporated	
Total	5,000,000

The underwriting agreement provides that the obligations of the several underwriters are subject to various conditions. The underwriting agreement also provides that the underwriters will purchase and pay for all of the shares of common stock listed above if any of the shares are purchased.

The underwriting agreement provides that we and the selling stockholder will indemnify the underwriters against liabilities specified in the underwriting agreement under the Securities Act, or will contribute to payments that the underwriters may be required to make relating to these liabilities.

### Over-Allotment Option

We and the selling stockholder have granted the underwriters a 30-day option to purchase up to a total of 750,000 additional shares of our common stock from us, the selling stockholder, or both, at the initial public offering price, less the underwriting discounts and commissions payable by us, as set forth on the cover page of this prospectus. The underwriters may exercise this option only to cover over-allotments made in connection with the sale of the common stock offered by us and the selling stockholder in this prospectus. If the underwriters exercise this option in whole or in part, then each of the underwriters will be separately committed, subject to conditions described in the underwriting agreement, to purchase a number of additional shares of our common stock proportionate to that underwriter's initial amount reflected in the table above.

### Commissions and Discounts

The underwriters propose to offer the shares of common stock directly to the public at the public offering price described on the cover page of this prospectus, and to dealers at that price less a concession not in excess of \$ \_\_\_\_\_ per share. The underwriters may allow and the dealers may reallow a concession not in excess of \$ \_\_\_\_\_ per share on sales to certain other brokers and dealers. After the initial public offering, the underwriters may vary the public offering price or other selling terms.

The following table shows the per share and total public offering price, the underwriting discount and the proceeds we will receive before expenses in connection with this offering:

	Total	
	Per Share	Without Over-Allotment
Public offering price	\$	\$
Underwriting discount	\$	\$
Proceeds, before expenses, to us	\$	\$

Upon the underwriter's exercise of the over-allotment option, we will have the option of selling all or a portion of the additional shares to the underwriters, and the selling stockholder will sell the remaining shares, if any. Each of us and the selling stockholder will receive \$ \_\_\_\_\_ per share for each share sold upon exercise of the over-allotment, if any.

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## [Table of Contents](#)

### **Determination of Offering Price**

Prior to this offering, there has been no public market for our common stock. The initial public offering price for the shares of our common stock was determined through negotiations among us and the representatives. The primary factors considered in determining the initial public offering price were:

- prevailing market conditions;
- our financial information;
- the history of and prospects for our industry;
- an assessment of our management, our past and present operations, and the prospects for, and timing of, our future revenues;
- the present state of our development and the progress of our business plan; and
- the consideration of these factors in relation to the market valuation of other companies engaged in activities similar to ours.

We cannot assure you that an active or orderly trading market will develop for our common stock or that our common stock will trade in the public markets subsequent to this offering at or above the initial offering price.

### **Indemnification of Underwriters**

We and the selling stockholder have agreed to indemnify the underwriters against some civil liabilities, including liabilities under the Securities Act and liabilities arising from breaches of our representations and warranties contained in the underwriting agreement. If we or the selling stockholder are unable to provide this indemnification, we and the selling stockholder will contribute to payments the underwriters may be required to make in respect of those liabilities.

### **Reserved Shares**

The underwriters, at our request, have reserved for sale at the initial public offering price a number of shares that will not exceed 5% of the aggregate shares of common stock to be sold in this offering for sale to our employees and other persons designated by us. The number of shares available for sale to the general public will be reduced to the extent that any reserved shares are purchased. Any reserved shares not purchased in this manner will be offered by the underwriters on the same basis as the other shares offered in this offering.

### **No Sales of Similar Securities**

Each of our directors and officers and all of our stockholders, including the selling stockholder, have agreed not to offer, sell, agree to sell, directly or indirectly, or otherwise dispose of any shares of common stock or any securities convertible into or exchangeable for shares of common stock without the prior written consent of Thomas Weisel Partners LLC for a period of 180 days after the date of this prospectus.

We have agreed that for a period of 180 days after the date of this prospectus we will not, without the prior written consent of Thomas Weisel Partners LLC, offer, sell, or otherwise dispose of any shares of common stock, except for the shares of common stock offered in the offering and the shares of common stock issuable upon exercise of options and warrants outstanding on the date of this prospectus.

### **Nasdaq National Market Listing**

We have applied for listing of our common stock on the Nasdaq National Market under the symbol "CORT".

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## [Table of Contents](#)

### **Discretionary Accounts**

The underwriters do not expect sales of shares of common stock offered by this prospectus to any accounts over which they exercise discretionary authority to exceed five percent of the shares offered.

### **Short Sales, Stabilizing Transactions and Penalty Bids**

In order to facilitate this offering, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of our common stock during and after this offering. Specifically, the underwriters may engage in the following activities in accordance with the rules of the SEC.

*Short Sales.* Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. “Covered” short sales are sales made in an amount not greater than the underwriters’ option to purchase additional shares from the issuer in the offering. The underwriters may close out any covered short position by either exercising their option to purchase shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. “Naked” short sales are any sales in excess of such over-allotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering.

*Stabilizing Transactions.* The underwriters may make bids for or purchases of the shares in the open market for the purpose of pegging, fixing or maintaining the price of the shares, so long as stabilizing bids do not exceed a specified maximum.

*Penalty Bids.* The underwriters may impose penalty bids. This means that if the underwriters purchase shares in the open market in a stabilizing transaction or syndicate covering transaction, they may reclaim a selling concession from the underwriters and selling group members who sold those shares as part of this offering.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of the common stock. As a result, the price of our common stock may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may occur on the Nasdaq National Market or otherwise and, if commenced, they may be discontinued without notice at any time.

A prospectus in electronic format may be made available on the web sites maintained by one or more of the underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. No form of prospectus other than printed prospectuses and electronically distributed prospectuses that are printable in Adobe PDF format will be used in connection with this offering.

From time to time in the ordinary course of their respective businesses, certain of the underwriters have performed and may in the future perform investment banking and advisory services for us, for which they have received or may receive customary fees and expenses.

Three individuals affiliated with Piper Jaffray & Co., one of the representatives of the underwriters, purchased an aggregate of 8,821 shares of Series C preferred stock at a purchase price of \$7.07 per share in our Series C financings in June 2001 and December 2002.



**UNITED STATES FEDERAL INCOME TAX CONSEQUENCES  
TO NON-UNITED STATES HOLDERS**

The following is a summary of the material United States federal income tax consequences of the ownership and disposition of our common stock to non-United States holders, but does not purport to be a complete analysis of all the potential tax considerations relating thereto. This summary is based upon the provisions of the Internal Revenue Code of 1986, as amended, or the Code, Treasury regulations promulgated thereunder, administrative rulings and judicial decisions, all as of the date hereof. These authorities may be changed, possibly retroactively, so as to result in United States federal income tax consequences different from those set forth below. We have not sought any ruling from the Internal Revenue Service, or the IRS, with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS will agree with such statements and conclusions.

This summary also does not address the tax considerations arising under the laws of any foreign, state or local jurisdiction. In addition, this discussion does not address tax considerations applicable to an investor's particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

- banks, insurance companies, or other financial institutions;
- persons subject to the alternative minimum tax;
- tax-exempt organizations;
- dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;
- persons that own, or are deemed to own, more than five percent of our company (except to the extent specifically set forth below);
- certain former citizens or long-term residents of the United States;
- persons who hold our common stock as a position in a hedging transaction, "straddle," "conversion transaction" or other risk reduction transaction; or
- persons deemed to sell our common stock under the constructive sale provisions of the Code.

In addition, if a partnership holds our common stock, the tax treatment of a partner generally will depend on the status of the partner and upon the activities of the partnership. Accordingly, partnerships which hold our common stock, and partners in such partnerships, should consult their tax advisors.

**YOU ARE URGED TO CONSULT YOUR TAX ADVISOR WITH RESPECT TO THE APPLICATION OF THE UNITED STATES FEDERAL INCOME TAX LAWS TO YOUR PARTICULAR SITUATION, AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE UNITED STATES FEDERAL ESTATE OR GIFT TAX RULES OR UNDER THE LAWS OF ANY STATE, LOCAL, FOREIGN OR OTHER TAXING JURISDICTION OR UNDER ANY APPLICABLE TAX TREATY.**

**Non-United States Holder Defined**

For purposes of this discussion, you are a non-United States holder if you are a holder that, for United States federal income tax purposes, is not a United States person. For purposes of this discussion, you are a United States person if you are:

- an individual citizen or resident of the United States;
- a corporation or other entity taxable as a corporation, or a partnership or entity taxable as a partnership, created or organized in the United States or under the laws of the United States or any political subdivision thereof;

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## [Table of Contents](#)

- an estate whose income is subject to United States federal income tax regardless of its source; or
- a trust (x) whose administration is subject to the primary supervision of a United States court and which has one or more United States persons who have the authority to control all substantial decisions of the trust or (y) which has made an election to be treated as a United States person.

### **Distributions**

We have not made any distributions on our common stock, and we do not plan to make any distributions for the foreseeable future. However, if we do make distributions on our common stock, those payments will constitute dividends for United States tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under United States federal income tax principles. To the extent those distributions exceed both our current and our accumulated earnings and profits, they will constitute a return of capital and will first reduce your basis in our common stock, but not below zero, and then will be treated as gain from the sale of stock.

Any dividend paid to you generally will be subject to United States withholding tax either at a rate of 30% of the gross amount of the dividend or such lower rate as may be specified by an applicable income tax treaty. In order to receive a reduced treaty rate, you must provide us with an IRS Form W-8BEN or other appropriate version of IRS Form W-8 certifying qualification for the reduced rate.

