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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2004

or

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

For the transition period from to

Commission File Number:
000-50679

CORCEPT THERAPEUTICS INCORPORATED

(Exact Name of Corporation as Specified in Its Charter)

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

275 Middlefield Road, Suite A
Menlo Park, CA 94025
(Address of principal executive offices, including zip code)

(650) 327-3270
(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

On August 9, 2004 there were 22,686,636 shares of common stock outstanding at a par value $.001 per share.

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Form 10-Q
For the three and six months ended June 30, 2003 and 2004

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CORCEPT THERAPEUTICS INCORPORATED
(A DEVELOPMENT STAGE COMPANY)

BALANCE SHEETS

	December 31, 2003 (See Note 1)	June 30, 2004 (Unaudited)
Assets		
Current assets:		
Cash and cash equivalents	$ 10,073,103	$ 35,235,142
Short-term investments	1,504,180	16,798,485
Prepaid expenses and other current assets	165,341	878,689
Total current assets	11,742,624	52,912,316
Long-term investment	—	3,160,107
Property and equipment, net of accumulated depreciation	531	—
Other assets	37,805	51,856
Total assets	$ 11,780,960	$ 56,124,279
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 321,806	$ 629,765
Accrued clinical expenses	334,362	483,917
Other accrued liabilities	357,818	286,882
Total current liabilities	1,013,986	1,400,564
Convertible note payable	523,689	—
Total liabilities	1,537,675	1,400,564
Commitments		
Convertible preferred stock, $0.001 par value, 10,000,000 shares authorized; 6,768,558 shares issued and outstanding at December 31, 2003; (no shares designated or outstanding at June 30, 2004)	41,715,974	
Stockholders' equity (net capital deficiency):		
Preferred Stock, $0.001 par value, undesignated; 10,000,000 shares authorized; no shares outstanding at June 30, 2004		—
Common stock, $0.001 par value; at December 31, 2003, 30,000,000 shares authorized, 9,334,982 shares issued and outstanding; at June 30, 2004, 140,000,000 shares authorized, 22,686,636 shares issued and outstanding	9,335	22,687
Additional paid-in capital	8,981,827	101,549,861
Notes receivable from stockholders	(246,258)	(246,258)
Deferred compensation	(2,279,524)	(2,496,955)
Deficit accumulated during the development stage	(37,937,426)	(44,072,096)
Accumulated other comprehensive loss	(643)	(33,524)
Total stockholders' equity (net capital deficiency)	(31,472,689)	54,723,715
Total liabilities and stockholders' equity	$ 11,780,960	$ 56,124,279

See accompanying notes.

CORCEPT THERAPEUTICS INCORPORATED
(A DEVELOPMENT STAGE COMPANY)

STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,		Period from inception (May 13, 1998) to June 30, 2004
	2003	2004	2003	2004	
Operating expenses:					
Research and development*	$ 2,308,352	$ 2,569,419	$ 5,493,207	$ 4,146,003	$ 32,627,088
General and administrative*	614,625	1,125,027	295,715	2,118,472	12,628,355
Total operating expenses	2,922,977	3,694,446	5,788,922	6,264,475	45,255,443
Interest and other income, net	46,530	115,913	105,901	140,221	1,288,568
Interest expense	(5,208)	(5,208)	(10,416)	(10,416)	(105,221)
Net loss	$ (2,881,655)	$ (3,583,741)	$ (5,693,437)	$ (6,134,670)	$ (44,072,096)
Basic and diluted net loss per share	$ (0.37)	$ (0.18)	$ (0.73)	$ (0.43)	
Shares used in computing basic and diluted net loss per share	7,877,765	19,777,534	7,791,082	14,291,397	
* Includes non-cash stock-based compensation expense (credits) of the following:					
Research and development	$ 138,400	$ 117,140	$ 289,041	$ 258,142	$ 4,077,462
General and administrative	217,987	439,992	(726,500)	830,482	3,347,589
Total non-cash stock-based compensation	$ 356,387	$ 557,132	$ (437,459)	$ 1,088,624	$ 7,425,051

See accompanying notes.