Dividends received by you that are effectively connected with your conduct of a United States trade or business are exempt from such withholding tax. In order to obtain this exemption, you must provide us with an IRS Form W-8ECI properly certifying such exemption. Such effectively connected dividends, although not subject to withholding tax, are taxed at the same graduated rates applicable to United States persons, net of certain deductions and credits. In addition, if you are a corporate non-United States holder, dividends you receive that are effectively connected with your conduct of a United States trade or business may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty.

If you are eligible for a reduced rate of withholding tax pursuant to a tax treaty, you may obtain a refund of any excess amounts currently withheld if you file an appropriate claim for refund with the IRS.

### **Gain on Disposition of Common Stock**

You generally will not be required to pay United States federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

- the gain is effectively connected with your conduct of a United States trade or business;
- you are an individual who holds our common stock as a capital asset (generally, an asset held for investment purposes) and who is present in the United States for a period or periods aggregating 183 days or more during the calendar year in which the sale or disposition occurs and certain other conditions are met; or
- our common stock constitutes a United States real property interest by reason of our status as a “United States real property holding corporation” for United States federal income tax purposes (a “USRPHC”) at any time within the shorter of the five-year period preceding the disposition or your holding period for our common stock.

We believe that we are not currently and will not become a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our United States real property relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, however, as long as our common stock is regularly traded on an established securities market, such common stock will be treated as United States real property interests only if you actually or constructively hold more than 5% of such regularly traded common stock.

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[Table of Contents](#)

If you are a non-United States holder described in the first bullet above, you will be required to pay tax on the net gain derived from the sale under regular graduated United States federal income tax rates, and corporate non-United States holders described in the first bullet above may be subject to the branch profits tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. If you are an individual non-United States holder described in the second bullet above, you will be required to pay a flat 30% tax on the gain derived from the sale, which tax may be offset by United States source capital losses (even though you are not considered a resident of the United States). You should consult any applicable income tax treaties that may provide for different rules.

**Backup Withholding and Information Reporting**

Generally, we must report annually to the IRS the amount of dividends paid to you, your name and address, and the amount of tax withheld, if any. A similar report is sent to you. Pursuant to applicable income tax treaties or other agreements, the IRS may make these reports available to tax authorities in your country of residence.

Payments of dividends or of proceeds on the disposition of stock made to you may be subject to information reporting and backup withholding unless you establish an exemption, for example by properly certifying your non-United States status on a Form W-8BEN or another appropriate version of IRS Form W-8. Notwithstanding the foregoing, backup withholding and information reporting may apply if either we or our paying agent has actual knowledge, or reason to know, that you are a United States person.

Backup withholding is not an additional tax; rather, the United States income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If withholding results in an overpayment of taxes, a refund or credit may be obtained, provided that the required information is furnished to the IRS in a timely manner.

## LEGAL MATTERS

The validity of the common stock being offered by this prospectus will be passed upon for us by Heller Ehrman White & McAuliffe LLP, Menlo Park, California which has acted as our counsel in connection with this offering. As of the date of this prospectus, Heller Ehrman White & McAuliffe LLP owns 33,750 shares of our common stock and partners of Heller Ehrman White & McAuliffe LLP own an additional 64,441 shares of common stock individually and through an investment limited liability company. The underwriters have been represented by Latham & Watkins LLP, Costa Mesa, California.

## EXPERTS

Ernst & Young LLP, independent auditors, have audited our financial statements at December 31, 2002 and 2003, and for each of the three years in the period ended December 31, 2003, and for the period from inception (May 13, 1998) to December 31, 2003, as set forth in their report. We have included our financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

## WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 (including exhibits and schedules) under the Securities Act, with respect to the shares of common stock offered by us and the selling stockholder in this offering. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement; some items are contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information on Corcept and the common stock offered in this prospectus, reference is made to the registration statement, including the exhibits thereto, and the financial statements and notes filed as a part of the registration statement. With respect to each document filed with the SEC as an exhibit to the registration statement, reference is made to the exhibit for a more complete description of the matter involved. When we complete this offering, we will also be required to file annual, quarterly and special reports, proxy statements and other information with the SEC.

You can read our SEC filings, including the registration statement, over the Internet at the SEC's web site at [www.sec.gov](http://www.sec.gov). You may also read and copy any document we file with the SEC at its public reference facility at 450 Fifth Street, N.W., Washington, D.C. 20549. You may also obtain copies of the document at prescribed rates by writing to the Public Reference Section of the SEC at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

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[Table of Contents](#)

**CORCEPT THERAPEUTICS INCORPORATED**  
**(A DEVELOPMENT STAGE COMPANY)**  
**INDEX TO FINANCIAL STATEMENTS**

	<u>Page</u>
<a href="#">Report of Ernst &amp; Young LLP, Independent Auditors</a>	F-2
Audited Financial Statements	
<a href="#">Balance Sheets</a>	F-3
<a href="#">Statements of Operations</a>	F-4
<a href="#">Statements of Convertible Preferred Stock and Stockholders' Equity (Net Capital Deficiency)</a>	F-5
<a href="#">Statements of Cash Flows</a>	F-9
<a href="#">Notes to Financial Statements</a>	F-10

**REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS**

The Board of Directors and Stockholders  
Corcept Therapeutics Incorporated

We have audited the accompanying balance sheets of Corcept Therapeutics Incorporated (a development stage company) as of December 31, 2002 and 2003, and the related statements of operations, convertible preferred stock and stockholders' equity (net capital deficiency), and cash flows for each of the three years in the period ended December 31, 2003, and for the period from inception (May 13, 1998) to December 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Corcept Therapeutics Incorporated (a development stage company) at December 31, 2002 and 2003 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2003 and for the period from inception (May 13, 1998) to December 31, 2003, in conformity with accounting principles generally accepted in the United States.

/s/ Ernst & Young LLP

Palo Alto, California  
January 20, 2004,  
except for Note 11,  
as to which the date is  
March 11, 2004

[Table of Contents](#)

**CORCEPT THERAPEUTICS INCORPORATED**  
**(A DEVELOPMENT STAGE COMPANY)**  
**BALANCE SHEETS**

	December 31,		Unaudited Pro forma Stockholders' Equity at December 31, 2003
	2002	2003	
<b>Assets</b>			
Current assets:			
Cash and cash equivalents (including restricted cash of \$429,515 and \$0 at December 31, 2002 and 2003, respectively)	\$ 18,400,992	\$ 10,073,103	
Short-term investments	3,142,180	1,504,180	
Prepaid expenses and other current assets	195,430	165,341	
<b>Total current assets</b>	<b>21,738,602</b>	<b>11,742,624</b>	
Property and equipment, net of accumulated depreciation	23,082	531	
Other assets	33,043	37,805	
<b>Total assets</b>	<b>\$ 21,794,727</b>	<b>\$ 11,780,960</b>	
<b>Liabilities and stockholders' equity</b>			
Current liabilities:			
Accounts payable	\$ 804,974	\$ 321,806	
Accrued clinical expenses	530,106	334,362	
Other accrued liabilities	181,544	357,818	
<b>Total current liabilities</b>	<b>1,516,624</b>	<b>1,013,986</b>	
Convertible note payable	502,857	523,689	
<b>Total liabilities</b>	<b>2,019,481</b>	<b>1,537,675</b>	
Commitments			
Convertible preferred stock, \$0.001 par value, issuable in series; 10,000,000 shares authorized and 6,768,558 shares issued and outstanding at December 31, 2002 and 2003 (no shares authorized or outstanding pro forma); aggregate liquidation preference of \$41,702,203 at December 31, 2003	41,715,974	41,715,974	
Stockholders' equity (net capital deficiency):			
Preferred stock, \$0.001 par value, undesignated; 10,000,000 shares authorized and no shares outstanding pro forma			\$ —
Common stock, \$0.001 par value; 30,000,000 shares authorized and 9,540,858 and 9,334,982 shares issued and outstanding at December 31, 2002 and 2003, respectively (18,142,128 shares outstanding pro forma)	9,541	9,335	18,142
Additional paid-in capital	10,881,514	8,981,827	50,688,994
Notes receivable from stockholders	(438,165)	(246,258)	(246,258)
Deferred compensation	(4,268,488)	(2,279,524)	(2,279,524)
Deficit accumulated during the development stage	(28,125,064)	(37,937,426)	(37,937,426)
Accumulated other comprehensive loss	(66)	(643)	(643)
<b>Total stockholders' equity (net capital deficiency)</b>	<b>(21,940,728)</b>	<b>(31,472,689)</b>	<b>\$ 10,243,285</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 21,794,727</b>	<b>\$ 11,780,960</b>	

See accompanying notes.

**CORCEPT THERAPEUTICS INCORPORATED**  
**(A DEVELOPMENT STAGE COMPANY)**

**STATEMENTS OF OPERATIONS**

	Years ended December 31,			Period from inception (May 13, 1998) to December 31, 2003
	2001	2002	2003	
Operating expenses:				
Research and development*	\$ 5,390,411	\$ 13,150,078	\$ 8,107,629	\$ 28,107,548
General and administrative*	2,615,734	5,653,040	1,886,967	10,917,014
Total operating expenses	8,006,145	18,803,118	9,994,596	39,024,562
Interest and other income, net	600,420	320,000	203,066	1,181,941
Interest expense	(48,113)	(20,832)	(20,832)	(94,805)
Net loss	\$ (7,453,838)	\$ (18,503,950)	\$ (9,812,362)	\$ (37,937,426)
Basic and diluted net loss per share	\$ (1.25)	\$ (2.50)	\$ (1.13)	
Shares used in computing basic and diluted net loss per share	5,980,897	7,392,016	8,650,471	
Pro forma basic and diluted net loss per share			\$ (0.55)	
Shares used in computing pro forma basic and diluted net loss per share			17,757,617	
*Includes non-cash stock-based compensation of the following:				
Research and development	\$ 1,213,649	\$ 1,956,874	\$ 551,176	\$ 3,819,320
General and administrative	680,158	2,144,721	(307,772)	2,517,107
Total non-cash stock-based compensation	\$ 1,893,807	\$ 4,101,595	\$ 243,404	\$ 6,336,427

See accompanying notes.



**CORCEPT THERAPEUTICS INCORPORATED**  
(A DEVELOPMENT STAGE COMPANY)

**STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)**

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Notes Receivable from Stockholders	Deferred Compensation	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Net Capital Deficiency)
	Shares	Amount	Shares	Amount						
Balance at inception (May 13, 1998)	—	\$ —	—	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Issuance of common stock to directors for cash in June and July 1998	—	—	7,500,000	7,500	(5,000)	—	—	—	—	2,500
Issuance of common stock to a director for cash in May 1999	—	—	1,770,939	1,771	63,163	—	—	—	—	64,934
Issuance of common stock to Stanford and directors in conjunction with a license agreement in October 1999	—	—	30,000	30	1,070	—	—	—	—	1,100
Issuance of Series A convertible preferred stock to institutional and individual investors at \$1.08 per share for cash and conversion of notes payable, net of issuance costs of \$33,756 in May 1999	607,761	622,626	—	—	—	—	—	—	—	—
Common stock issued to attorneys and consultants in exchange for services in May 1999	—	—	48,750	49	1,739	—	—	—	—	1,788
Issuance of common stock upon option exercise	—	—	60,000	60	(40)	—	—	—	—	20
Repurchase of common stock held by director in March 1999	—	—	(750,000)	(750)	500	—	—	—	—	(250)
Deferred compensation related to options granted to nonemployees	—	—	—	—	64,935	—	(64,935)	—	—	—
Amortization of deferred compensation	—	—	—	—	—	—	7,350	—	—	7,350
Net loss from inception to December 31, 1999	—	—	—	—	—	—	—	(321,110)	—	(321,110)
<b>Balance at December 31, 1999</b>	<b>607,761</b>	<b>622,626</b>	<b>8,659,689</b>	<b>8,660</b>	<b>126,367</b>	<b>—</b>	<b>(57,585)</b>	<b>(321,110)</b>	<b>—</b>	<b>(243,668)</b>
Issuance of Series B convertible preferred stock to institutional and individual investors at \$3.00 per share for cash, net of issuance costs of \$19,232 in January 2000	399,999	1,180,765	—	—	—	—	—	—	—	—
Deferred compensation related to options granted to an employee and nonemployees	—	—	—	—	248,118	—	(248,118)	—	—	—
Amortization of deferred compensation	—	—	—	—	—	—	90,271	—	—	90,271
Net loss	—	—	—	—	—	—	—	(1,846,166)	—	(1,846,166)
<b>Balance at December 31, 2000 (carried forward)</b>	<b>1,007,760</b>	<b>1,803,391</b>	<b>8,659,689</b>	<b>8,660</b>	<b>374,485</b>	<b>—</b>	<b>(215,432)</b>	<b>(2,167,276)</b>	<b>—</b>	<b>(1,999,563)</b>

**CORCEPT THERAPEUTICS INCORPORATED**  
(A DEVELOPMENT STAGE COMPANY)

**STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY) (CONTINUED)**

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Notes Receivable from Stockholders	Deferred Compensation	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Net Capital Deficiency)
	Shares	Amount	Shares	Amount						
Balance at December 31, 2000 (brought forward)	1,007,760	\$ 1,803,391	8,659,689	\$ 8,660	\$ 374,485	\$ —	\$ (215,432)	\$ (2,167,276)	\$ —	\$ (1,999,563)
Issuance of Series B convertible preferred stock to consultants in exchange for services in January and April 2001	11,534	204,709	—	—	—	—	—	—	—	—
Issuance of Series BB convertible preferred stock to institutional and individual investors at \$4.033 per share upon conversion of promissory notes in May 2001	268,077	1,081,155	—	—	—	—	—	—	—	—
Issuance of Series C convertible preferred stock to institutional and individual investors at \$7.066 per share for cash, net of issuance costs of approximately \$95,000 in May and June 2001	3,806,957	26,804,967	—	—	—	—	—	—	—	—
Issuance of Series C convertible preferred stock to consultants in exchange for services in October 2001	1,326	20,049	—	—	—	—	—	—	—	—
Issuance of common stock to a consultant for cash below fair value in April 2001	—	—	50,000	50	49,950	—	—	—	—	50,000
Issuance of common stock upon option exercises	—	—	767,835	768	438,324	(438,165)	—	—	—	927
Issuance of common stock in conjunction with a license agreement	—	—	1,000	1	15,106	—	—	—	—	15,107
Deferred compensation related to options granted to employees and nonemployees	—	—	—	—	10,225,292	—	(10,225,292)	—	—	—
Amortization of deferred compensation	—	—	—	—	—	—	1,848,807	—	—	1,848,807
Net loss	—	—	—	—	—	—	—	(7,453,838)	—	(7,453,838)
Balance at December 31, 2001 (carried forward)	5,095,654	29,914,271	9,478,524	9,479	11,103,157	(438,165)	(8,591,917)	(9,621,114)	—	(7,538,560)

**CORCEPT THERAPEUTICS INCORPORATED**  
(A DEVELOPMENT STAGE COMPANY)

**STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY) (CONTINUED)**

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Notes Receivable from Stockholders	Deferred Compensation	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Net Capital Deficiency)
	Shares	Amount	Shares	Amount						
Balance at December 31, 2001 (brought forward)	5,095,654	\$ 29,914,271	9,478,524	\$ 9,479	\$ 11,103,157	\$ (438,165)	\$ (8,591,917)	\$ (9,621,114)	\$—	\$ (7,538,560)
Issuance of Series C convertible preferred stock to institutional and individual investors at \$7.066 per share for cash, net of issuance costs of approximately \$19,036 in December 2002	1,672,904	11,801,703	—	—	—	—	—	—	—	—
Issuance of common stock upon option exercises	—	—	62,334	62	191	—	—	—	—	253
Amortization of deferred compensation	—	—	—	—	—	—	4,083,707	—	—	4,083,707
Reduction of deferred compensation related to the unamortized portion of deferred stock compensation related to a terminated employee	—	—	—	—	(239,722)	—	239,722	—	—	—
Reversal of previously expensed deferred compensation related to a terminated employee based on the straight line method	—	—	—	—	(50,112)	—	—	—	—	(50,112)
Stock-based compensation related to lapsing repurchase right of stock held by a non-employee	—	—	—	—	68,000	—	—	—	—	68,000
Net loss	—	—	—	—	—	—	—	(18,503,950)	—	(18,503,950)
Unrealized loss on short-term investments	—	—	—	—	—	—	—	—	(66)	(66)
<b>Total comprehensive loss</b>										<b>(18,504,016)</b>
Balance at December 31, 2002 (carried forward)	6,768,558	41,715,974	9,540,858	9,541	10,881,514	(438,165)	(4,268,488)	(28,125,064)	(66)	(21,940,728)

**CORCEPT THERAPEUTICS INCORPORATED**  
(A DEVELOPMENT STAGE COMPANY)

**STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY) (CONTINUED)**

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Notes Receivable from Stockholders	Deferred Compensation	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Net Capital Deficiency)
	Shares	Amount	Shares	Amount						
Balance at December 31, 2002 (brought forward)	6,768,558	\$ 41,715,974	9,540,858	\$ 9,541	\$ 10,881,514	\$ (438,165)	\$ (4,268,488)	\$ (28,125,064)	\$ (66)	\$ (21,940,728)
Issuance of common stock upon option exercises	—	—	367	—	274	—	—	—	—	274
Deferred compensation related to options granted to employees and nonemployees	—	—	—	—	1,158,943	—	(1,158,943)	—	—	—
Amortization of deferred compensation	—	—	—	—	—	—	1,559,389	—	—	1,559,389
Reduction of deferred compensation related to the unamortized portion of deferred stock compensation related to terminated employees	—	—	—	—	(1,588,518)	—	1,588,518	—	—	—
Reversal of previously expensed deferred compensation related to terminated employees	—	—	—	—	(1,383,985)	—	—	—	—	(1,383,985)
Repurchase of common stock and reduction of note payable upon termination of employees	—	—	(206,243)	(206)	(154,401)	154,607	—	—	—	—
Repayment of note receivable from stockholder	—	—	—	—	—	37,300	—	—	—	37,300
Stock-based compensation related to lapsing repurchase right of stock held by a non-employee	—	—	—	—	68,000	—	—	(9,812,362)	—	68,000
Net loss	—	—	—	—	—	—	—	—	—	(9,812,362)
Unrealized loss on short-term investments	—	—	—	—	—	—	—	—	(577)	(577)
<b>Total comprehensive loss</b>										<b>(9,812,939)</b>
Balance at December 31, 2003	6,768,558	\$ 41,715,974	9,334,982	\$ 9,335	\$ 8,981,827	\$ (246,258)	\$ (2,279,524)	\$ (37,937,426)	\$ (643)	\$ (31,472,689)

See accompanying notes.