CORCEPT THERAPEUTICS INCORPORATED
(A DEVELOPMENT STAGE COMPANY)

STATEMENTS OF CASH FLOWS
(Unaudited)

	Six Months Ended June 30,		Period from inception (May 13, 1998) to June 30, 2004
	2003	2004	
Operating activities			
Net loss	$ (5,693,437)	$ (6,134,670)	$ (44,072,096)
Adjustments to reconcile net loss to net cash used in operations:			
Depreciation	12,784	531	53,966
Amortization of deferred compensation, net of reversals	(471,459)	1,054,624	7,202,701
Expense related to stock issued for services	—	—	45,696
Expense related to stock issued in conjunction with license agreement	—	—	14,570
Expense related to stock issued below fair value	34,000	34,000	397,487
Interest accrued on convertible promissory notes	10,416	10,416	103,769
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(118,677)	(713,348)	(878,689)
Other assets	6,386	(14,051)	(51,856)
Accounts payable	(479,439)	307,959	629,765
Accrued liabilities	136,804	78,619	778,103
Net cash used in operating activities	(6,562,622)	(5,375,920)	(35,776,584)
Investing activities			
Purchases of property and equipment	—	—	(53,966)
Purchases of short-term investments	(7,916,217)	(19,992,116)	(34,801,939)
Maturities of short-term investments	—	1,504,823	14,809,823
Net cash provided by (used in) investing activities	(7,916,217)	(18,487,293)	(20,046,082)
Financing activities			
Proceeds from issuance of common stock, net of cash paid for issuance costs	—	49,025,252	49,099,160
Proceeds from issuance of convertible note payable	—	—	462,929
Proceeds from issuance of convertible promissory notes	—	—	1,080,000
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	—	—	40,378,669
Net cash provided by (used in) financing activities	37,300	49,025,252	91,057,808
Net (decrease) increase in cash and cash equivalents	(14,441,539)	25,162,039	35,235,142
Cash and cash equivalents at beginning of period	18,400,992	10,073,103	—
Cash and cash equivalents at end of period	$ 3,959,453	$ 35,235,142	$ 35,235,142

See accompanying notes.

CORCEPT THERAPEUTICS INCORPORATED
(A DEVELOPMENT STAGE COMPANY)

NOTES TO FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Description of Business and Basis of Presentation

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 pharmaceutical 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. See Note 4 for discussion regarding the Company's sale of shares of common stock in April 2004 in its initial public offering.

The accompanying unaudited balance sheet as of June 30, 2004 and statements of operations for the three-month and six-month periods ended June 30, 2004 and 2003 have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting only of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three-month and six-month periods ended June 30, 2004 are not necessarily indicative of the results that may be expected for the year ending December 31, 2004 or any other period. These financial statements and notes should be read in conjunction with the financial statements for the year ended December 31, 2003 included in the Company's Registration Statement on Form S-1 (Registration No. 333-112676), as amended (the "Form S-1"). The accompanying balance sheet as of December 31, 2003 has been derived from audited financial statements at that date.

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.

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.

CORCEPT THERAPEUTICS INCORPORATED
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NOTES TO FINANCIAL STATEMENTS

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 and diluted net loss per share until the Company's time-based repurchase rights have lapsed.

Basic and diluted net loss per share has been computed as follows:

	Three-Months ended June 30,		Six-Months ended June 30,	
	2003	2004	2003	2004
	(In thousands, except per share amounts)			
Net loss applicable to common stockholders (numerator)	$(2,882)	$ (3,584)	$(5,693)	$ (6,135)
Shares used in computing historical basic and diluted net loss per share applicable to common stockholders (denominator)				
Weighted-average common shares outstanding	9,335	20,011	9,419	14,672
Less weighted-average shares subject to repurchase	(1,457)	(233)	(1,628)	(381)
Denominator for basic and diluted net loss per share	7,878	19,778	7,791	14,291
Basic and diluted net loss per share applicable to common stockholders	$ (0.37)	$ (0.18)	$ (0.73)	$ (0.43)

In connection with the closing of the Company's initial public offering in April 2004 (the "IPO"), shares of convertible preferred stock outstanding immediately prior to the closing automatically converted into 8,807,146 shares of common stock. These shares of common stock, together with the 4,500,000 shares of the Company's common stock sold in the IPO, are reflected in the computation of basic and diluted net loss per share on a weighted average basis from the date of the IPO's closing.

The Company has excluded the impact of all convertible preferred stock (prior to its automatic conversion into shares of common stock as described above), stock options and shares of common stock subject to repurchase from the calculation of 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 diluted net loss per share was 10,572,996 and 2,789,075 for the three-month periods ended June 30, 2003 and 2004, respectively, and 10,744,621 and 6,470,022 for the six-month periods ended June 30, 2003 and 2004, respectively.