**CORCEPT THERAPEUTICS INCORPORATED**  
**(A DEVELOPMENT STAGE COMPANY)**  
**STATEMENTS OF CASH FLOWS**

	Years ended December 31,			Period from inception (May 1, 1998) to December 31, 2003
	2001	2002	2003	
<b>Operating activities</b>				
Net loss	\$ (7,453,838)	\$ (18,503,950)	\$ (9,812,362)	\$ (37,937,426)
Adjustments to reconcile net loss to net cash used in operations:				
Depreciation	9,153	20,138	22,551	53,435
Amortization of deferred compensation, net of reversals	1,848,807	4,033,595	175,404	6,148,077
Expense related to stock issued for services	9,375	—	—	45,696
Expense related to stock issued in conjunction with license agreement	13,470	—	—	14,570
Interest accrued on convertible promissory notes	46,763	20,832	20,832	93,353
Expense related to stock issued below fair value	227,487	68,000	68,000	363,487
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	(649,865)	468,639	30,089	(165,341)
Other assets	(578,752)	545,709	(4,762)	(37,805)
Accounts payable	789,691	(56,236)	(483,168)	321,806
Accrued liabilities	307,327	171,850	(19,470)	699,484
Net cash used in operating activities	(5,430,382)	(13,231,423)	(10,002,886)	(30,400,664)
<b>Investing activities</b>				
Purchases of property and equipment	(14,087)	(7,035)	—	(53,966)
Purchases of short-term investments	—	(3,142,246)	(11,667,577)	(14,809,823)
Maturities of short-term investments	—	—	13,305,000	13,305,000
Net cash provided by (used in) investing activities	(14,087)	(3,149,281)	1,637,423	(1,558,789)
<b>Financing activities</b>				
Proceeds from issuance of convertible note payable	462,929	—	—	462,929
Proceeds from convertible promissory notes	150,000	—	—	1,080,000
Proceeds from issuance of common stock	5,927	253	274	73,908
Proceeds from repayment of stockholder note	—	—	37,300	37,300
Payment to repurchase common stock	—	—	—	(250)
Proceeds from issuance of convertible preferred stock, net of cash paid for issuance costs	26,804,958	11,801,703	—	40,378,669
Net cash provided by financing activities	27,423,814	11,801,956	37,574	42,032,556
Net (decrease) increase in cash and cash equivalents	21,979,345	(4,578,748)	(8,327,889)	10,073,103
Cash and cash equivalents at beginning of period	1,000,395	22,979,740	18,400,992	—
Cash and cash equivalents at end of period	\$ 22,979,740	\$ 18,400,992	\$ 10,073,103	\$ 10,073,103
<b>Supplemental disclosure of noncash financing activities</b>				
Conversion of convertible promissory notes and accrued interest to convertible preferred stock	\$ 1,081,155	\$ —	\$ —	\$ 1,111,155
Issuance of preferred stock for services	\$ 34,533	\$ —	\$ —	\$ 34,533
<b>Supplemental disclosure of cash flow information</b>				
Interest paid	\$ 1,686	\$ —	\$ —	\$ 1,788
Income taxes paid	\$ —	\$ —	\$ —	\$ 1,121

See accompanying notes.

**CORCEPT THERAPEUTICS INCORPORATED**  
**(A DEVELOPMENT STAGE COMPANY)**  
**NOTES TO FINANCIAL STATEMENTS**

**1. Summary of Significant Accounting Policies**

**Description of Business**

Corcept Therapeutics Incorporated (the “Company” or “Corcept”) was incorporated in the state of Delaware on May 13, 1998, and its facilities are located in Menlo Park, California. Corcept is a biopharmaceutical company engaged in the development of drugs for the treatment of severe psychiatric and neurological diseases.

The Company’s primary activities since incorporation have been establishing its offices, recruiting personnel, conducting research and development, performing business and financial planning, raising capital, and overseeing clinical trials. Accordingly, the Company is considered to be in the development stage.

In the course of its development activities, the Company has sustained operating losses and expects such losses to continue for at least the next several years. The Company plans to continue to finance its operations through the sale of its equity and debt securities. The Company’s ability to continue as a going concern is dependent upon successful execution of its financing strategy and, ultimately, upon achieving profitable operations. The Company currently anticipates raising additional equity capital during 2004 to continue operating under its current plans, which include conducting continuing clinical trials of its lead product candidate, CORLUX™. If additional capital is not available, the Company will need to reevaluate its operating plans.

**Use of Estimates**

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

**Research and Development**

Research and development expenses consist of costs incurred for Company-sponsored research and development activities. These costs include direct expenses (including nonrefundable payments to third parties) and research-related overhead expenses, as well as the cost of funding clinical trials and the contract development of second-generation compounds, and are expensed as incurred. Costs to acquire technologies and materials that are utilized in research and development and that have no alternative future use are expensed when incurred (see Note 2).

Cost accruals for clinical trials are based upon estimates of work completed under service agreements, milestones achieved, patient enrollment and past experience with similar contracts. The Company’s estimates of work completed and associated cost accruals include its assessments of information received from third-party contract research organizations and the overall status of clinical trial activities.

**Income Taxes**

The Company accounts for income taxes under Statement of Financial Accounting Standards (“SFAS”) No. 109, *Accounting for Income Taxes*. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates that will be in effect when the differences are expected to reverse. A valuation allowance is recorded when it is more likely than not that the deferred tax asset will not be recovered.

**CORCEPT THERAPEUTICS INCORPORATED**  
**(A DEVELOPMENT STAGE COMPANY)**  
**NOTES TO FINANCIAL STATEMENTS—(Continued)**

**Credit Risks and Concentrations**

The Company's concentration of credit risk consists of cash, cash equivalents, and short-term investments. The Company is exposed to credit risk in the event of default by the financial institutions holding the cash, cash equivalents, and short-term investments to the extent of the amount recorded on the balance sheets.

**Segment Reporting**

The Company has adopted SFAS No. 131, *Disclosure About Segments of an Enterprise and Related Information*, which requires companies to report selected information about operating segments, as well as enterprisewide disclosures about products, services, geographical areas, and major customers. Operating segments are determined based on the way management organizes its business for making operating decisions and assessing performance. The Company has only one operating segment, the development of pharmaceutical products.

**Cash, Cash Equivalents, and Short-Term Investments**

The Company invests its excess cash in bank deposits, money market accounts, corporate debt securities, and U.S. government obligations. The Company considers all highly liquid investments purchased with maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents are carried at fair value, which approximates cost, and primarily consist of money market funds maintained at major U.S. financial institutions.

All short-term investments, which primarily represent marketable debt securities, have been classified as "available-for-sale." Purchased premiums or discounts on debt securities are amortized to interest income through the stated maturities of the debt securities. The difference between amortized cost and fair values of the debt securities are recorded as a component of accumulated other comprehensive income. Management determines the appropriate classification of its investments in debt securities at the time of purchase and evaluates such designation as of each balance sheet date. Unrealized gains and losses are included in accumulated other comprehensive loss and reported as a separate component of stockholders' equity. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other expenses. The cost of securities sold is based on the specific identification method. Interest earned on short-term investments is included in interest income.

**Property and Equipment**

Property and equipment are stated at cost less accumulated depreciation. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets, ranging from three to five years.

**Stock-Based Compensation**

The Company accounts for stock-based compensation using the intrinsic value method prescribed in Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB 25"), and has adopted the disclosure-only alternative of SFAS No. 123, *Accounting for Stock-Based Compensation* ("SFAS 123"), as amended by SFAS No. 148, *Accounting for Stock-Based Compensation – Transition and Disclosure* ("SFAS 148"). Options granted to nonemployees are accounted for in accordance with Emerging Issues Task Force Issue No. 96-18, *Accounting for Equity Instruments That*

**CORCEPT THERAPEUTICS INCORPORATED**  
**(A DEVELOPMENT STAGE COMPANY)**  
**NOTES TO FINANCIAL STATEMENTS—(Continued)**

Are Issued to Other Than Employees for Acquiring or in Conjunction with Selling, Goods or Services (“EITF 96-18”), and are periodically remeasured as they are earned.

The information set forth below regarding pro forma net loss prepared in accordance with SFAS 123 has been determined as if the Company had accounted for employee stock options under the fair value method proscribed by SFAS 123. The resulting effect on net loss pursuant to SFAS 123 is not likely to be representative of the effects in future years, due to subsequent years including additional grants and year of vesting.

The Company estimates the fair value of these options at the date of grant using the minimum value option pricing model with the following weighted-average assumptions for grants in 2001, 2002 and 2003, respectively: risk-free interest rate of 4%, 5.5%, and 4%; expected life of the options of 10 years and a dividend yield of zero. The weighted-average grant date fair value of stock options granted in 2001, 2002 and 2003 was \$6.96, \$2.31, and \$7.39, respectively. The Company’s assumptions used in prior periods are materially consistent with those used in the periods presented.

As required under SFAS 123 as amended by SFAS 148, the following pro forma net loss presentation reflects the amortization of the fair value of the stock option grants as expense. For purposes of this disclosure, the fair value of the stock options is amortized to expense over the options’ vesting periods using the graded-vesting method.

	December 31,			Period from inception (May 13, 1998) to December 31, 2003
	2001	2002	2003	
Net loss—as reported	\$ (7,453,838)	\$ (18,503,950)	\$ (9,812,362)	\$ (37,937,426)
Add back: Amortization of deferred compensation related to employees	1,533,000	4,020,679	1,470,384	7,031,685
Deduct: Stock-based employee compensation expense determined under SFAS 123	(998,034)	(4,376,579)	(1,770,770)	(7,152,646)
<b>Pro forma net loss</b>	<b>\$ (6,918,872)</b>	<b>\$ (18,859,850)</b>	<b>\$ (10,112,748)</b>	<b>\$ (38,058,387)</b>
As reported net loss per share—basic and diluted	\$ (1.25)	\$ (2.50)	\$ (1.13)	
Pro forma net loss per share—basic and diluted	\$ (1.16)	\$ (2.55)	\$ (1.17)	

**Recently Issued Accounting Standards**

In January 2003, the FASB issued Financial Interpretation number 46, Consolidation of Variable Interest Entities (“FIN 46”). This interpretation requires existing unconsolidated variable interest entities to be consolidated by their primary beneficiaries if the entities do not effectively disperse risks among parties involved. It explains how to identify variable interest entities and how an enterprise assesses its interest in a variable interest entity to decide whether to consolidate that entity. This interpretation, as amended, applies in the first fiscal year or interim period beginning after December 15, 2003, to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. Since the Company does not currently have any unconsolidated variable interest entities, the Company does not expect the adoption of FIN 46 to have a material impact on its financial position or results of operations.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity. SFAS No. 150 requires that certain financial instruments, which under previous guidance were accounted for as equity, must now be accounted for as liabilities. The financial instruments affected include mandatorily redeemable stock, certain financial instruments



**CORCEPT THERAPEUTICS INCORPORATED**  
**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO FINANCIAL STATEMENTS—(Continued)**

that require or may require the issuer to buy back some of its shares in exchange for cash or other assets and certain obligations that can be settled with shares of stock. SFAS No. 150 is effective for all financial instruments entered into or modified after May 31, 2003 and otherwise is effective at the beginning of the first interim period after June 15, 2003. The adoption of SFAS No. 150 did not have a material impact on the Company's financial position or results of operations.

**2. Collaborative and License Agreements**

**Stanford License Agreement**

In October 1998, the Company entered into an agreement with The Board of Trustees of Leland Stanford Junior University ("Stanford") in which Stanford granted the Company an exclusive option to acquire an exclusive license for inventions and patents related to "Mifepristone for Psychotic Major Depression" and "Mifepristone and Alzheimer's Disease" owned by Stanford.

In October 1999, the Company exercised its option to acquire an exclusive license to patents covering the use of glucocorticoid receptors antagonists for the treatment of psychotic major depression, early dementia, and cocaine-induced psychosis, as specified in the license agreement. This license agreement expires upon the expiration of the related patents or upon notification by the Company to Stanford. In exchange for the license, the Company agreed to pay Stanford \$47,000 and immediately issue 30,000 shares of the Company's common stock to Stanford. The Company is further required to pay Stanford \$50,000 per year as a nonrefundable royalty payment. The annual royalty payments are creditable against future royalties. The Company is also obligated to pay a \$50,000 milestone upon filing of the first New Drug Application with the United States Food and Drug Administration ("FDA") and a \$200,000 milestone upon FDA approval of the related drug. The milestone payments are also creditable against future royalties. The Company has expensed the \$47,000 payment made up front and the \$50,000 nonrefundable royalty payments and value of the common stock issued to Stanford as research and development costs.

In March 2001, the Company entered into another agreement with Stanford in which Stanford granted the Company an exclusive license agreement for invention and patents related to "Glucocorticoid Blocking Agents for Increasing Blood-Brain Permeability" owned by Stanford. This license agreement expires upon the expiration of the related patents or upon notification by the Company to Stanford. In exchange for the license, the Company agreed to pay Stanford \$20,000 and immediately issue 1,000 shares of the Company's common stock. The Company is further required to pay Stanford \$10,000 per year as a nonrefundable royalty payment. The annual royalty payments are creditable against future royalties. The Company is also obligated to make a \$100,000 milestone payment upon the commencement of Phase III trials associated with this license and a \$250,000 milestone payment upon FDA approval of the related drug for this indication, as well as royalties on any future sales that result from the license. The milestone payments are also creditable against future royalties. The Company has expensed the \$20,000 payment made up front and the \$10,000 nonrefundable royalty payments and the fair value of the common stock issued to Stanford as research and development costs.

**Manufacturing Agreement**

In June 2000, the Company entered into a Memorandum of Understanding with a pharmaceutical manufacturer, ScinoPharm Taiwan, in which the manufacturer agreed to produce CORLUX for the Company. In exchange, the Company agreed to share initial research and development costs related to the manufacturing process, which consisted of the acquisition of starting materials and equipment, as well as personnel costs, to complete the technology transfer, process development, and scale-up studies.

**CORCEPT THERAPEUTICS INCORPORATED**  
**(A DEVELOPMENT STAGE COMPANY)**  
**NOTES TO FINANCIAL STATEMENTS—(Continued)**

The Company paid the manufacturer approximately \$150,000 and \$410,000 for these activities and expensed these amounts as incurred in 2001 and 2002, respectively. No such costs were incurred in 2003. Further, the Company has committed to purchase \$1,000,000 of CORLUX per year from the manufacturer following the receipt of marketing approval and initiation of sales of CORLUX.

**Institute for the Study of Aging Note Payable**

In January 2001, the Company issued a convertible note payable to the Institute for the Study of Aging whereby the Company received \$462,929 in exchange for conducting specified research related to the treatment of Alzheimer's disease. The note bears interest at a rate of 4.5% per year and is payable on demand beginning in January 2008, if not earlier converted. The principal and accrued interest is convertible at the election of the holder following the first to occur of the following events: (1) upon an initial public offering, the note converts into common stock at the offering price; (2) upon a merger or acquisition whereby the holders of the Company's stock do not retain majority voting power, the note converts into preferred stock at the price paid per share in the most recent round of preferred stock financing; or (3) upon approval to market by the FDA of CORLUX for treatment of Alzheimer's disease, the note converts into preferred stock at the price paid per share in the most recent round of preferred stock financing. The Company may prepay all or any portion of the note at any time without penalty. The interest accrued for this note is included in other accrued liabilities on the balance sheets and interest costs are reported as interest expense.

**Argenta Discovery Limited**

In January 2003, the Company entered into a contract research agreement with Argenta Discovery Limited ("Argenta") in which Argenta agreed to conduct research toward identifying a novel small molecule glucocorticoid receptor antagonist for the treatment of psychotic major depression, Alzheimer's disease, and other psychiatric and neurological disorders. The project is expected to last at least two years, during which time the Company will make payments to Argenta based upon agreed-upon FTE (full-time equivalent) rates. During 2003, the Company recorded approximately \$1.9 million as research and development expense related to this contract.

**3. Financial Instruments**

The following is a summary of cash, cash equivalents, and short-term investments as of December 31, 2002 and 2003:

	Cost	Unrealized Gain/(Loss)	Fair Value
<b>December 31, 2002</b>			
Cash	\$ 590,238	\$ —	\$ 590,238
Money market funds	16,810,267	—	16,810,267
Corporate debt securities	3,389,354	(287)	3,389,067
United States government obligations	753,379	221	753,600
	<u>\$ 21,543,238</u>	<u>\$ (66)</u>	<u>\$ 21,543,172</u>
Reported as:			
Cash and cash equivalents	\$ 18,400,992	\$ —	\$ 18,400,992
Short-term investments	3,142,246	(66)	3,142,180
	<u>\$ 21,543,238</u>	<u>\$ (66)</u>	<u>\$ 21,543,172</u>

**CORCEPT THERAPEUTICS INCORPORATED**  
**(A DEVELOPMENT STAGE COMPANY)**  
**NOTES TO FINANCIAL STATEMENTS—(Continued)**

	Cost	Unrealized Gain/(Loss)	Fair Value
<b>December 31, 2003</b>			
Cash	\$ 160,442	\$ —	\$ 160,442
Money market funds	9,912,661	—	9,912,661
Corporate debt securities	1,003,328	(553)	1,002,775
United States government obligations	501,495	(90)	501,405
	<u>\$ 11,577,926</u>	<u>\$ (643)</u>	<u>\$ 11,577,283</u>
<b>Reported as:</b>			
Cash and cash equivalents	\$ 10,073,103	\$ —	\$ 10,073,103
Short-term investments	1,504,823	(643)	1,504,180
	<u>\$ 11,577,926</u>	<u>\$ (643)</u>	<u>\$ 11,577,283</u>

All short-term investments at December 31, 2003 have remaining contractual maturities of less than two months.

Included in cash and cash equivalents at December 31, 2002 is \$429,515 representing the proceeds of the convertible note payable issued to the Institute for the Study of the Aging (see Note 2) that were restricted under the terms of that note to be used for certain Alzheimer's disease research. These restricted funds were fully utilized during 2003.

**4. Property and Equipment**

Property and equipment consists of the following:

	December 31,	
	2002	2003
Computer equipment	\$ 46,931	\$ 46,931
Software	7,035	7,035
Less: accumulated depreciation	(30,884)	(53,435)
	<u>\$ 23,082</u>	<u>\$ 531</u>

Depreciation expense amounted to \$9,153, \$20,138 and \$22,551 in 2001, 2002 and 2003, respectively, and \$53,435 for the period from inception (May 13, 1998) to December 31, 2003. As of December 31, 2003, the Company had not entered into any capital leases.

**5. Convertible Promissory Notes**

In December 2000, the Company entered into convertible promissory notes with several investors for a total of \$900,000, including \$50,000 with a founder (who is also an officer). The notes accrued interest at 8% per year and were to mature on December 31, 2001, if not earlier converted into Series BB convertible preferred stock. In January 2001, the Company issued an additional \$150,000 convertible note payable to a founder (who is also an officer). In May 2001, the Company converted the notes and accrued interest of \$31,211 into 268,077 shares of Series BB convertible preferred stock at \$4.033 per share.