The basic and diluted net loss per share amounts for periods prior to this current period have been revised to reflect a change in the calculation of the weighted average number of shares outstanding used to compute net loss per share. Because these revisions relate only to the weighting of the shares used in the net loss per share computations, all of the information in the Company's final prospectus dated April 14, 2004 and in the Company's Form 10-Q for the three month period ended March 31, 2004 regarding the actual number of shares outstanding is correct. These changes also had no impact on the Company's previously reported total operating expenses, net loss, cash flows or balance sheets for any period.

Revised figures for shares used as the denominator in computing basic and diluted net loss per share are: 5,375,764; 6,719,787 and 8,068,560 for the years ended December 31, 2001, 2002 and 2003, respectively, compared to: 5,980,897; 7,392,016 and 8,650,471, respectively, as originally reported. Revised figures for shares used as the denominator in computing basic and diluted net loss per share for the three months ended March 31, 2003 and 2004 are 7,703,435 and 8,805,270, respectively, compared to 7,894,069 and 8,959,793, respectively, as originally reported. Revised figures for shares used as the denominator in computing pro forma basic and diluted net loss per share are: 12,200,681; 15,282,718 and 17,534,237 for the years ended December 31, 2001, 2002 and 2003, respectively, compared to: 12,476,159; 15,596,674 and 17,757,617, respectively, as originally reported.

Revised basic and diluted net loss per share amounts are: $1.39; $2.75 and $1.22 for the years ended December 31, 2001, 2002 and 2003, respectively, compared to: $1.25; $2.50 and $1.13, respectively, as originally reported. Revised basic and diluted net loss per share amounts for the three months ended March 31, 2003 and 2004 are $0.37 and $0.29, respectively, compared to $0.36 and $0.28, respectively, as originally reported. Revised pro forma net loss per share amount for the year ended December 31, 2003 is $0.56 compared to the originally reported amount of $0.55 per share.

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NOTES TO FINANCIAL STATEMENTS

As discussed above, the Company has changed the calculation of the weighted average number of shares outstanding used to compute net loss per share prior to this current period. The revised figures for the total number of shares excluded from the calculations of historical diluted net loss per share are: 10,866,732; 11,880,748 and 10,585,914 for the years ended December 31, 2001, 2002 and 2003, respectively, compared to: 9,021,344; 10,188,519 and 9,661,881, respectively, as originally reported. Revised figures for the total number of shares excluded from the calculations of diluted net loss per share for the three months ended March 31, 2003 and 2004 are 11,079,653 and 10,067,358, respectively, compared to 10,049,019 and 9,792,835, respectively, as originally reported.

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 Statement of Financial Accounting Standards (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 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.

During the six-month period ended June 30, 2004, the Company granted options to purchase a total of 358,600 shares of common stock to employees at a weighted-average exercise price of $9.36. As a result the Company recognized $1,400,000 in deferred compensation for an employee stock option to purchase common stock granted at an exercise price deemed to be below the fair value of common stock on the date of grant. This amount will be amortized to expense over the vesting period, which is 5 years, using the graded vesting method.

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 the inclusion in subsequent years of additional grants and years of vesting.

The Company estimates the fair value of these options at the date of grant in accordance with SFAS 123, which allows non-public companies to use the minimum value option pricing model and requires the use of a model such as the Black-Scholes option pricing model for options granted by public companies. The Company has estimated the fair value of options granted prior to February 10, 2004, the date of filing of the Form S-1, using the minimum value option pricing model and has used the Black-Scholes option pricing model for determining the fair value of options granted on or after that date.

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.

	Three-Months Ended June 30,		Six-Months Ended June 30,	
	2003	2004	2003	2004
Net loss—as reported	$(2,881,655)	$(3,583,741)	$(5,693,437)	$(6,134,670)
Add back: Amortization of deferred compensation related to employees	319,033	517,184	875,554	1,000,138
Deduct: Stock-based employee compensation expense determined under SFAS 123	(360,634)	(823,893)	(1072,028)	(1,413,206)
Pro forma net loss	$(2,923,256)	$(3,890,450)	$(5,889,911)	$(6,547,738)
Net loss per share				
As reported — basic and diluted	$ (0.37)	$ (0.18)	$ (0.73)	$ (0.43)
Pro forma — basic and diluted	$ (0.37)	$ (0.20)	$ (0.76)	$ (0.46)

CORCEPT THERAPEUTICS INCORPORATED
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NOTES TO FINANCIAL STATEMENTS

As discussed above, basic and diluted net loss per share amounts prior to the current period have been revised to reflect a change in the calculation of the weighted average number of shares outstanding used to compute net loss per share. Revised pro forma net loss per share amounts reflecting the stock based employee compensation expense determined under SFAS 123 are: $1.29; $2.81 and $1.25 for the years ended December 31, 2001, 2002 and 2003, respectively, compared to: $1.16; $2.55 and $1.17, respectively, as originally reported. Revised pro forma net loss per share amounts reflecting the stock based employee compensation expense determined under SFAS 123 for the three months ended March 31, 2003 and 2004 are $0.39 and $0.30, respectively, compared to $0.38 and $0.30, respectively, as originally reported.