**6. Related Party Transactions**

The Company leases its facilities under an operating lease arrangement with a stockholder that is also an affiliate of a person who served as a member of the Company's board of directors until January 2004. Under this arrangement, the Company leases approximately 3,200 square feet for general corporate purposes in Menlo Park, California. The lease arrangement is currently month-to-month, with a minimum

**CORCEPT THERAPEUTICS INCORPORATED**  
**(A DEVELOPMENT STAGE COMPANY)**  
**NOTES TO FINANCIAL STATEMENTS—(Continued)**

of 180 days notice required by either party to terminate the lease. The cost of this lease is approximately \$17,000 per month and is recorded in general and administrative expense. Rent expense amounted to approximately \$165,018, \$198,806, \$204,640, and \$583,444 for the years ended December 31, 2001, 2002 and 2003, and the period from inception (May 13, 1998) to December 31, 2003, respectively. This stockholder also provides legal services to the Company. Legal expenses incurred with this stockholder were \$462,821, \$814,320, \$99,999, and \$1,453,454 for the years ended December 31, 2001, 2002 and 2003, and the period from inception (May 13, 1998) to December 31, 2003, respectively, and were recorded as general and administrative expense in each period.

## 7. Convertible Preferred Stock and Stockholders' Equity

### Convertible Preferred Stock

As of December 31, 2003, the Company was authorized to issue up to 10,000,000 shares of convertible preferred stock, issuable in series, with the rights and preferences of each designated series to be determined by the Company's board of directors. The Company has designated convertible preferred stock consisting of Series A, B, BB, and C convertible preferred stock, collectively referred to as "preferred stock."

Preferred stock at December 31, 2003 is summarized below:

	Designated Shares	Shares Issued and Outstanding	Per Share Liquidation Preference	Aggregate Liquidation Preference
Series A convertible preferred stock	610,000	607,761	\$ 1.08	\$ 656,382
Series B convertible preferred stock	415,000	411,533	\$ 3.00	1,234,599
Series BB convertible preferred stock	268,077	268,077	\$ 4.033	1,081,155
Series C convertible preferred stock	5,506,557	5,481,187	\$ 7.066	38,730,067
Balance at December 31, 2003	6,799,634	6,768,558		\$ 41,702,203

Series A, B, BB, and C convertible preferred stockholders are entitled to receive noncumulative dividends at the annual rate of \$0.0648, \$0.18, \$0.24198, and \$0.42396 per share, respectively, when and if declared by the board of directors and payable in preference to common stock dividends. As of December 31, 2003, no dividends had been declared or paid by the Company.

The holders of each share of preferred stock are entitled to one vote for each share of common stock into which such share is convertible. Each share of preferred stock is convertible into common stock at the option of the holder. Each share of Series A and B convertible preferred stock converts into three shares of common stock, and each share of Series BB and C convertible preferred stock converts into one share of common stock. Conversion is automatic upon the earlier of (1) an underwritten public offering of the Company's common stock with aggregate proceeds in excess of \$35,000,000 and a per share price of not less than \$10.00, or (2) upon the written consent of the holders of a majority of the outstanding shares of preferred stock. The preferred stock conversion rate is subject to adjustment in the event of any stock combination, stock split, stock dividend, recapitalization, or other similar transaction.

Each holder of preferred stock shall be entitled to receive, prior and in preference to any distribution of the assets or surplus funds of the Company to the holders of common stock, the amount of the liquidation preference of each share plus an amount equal to all declared but unpaid dividends on such shares. If, upon the occurrence of a liquidation event, the assets and funds available to be distributed among preferred stockholders are insufficient to permit payment of the full preferential amount, then the assets and funds of the Company will be distributed ratably based on the total

**CORCEPT THERAPEUTICS INCORPORATED**  
**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO FINANCIAL STATEMENTS—(Continued)**

preferential amount due to each preferred stockholder. After full payment has been made to the preferred stockholders, the remaining assets of the Company available for distribution will be distributed ratably among the common stockholders. The definition of a liquidation event includes a change in control. As the liquidation event is outside of the control of the Company, all shares of convertible preferred stock have been presented outside of permanent equity in accordance with EITF Topic D-98, "Classification and Measurement of Redeemable Securities."

**Common Stock**

At December 31, 2002 and 2003, the Company was authorized to issue 30,000,000 shares of common stock. Holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders of the Company.

In June 1999, the Company issued 1,770,939 shares of common stock at fair value to a director for cash proceeds of \$64,934. The Company has the right to repurchase a portion of the common stock shares upon termination of services at the original exercise price. The Company's right of repurchase lapses with respect to 20% of the total number of shares of common stock on the first anniversary of the date of the original agreement, with the remaining repurchase rights lapsing ratably at the end of each month over the remaining four years.

In April 2001, the Company issued 50,000 shares of common stock at a price below fair value to a scientific advisor for cash proceeds of \$5,000. The Company has the right to repurchase a portion of the common stock shares upon termination of services at the original exercise price. The Company recorded research and development expense of \$45,000, \$68,000, \$68,000, and \$181,000 in the years ended December 31, 2001, 2002, 2003, and the period from inception (May 13, 1998) to December 31, 2003, respectively, for the difference between the fair value and price paid by the advisor related to the portion of the shares for which the Company's right of repurchase lapsed in each period.

At December 31, 2002 and 2003, 2,137,086 and 684,235 common stock shares issued were subject to repurchase, respectively, with repurchase prices ranging from \$0.0001 to \$0.75 per share at December 31, 2002 and 2003. The Company's repurchase rights with respect to certain shares automatically lapse upon completion of a public offering of the Company's common stock.

Shares of common stock reserved for future issuance are as follows:

	December 31,	
	2002	2003
Common stock:		
Conversion of convertible preferred stock	8,807,146	8,807,146
Exercise of outstanding options	264,000	470,500
Shares available for grant under stock option plans	1,145,831	938,964
	<u>10,216,977</u>	<u>10,216,610</u>

**Stock Option Plan**

In October 2000, the Company adopted the 2000 Stock Option Plan (the "2000 Plan"), which provides for the issuance of option grants for up to 1,000,000 shares of the Company's common stock to eligible participants. Under the 2000 Plan, options to purchase common stock may be granted at no less than 100% of fair value on the date of grant for incentive stock options and 85% of fair value on the date of grant for nonqualified options, as determined by the board of directors. Options become exercisable at such times and under such conditions as determined by the board of directors. The 2000 Plan

**CORCEPT THERAPEUTICS INCORPORATED**  
**(A DEVELOPMENT STAGE COMPANY)**  
**NOTES TO FINANCIAL STATEMENTS—(Continued)**

provides for grants of immediately exercisable options; however, the Company has the right to repurchase any common stock upon termination of employment or services at the original exercise price where the right of repurchase has not lapsed. Shares repurchased by the Company return to the option pool. Options generally vest over a four- or five-year period and have a maximum term of ten years. Incentive stock options generally vest at a rate of 20% at the end of the first year of vesting, with the remaining balance vesting ratably on a monthly basis over the remaining four years.

In May 2001, the Company increased the number of shares of common stock authorized for issuance under the 2000 Plan by 1,000,000 shares, to a total of 2,000,000 shares.

**Stock-Based Compensation**

The following table summarizes all stock plan activity:

	Stock Options			
	Shares Available	Shares Outstanding	Price Per Share	Weighted-Average Exercise Price
Shares authorized upon 2000 Plan adoption	1,000,000	—	—	—
Shares granted	(60,000)	60,000	\$0.10	\$ 0.10
Shares exercised	—	—	—	—
	940,000	60,000	\$0.10	\$ 0.10
Balance at December 31, 2000				
Additional shares authorized	1,000,000	—	—	—
Shares granted	(661,500)	661,500	\$0.10 - 0.75	\$ 0.74
Shares exercised	—	(587,835)	\$0.10 - 0.75	\$ 0.75
	1,278,500	133,665	\$0.10 - 0.75	\$ 0.42
Balance at December 31, 2001				
Shares granted	(152,500)	152,500	\$7.00	\$ 7.00
Shares exercised	—	(2,334)	\$0.10	\$ 0.10
Shares forfeited	19,831	(19,831)	\$0.10 - 0.75	\$ 0.26
	1,145,831	264,000	\$0.10 - 7.00	\$ 4.24
Balance at December 31, 2002				
Shares granted	(207,500)	207,500	\$7.00	\$ 7.00
Shares exercised	—	(367)	\$0.75	\$ 0.75
Shares forfeited	633	(633)	\$0.75	\$ 0.75
	938,964	470,500	\$0.10 - 7.00	\$ 5.46
Balance at December 31, 2003				

In addition, in 2002, the Company issued 60,000 shares of common stock at \$0.0003 per share upon exercise of stock options granted outside of the 2000 Plan.

Stock options outstanding at December 31, 2003 have a weighted-average remaining contractual life of 8.7 years. As of December 31, 2003, options to purchase 109,324 shares were vested and exercisable at a weighted-average exercise price of \$3.13 per share.

As discussed in Note 1, the Company applies APB 25 and related interpretations in accounting for the 2000 Plan. For the period from inception (May 13, 1998) to December 31, 2003, the Company recorded \$9,015,891 in deferred compensation for employee stock options to purchase common stock granted at exercise prices deemed to be below the fair value of common stock. Compensation expense of \$1,533,000, \$3,970,567, \$86,399 and \$5,597,588 was recognized for employee options using the graded-vesting method during the years ended December 31, 2001, 2002 and 2003, and for the period from inception (May 13, 1998) to December 31, 2003, respectively, net of reversals. In 2002, the Company reversed \$239,722 from deferred compensation related to an employee who was terminated during 2002, as the terminated employee had not vested in the underlying shares. Additionally, the

**CORCEPT THERAPEUTICS INCORPORATED**  
**(A DEVELOPMENT STAGE COMPANY)**  
**NOTES TO FINANCIAL STATEMENTS—(Continued)**

difference between the expense recorded under the graded-vesting method and the expense that would have been recorded based upon the vesting of the related option of \$50,112 was reversed in 2002 upon termination of the employee. In 2003, the Company reversed \$1,588,518 from deferred compensation related to outstanding options forfeited by employees and a director who were terminated or reduced their level of service to the Company during 2003, as the terminated employees and director had not vested in the underlying shares. Further, the difference between the expense recorded under the graded-vesting method and the expense that would have been recorded based upon the vesting of the related option of \$1,383,985 was reversed in 2003 upon these events.

The Company amortizes the deferred stock-based compensation of employee options to compensation expense based on the graded-vesting method over the vesting periods of the applicable stock options, generally five years. The graded-vesting method provides for vesting of portions of the overall awards at interim dates and results in greater vesting in earlier years than the straight-line method. As of December 31, 2003, the Company expects to record stock-based compensation expense of approximately \$1,131,000, \$563,000, \$206,000, \$66,000, and \$19,000 in the years ending December 31, 2004, 2005, 2006, 2007, and 2008, respectively, related to employee options.

**Stockholder Notes Receivable**

In 2001, the Company recorded notes receivable from stockholders in the aggregate amount of \$438,165 in connection with the exercise of 585,000 shares of common stock options issued under the 2000 Plan. The notes are secured by the related shares of common stock and are full recourse notes, with interest compounded annually at the rate of 6.5% per year. The notes mature ten years from the date of issuance.

One of the employees who terminated in 2003 and the director who reduced their level of service to the Company in 2003 originally purchased common stock through the exercise of stock options and the execution of stockholder notes receivable as described in the preceding paragraph. The Company repurchased 150,000 unvested shares held by the employee in accordance with the terms of the related share purchase agreement. Upon termination, the outstanding note receivable of \$37,300 related to the vested portion of the stock held by the employee was repaid in full. The Company repurchased 56,243 unvested shares held by the director in accordance with the terms of the related share purchase agreement, and the remaining vested shares held by the director remain subject to the note receivable.

**Stock Options to Consultants**

As of December 31, 2003, the Company had granted options to purchase 355,500 shares of common stock to consultants, 300,000 of which were exercised, none of which were subject to repurchase, and 27,843 of which were unvested. These options were granted in exchange for consulting services to be rendered and vest over periods of three to five years. For the period from inception (May 13, 1998) to December 31, 2003, the Company recorded \$853,159 in deferred compensation for options to consultants, based upon the fair value of the option. The Company recorded charges to operations for stock options granted to consultants using the straight-line vesting method of approximately \$316,000, \$63,000, \$89,000, and \$558,000 for the years ended December 31, 2001, 2002 and 2003, and the period from inception (May 13, 1998) to December 31, 2003, respectively.

The unvested shares held by consultants have been and will be revalued using the Company's estimate of fair value at each balance sheet date pursuant to EITF 96-18.

**CORCEPT THERAPEUTICS INCORPORATED**  
**(A DEVELOPMENT STAGE COMPANY)**  
**NOTES TO FINANCIAL STATEMENTS—(Continued)**

**8. Net Loss Per Share**

The Company follows the provisions of Statement of Financial Accounting Standards No. 128, "Earnings Per Share." Basic and diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding during the period less outstanding shares subject to repurchase. Outstanding shares subject to repurchase are not included in the computation of basic net loss per share until the Company's time-based repurchase rights have lapsed.

Pro forma loss per share gives effect to (i) the effect of the automatic conversion of all outstanding shares of preferred stock into shares of common stock and (ii) the accelerated vesting of certain outstanding shares of common stock subject to the Company's right of repurchase, both in connection with the proposed initial public offering.

	Years ended December 31,		
	2001	2002	2003
	(In thousands, except per share amounts)		
Net loss applicable to common stockholders (numerator)	\$ (7,454)	\$ (18,504)	\$ (9,812)
Shares used in computing historical basic and diluted net loss per share applicable to common stockholders (denominator)			
Weighted-average common shares outstanding	8,915	9,529	9,335
Less weighted-average shares subject to repurchase	(2,934)	(2,137)	(685)
Denominator for basic and diluted net loss per share	5,981	7,392	8,650
Weighted-average shares of common stock issued upon conversion of preferred stock (pro forma)	4,755	7,185	8,807
Acceleration of repurchase rights upon initial public offering (pro forma)	1,740	1,020	301
Denominator for pro forma basic and diluted net loss per share	12,476	15,597	17,758
Historical basic and diluted net loss per share applicable to common stockholders	\$ (1.25)	\$ (2.50)	\$ (1.13)
Pro forma basic and diluted net loss per share applicable to common stockholders			\$ (0.55)

The Company has excluded the impact of all convertible preferred stock, stock options and shares of common stock subject to repurchase from the calculation of historical diluted net loss per common share because all such securities are antidilutive for all periods presented. The total number of shares excluded from the calculations of historical diluted net loss per share was 9,021,344, 10,188,519 and 9,661,881 for the years ended December 31, 2001, 2002 and 2003, respectively.

**9. Accrued Liabilities**

At December 31, 2002 and 2003 other accrued liabilities consisted of the following:

	December 31,	
	2002	2003
Accrued compensation	\$ 107,400	\$ 253,285
Accrued legal fees	41,269	71,767
Other	32,875	32,766
	\$ 181,544	\$ 357,818



**CORCEPT THERAPEUTICS INCORPORATED**  
**(A DEVELOPMENT STAGE COMPANY)**  
**NOTES TO FINANCIAL STATEMENTS—(Continued)**

**10. Income Taxes**

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows:

	December 2002	December 31, 2003
<b>Deferred tax assets:</b>		
Federal and state net operating losses	\$ 3,778,434	\$ 5,405,561
Research credits	288,824	288,824
Other, net	467,734	299,079
Capitalized research and patent costs	4,184,288	6,531,169
<b>Total deferred tax assets</b>	<b>\$ 8,719,280</b>	<b>\$ 12,524,633</b>
Valuation allowance	(8,719,280)	(12,524,633)
<b>Net deferred tax assets</b>	<b>\$ —</b>	<b>\$ —</b>

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by \$3.8 million and \$6.0 million for the years ended December 31, 2003 and December 31, 2002, respectively.

As of December 31, 2003, the Company had net operating loss carryforwards for federal income tax purposes of approximately \$13.7 million, which expire in the years 2019 through 2023. The Company also has California net operating loss carryforwards of approximately \$12.5 million, which expire in the years 2009 through 2013. The Company also has federal and California research and development tax credits of approximately \$138,000 and \$229,000. The federal research credits will expire in the years 2019 through 2023 and the California research credits have no expiration date.

Utilization of the Company's net operating loss may be subject to substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code and similar state provisions. Such an annual limitation could result in the expiration of the net operating loss before utilization.

A reconciliation from the statutory federal income tax rate to the effective rate is as follows:

	December 2002	December 2003
U.S. federal taxes (benefit) at statutory rate	(6,291,343)	(3,336,203)
State Tax	—	—
Unutilized (utilized) net operating loss	4,891,195	3,248,356
Non-deductible stock based compensation	1,394,542	82,757
Other	5,606	5,090
<b>Total</b>	<b>0</b>	<b>0</b>

**11. Subsequent Events**

*Registration Statement*

On January 15, 2004, the Company's Board of Directors authorized the filing of a registration statement with the Securities and Exchange Commission in connection with the Company's proposed

**CORCEPT THERAPEUTICS INCORPORATED**  
**(A DEVELOPMENT STAGE COMPANY)**  
**NOTES TO FINANCIAL STATEMENTS—(Continued)**

initial public offering. If the offering is completed upon the terms presently contemplated, all outstanding shares of convertible preferred stock will automatically convert into 8,807,146 shares of common stock upon completion of the proposed offering. Upon the closing of this offering, the Company's authorized capital stock, after giving effect to a proposed amendment and restatement of the Company's certificate of incorporation, will consist of 140,000,000 shares of common stock, \$0.001 par value, and 10,000,000 shares of preferred stock, \$0.001 par value.

*Stock Option Grant to Officer*

In February 2004, the Company granted an option to purchase 200,000 shares of its common stock at an exercise price of \$7.00 per share in connection with the hiring of a new corporate officer. In connection with this option grant, the Company will record approximately \$1.4 million in deferred compensation that will be recognized as expense over the vesting period of the option using the graded-vesting method, including approximately \$700,000 in 2004.

*2004 Equity Incentive Plan*

In March 2004, the Company's board of directors and stockholders approved the 2004 Equity Incentive Plan, which will become effective upon the completion of this offering. The company has reserved a total of 3,000,000 shares of its common stock for issuance under the 2004 Equity Incentive Plan, all of which are available for future grant. Upon completion of the offering, no additional options will be issued under the 2000 plan.

*Unaudited Pro Forma Information*

Unaudited pro forma stockholders' equity at December 31, 2003 reflects the automatic conversion of outstanding shares of convertible preferred stock that would occur upon completion of the offering as if that conversion had happened as of the balance sheet date.

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[Table of Contents](#)

**PRELIMINARY PROSPECTUS APRIL  
14, 2004**



**5,000,000 Shares  
Common Stock**

**Thomas Weisel Partners LLC  
Piper Jaffray  
Legg Mason Wood Walker  
Incorporated**

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Until \_\_\_\_\_, 2004 (25 days after the commencement of this offering), all dealers that effect transactions in our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

**PART II**  
**Information Not Required In Prospectus**

**Item 13. Other Expenses of Issuance and Distribution.**

The following table sets forth all expenses to be paid by Corcept, other than the underwriting discounts and commissions payable by Corcept in connection with the sale of the common stock being registered. All amounts shown are estimates except for the registration fee and the NASD filing fee.