Recently Issued Accounting Standards

On March 31, 2004, the FASB issued an Exposure Draft, “Share-Based Payment - An Amendment of FASB Statements No. 123 and 95.” The proposed statement addresses the accounting for transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise’s equity instruments or that may be settled by the issuance of such equity instruments. The proposed Statement would eliminate the ability to account for share-based compensation transactions using APB 25, and generally would require instead that such transactions be accounted for using a fair-value based method. As proposed, companies would be required to recognize an expense for compensation cost related to share-based payment arrangements including stock options and employee stock purchase plans. As proposed, the new rules would be applied on a modified prospective basis as defined in the exposure draft, and would be effective for public companies for fiscal years beginning after December 15, 2004. The Company is in the process of assessing the impact that this proposed statement may have on its future financial condition and results of operations.

Reclassification

Certain data for the three-month and six-month period ended June 30, 2003 and the period from inception to June 30, 2004 have been reclassified to conform to the current presentation.

2. Convertible Note Payable

On June 30, 2004, the Company converted the note payable to the Institute for the Study of Aging into common stock. Under the terms of the note, the principal amount plus any unpaid interest could be converted into common stock of the Company upon completion of the initial public offering of the Company’s common stock at the offering price. At the date of conversion, the principal and accrued interest aggregating $534,105 was converted into 44,508 shares of common stock.

3. Commitments

In March 2004, the Company signed an agreement for a 2-year rat carcinogenicity study for further development of our lead product, CORLUX™, for the treatment of the psychotic features of psychotic major depression, or PMD. The total commitment under this agreement is $1.6 million with expected payments totaling $614,000 in 2004 and $493,000 per year in 2005 and 2006.

See Note 6 regarding a commitment entered into in July 2004.

4. Common Stock

Initial Public Offering

On April 19, 2004, the Company sold 4,500,000 shares of common stock in its initial public offering at a price of $12.00 per share. The net proceeds from the sale of these shares were approximately $49.0 million, after deducting the underwriting discounts and commissions and offering expenses.

Upon completion of the Company’s initial public offering, all outstanding shares of convertible preferred stock automatically converted into 8,807,146 shares of common stock in accordance with the conversion ratios stipulated in the respective preferred stock agreements. In addition, upon completion of the initial public offering, the Company’s authorized capital stock, after giving effect to an amendment and restatement of the Company’s certificate of incorporation in connection with the Company’s initial public offering, consists of 140,000,000 shares of common stock, $0.001 par value, and 10,000,000 shares of preferred stock, $0.001 par value.

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NOTES TO FINANCIAL STATEMENTS

See discussion in Note 2 regarding the conversion of the Convertible Note Payable into common stock.

2004 Equity Incentive Plan

In March 2004, the Company's board of directors and stockholders approved the 2004 Equity Incentive Plan, which became effective upon the completion of the initial public offering. The Company has reserved a total of 3,000,000 shares of its common stock for issuance under the 2004 Equity Incentive Plan. No additional options will be issued under the 2000 plan.

5. Comprehensive Loss

Comprehensive loss is comprised of net loss and the change in unrealized gains and losses on available-for-sale securities. The following table presents the components of comprehensive loss for the periods presented.

	Net Loss as reported	Change in Unrealized Gain (Loss)	Comprehensive Net Loss
Three-month periods ended:			
June 30, 2003	$(2,881,655)	$ 1,477	$ (2,880,178)
June 30, 2004	$(3,583,741)	$ (33,524)	$ (3,617,265)
Six-month periods ended			
June 30, 2003	$(5,693,437)	$ 1,543	$ (5,691,894)
June 30, 2004	$(6,134,670)	$ (32,881)	$ (6,167,551)

6. Subsequent Event

On July 30, 2004 the Company executed a clinical development agreement with a contract research organization to assist us in the oversight of clinical trial activities at various institutions in connection with a planned pivotal trial of CORLUX for the psychotic features of PMD. This agreement, which reflects a total commitment estimated to be $7.6 million, may be terminated by us at any time upon thirty days' written notice.