	<b>Amount to be Paid</b>
Registration fee	\$ 10,136
NASD filing fee	8,500
Nasdaq National Market	117,649
Blue sky qualification fees and expenses	15,000
Printing and engraving expenses	50,000
Legal fees and expenses	440,000
Accounting fees and expenses	150,000
Transfer agent and registrar fees	10,000
Miscellaneous expenses	298,715
Total	<u>\$ 1,100,000</u>

**Item 14. Indemnification of Officers and Directors.**

Section 145 of the Delaware General Corporation Law permits indemnification of officers, directors and other corporate agents under certain circumstances and subject to certain limitations. Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws provide that we will indemnify our directors, officers, employees and agents to the full extent permitted by Delaware General Corporation Law, including in circumstances in which indemnification is otherwise discretionary under Delaware law. In addition, we have entered into separate indemnification agreements with our directors and executive officers which would require us, among other things, to indemnify them against certain liabilities which may arise by reason of their status or service (other than liabilities arising from willful misconduct of a culpable nature). The indemnification provisions in our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws and the indemnification agreements to be entered into between us and our directors and executive officers may be sufficiently broad to permit indemnification of our directors and executive officers for liabilities (including reimbursement of expenses incurred) arising under the Securities Act. We also intend to maintain director and officer liability insurance, if available on reasonable terms, to insure our directors and officers against the cost of defense, settlement or payment of a judgment under certain circumstances. In addition, the underwriting agreement filed as Exhibit 1.1 to this Registration Statement provides for indemnification by the underwriters of us and our officers and directors for certain liabilities arising under the Securities Act, or otherwise.

**Item 15. Recent Sales of Unregistered Securities.**

During the past three years, we have sold and issued the following unregistered securities:

We have issued an aggregate of 1,281,500 options to purchase shares of common stock to our directors, employees and consultants at exercise prices ranging from \$0.10 to \$14.50 and 590,536 shares of common stock have been issued pursuant to the exercise of options. The sales of the above securities were deemed to be exempt from registration pursuant to either Section 4(2) of the Securities Act or Rule 701 promulgated under the Securities Act. The recipients of securities in each of these transactions represented their intention to acquire the securities for investment only and not with view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the share certificates and instruments issued in such transactions. All recipients had adequate access, through their relationship with us, to information about us.

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## [Table of Contents](#)

In January 2001, we issued a convertible promissory note to the Institute for the Study of Aging, Inc., the principal amount of which was \$462,929. The note and accrued interest are convertible, at the option of the holder, into shares of common stock at the initial public offering price. The sale of this security was deemed to be exempt from registration pursuant to Section 4(2) of the Securities Act.

In May 2001, we issued 268,077 shares of Series BB preferred stock, convertible into 268,077 shares of common stock, to a total of 24 investors for an aggregate purchase price of \$1,081,158. The issuance of these securities was exempt from registration under the Securities Act pursuant to Rule 506 under Regulation D. Based on representations made to us by the investors, the investors were all accredited investors within the meaning of Rule 501 of Regulation D under the Securities Act and were able to bear the financial risk of their investment. The investors represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities. We did not make any offer to sell the securities by means of any general solicitation or general advertising within the meaning of Rule 502 of Regulation D of the Securities Act.

In May and June 2001 and December 2002, we issued 5,481,187 shares of Series C preferred stock, convertible into 5,481,187 shares of common stock, to a total of 60 investors for an aggregate purchase price of \$38,730,067. The issuance of these securities was exempt from registration under the Securities Act pursuant to Rule 506 under Regulation D. Based on representations made to us by the investors, the investors were all accredited investors within the meaning of Rule 501 of Regulation D under the Securities Act and were able to bear the financial risk of their investment. The investors represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities. We did not make any offer to sell the securities by means of any general solicitation or general advertising within the meaning of Rule 502 of Regulation D of the Securities Act.

During the past three years we have issued an aggregate of 240,000 shares of our common stock, 4,108 shares of Series B preferred stock, convertible into 12,324 shares of common stock, and 1,326 shares of Series C preferred stock, convertible into 1,326 shares of common stock, for \$80, \$12,324 and \$9,369, respectively, to consultants for services rendered to Corcept. The sales of the above securities were deemed to be exempt from registration pursuant to Section 4(2) of the Securities Act. The recipients of securities in each of these transactions represented their intention to acquire the securities for investment only and not with view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the share certificates and instruments issued in such transactions. All recipients had adequate access, through their relationship with us, to information about us.

There were no underwriters employed in connection with any of the transactions set forth in Item 15.

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[Table of Contents](#)

**Item 16. Exhibits and Financial Statement Schedules.**

(A) EXHIBITS

<u>Exhibit Number</u>	<u>Description of Document</u>
1.1†	Form of Underwriting Agreement
3.1†	Amended and Restated Certificate of Incorporation
3.2†	Amended and Restated Bylaws
4.1†	Specimen Common Stock Certificate
4.2†	Amended and Restated Information and Registration Rights Agreement by and among Concept Therapeutics Incorporated and certain holders of preferred stock, dated as of May 8, 2001
4.3†	Amendment No. 1 to Amended and Restated Information and Registration Rights Agreement by and among Concept Therapeutics Incorporated and certain holders of preferred stock, dated as of March 16, 2004
5.1†	Opinion of Heller Ehrman White & McAuliffe LLP
10.1†	2000 Stock Option Plan
10.2†	Employment offer letter to Robert L. Roe, M.D., dated October 18, 2001
10.3†	Employment offer letter to Fred Kurland, dated February 3, 2004
10.4†	Promissory Note and Pledge Agreement by and between Concept Therapeutics Incorporated and Robert L. Roe, M.D., dated as of October 22, 2001
10.5†	Form of Indemnification Agreement
10.6#†	License Agreement by and between The Board of Trustees of the Leland Stanford Junior University and Concept Therapeutics Incorporated, dated as of July 1, 1999
10.7†	Research Agreement/cGMP Manufacturing, by and between Concept Therapeutics Incorporated and KP Pharmaceutical Technology, Inc., dated as of February 12, 2002
10.8†	Master Clinical Development Agreement by and between Concept Therapeutics Incorporated and Scirex Corporation, dated as of July 12, 2001
10.9#†	Memorandum of Understanding, Supply and Services Agreement, by and between Concept Therapeutics Incorporated and ScinoPharm Taiwan, dated as of June 12, 2000
10.10†	Consulting, Confidential Information and Inventions Agreement by and between Concept Therapeutics Incorporated and Alan Schatzberg M.D., dated as of May 31, 1999
10.11†	2004 Equity Incentive Plan
10.12†	Master Services Agreement by and between Concept Therapeutics Incorporated and PPD Development, LP, dated as of January 17, 2003
23.1	Consent of Ernst & Young LLP, independent auditors
23.2	Consent of Heller Ehrman White & McAuliffe LLP (included in Exhibit 5.1)
24.1†	Power of Attorney
99.1†	Code of Ethics

# Confidential treatment requested

† Previously filed

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[Table of Contents](#)

(B) FINANCIAL STATEMENT SCHEDULE

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

**Item 17. Undertakings.**

The undersigned Registrant hereby undertakes to provide to the Underwriters at the closing specified in the Underwriting Agreement certificates in such denominations and registered in such names as required by the Underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification by the Registrant for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the provisions referenced in Item 14 of this Registration Statement or otherwise, the Registrant has been advised that in the opinion of the Commission such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer, or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered hereunder, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of Prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective; and

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of Prospectus shall be deemed to be a new Registration Statement relating to the securities offered therein, and the Offering of such securities at the time shall be deemed to be the initial bona fide offering thereof.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this Amendment No. 3 to Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Menlo Park, California, on the 14th day of April, 2004.

**CORCEPT THERAPEUTICS INCORPORATED**

By:           /s/ JOSEPH K. BELANOFF          

**Joseph K. Belanoff, M.D.,  
Chief Executive Officer**

**POWER OF ATTORNEY**

Pursuant to the requirements of the Securities Act, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated:

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>          /s/ JOSEPH K. BELANOFF          </u> <b>Joseph K. Belanoff, M.D.</b>	Chief Executive Officer and Director (Principal Executive Officer)	April 14, 2004
<u>          /s/ FRED KURLAND          </u> <b>Fred Kurland</b>	Chief Financial Officer (Principal Financial and Accounting Officer)	April 14, 2004
<u>          JAMES N. WILSON*          </u> <b>James N. Wilson</b>	Director and Chairman of the Board of Directors	April 14, 2004
<u>          ALAN F. SCHATZBERG*          </u> <b>Alan F. Schatzberg</b>	Director	April 14, 2004
<u>          G. LEONARD BAKER, JR.*          </u> <b>G. Leonard Baker, Jr.</b>	Director	April 14, 2004
<u>          DAVID B. SINGER*          </u> <b>David B. Singer</b>	Director	April 14, 2004
<u>          STEVEN KAPP*          </u> <b>Steven Kapp</b>	Director	April 14, 2004
<u>          ALIX MARDUEL*          </u> <b>Alix Marduel</b>	Director	April 14, 2004
<u>          JOSEPH C. COOK, JR.*          </u> <b>Joseph C. Cook, Jr.</b>	Director	April 14, 2004

\* By:           /s/ FRED KURLAND          

**Fred Kurland  
Attorney-in-Fact**



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[Table of Contents](#)

**Exhibit Index**

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24.1†	Power of Attorney (included on page II-5)
99.1†	Code of Ethics

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† Previously filed

Consent of Ernst & Young LLP, Independent Auditors

We consent to the reference to our firm under the caption "Experts" and to the use of our report dated January 20, 2004, except for Note 11, as to which the date is March 11, 2004, in Amendment No. 3 to the Registration Statement (Form S-1 No. 333-112676) and related Prospectus of Corcept Therapeutics Incorporated for the registration of 5,750,000 shares of its common stock.

/s/ Ernst & Young LLP

Palo Alto, California  
April 12, 2004