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

Forward-Looking Information

This Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the "Factors that May Affect Future Results" section of this Management's Discussion and Analysis of Financial Condition and Results of Operations. This Form 10-Q contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. When used in this report or elsewhere by management from time to time, the words "believe," "anticipate," "intend," "plan," "estimate," "expect," and similar expressions are forward-looking statements. Such forward-looking statements are based on current expectations. Any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties. Actual events or results may differ materially from those discussed in the forward-looking statements as a result of various factors. For a more detailed discussion of such forward-looking statements and the potential risks and uncertainties that may impact upon their accuracy, see the "Factors that May Affect Future Results" and "Overview" sections of this Management's Discussion and Analysis of Financial Condition and Results of Operations. These forward-looking statements reflect our view only as of the date of this report. Except as required by law, we undertake no obligations to update any forward looking statements. You should also carefully consider the factors set forth in other reports or documents that we file from time to time with the Securities and Exchange Commission.

OVERVIEW

We are a pharmaceutical company engaged in the development of 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 psychotic major depression, or 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 our drug 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 affairs; and
- intellectual property prosecution and expansion.

Historically, we have financed our operations and internal growth primarily through private placements of our preferred stock and the public sale of common stock rather than through collaborative or partnership agreements. Therefore, we have no research funding or collaborative payments payable to us. The loan we received from one research institution was converted into common stock on June 30, 2004.

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 June 30, 2004 we had a deficit accumulated of approximately $44.1 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.

RESULTS OF OPERATIONS

Three- and Six- Month Periods Ended June 30, 2004 and 2003

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 pre-clinical studies, clinical trial preparations, enrollment and monitoring expenses, regulatory costs and the costs of manufacturing development.

Research and development expenses increased 11% to $2.6 million for the three months ended June 30, 2004, from $2.3 million for the three months ended June 30, 2003. There was an increase of $500,000 in clinical trial expenses in the second quarter of 2004 necessary to prepare for the commencement of pivotal clinical trials for the treatment of the psychotic features of PMD using CORLUX. These trials are expected to commence during the second half of 2004. Included in this increased spending was a $300,000 increase in costs for the production of clinical supplies and $200,000 in preclinical activity. There was also an increase in discovery research spending of $68,000. Partially offsetting this increase was a $300,000 decrease in the costs of the Alzheimer's disease trial compared to spending in the first quarter of 2003 when significant commencement expenses for that trial were incurred.

Research and development expenses decreased 25% to $4.1 million for the six months ended June 30, 2004, from $5.5 million for the six months ended June 30, 2003. This was primarily attributable to a decrease in clinical trial expenses of approximately $1.5 million due to the completion of a double-blind PMD clinical trial in early 2003 and by a decrease of approximately $200,000 in the costs of the Alzheimer's disease trial. Partially offsetting these decreases were increased spending of $75,000 for discovery research, $150,000 for preclinical programs in PMD and $140,000 for production of clinical supplies.

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

	Three Months ended June 30,		Six Months ended June 30,	
Project	**2003**	**2004**	**2003**	**2004**
			(in thousands)	
CORLUX for the treatment of the psychotic features of PMD	$ 1,321	$1,843	$3,694	$2,517
CORLUX for the treatment of mild to moderate Alzheimer's disease	361	53	452	238
Drug discovery research	488	556	1,058	1,133
Total research and development expense (excluding non-cash stock-based compensation)	$ 2,170	$2,452	$5,204	$3,888

We expect that research and development expenditures will increase substantially during the remainder of 2004 and subsequent years due to the continuation and expansion of clinical trials and other development activities of CORLUX for PMD and 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 increased 83% to $1.1 million for the three months ended June 30, 2004, from $614,600 for the three months ended June 30, 2003. This increase of $510,400 was attributable to an increase of $220,000 in non-cash stock-based compensation due to the amortization of the deferred compensation for stock options to new employees in 2004 and increases in patent, legal and professional fees of $150,000, staffing costs of $75,000 and insurance costs of $65,000.

General and administrative expenses increased to $2.1 million for the six months ended June 30, 2004, from $295,700 for the six months ended June 30, 2003. This increase of $1.8 million was primarily attributable to an increase in non-cash stock-based compensation of $1.6 million and increases in patent, legal and professional fees of $270,000, and insurance costs of $65,000. During the quarter ended March 31, 2003, upon the termination of an employee and the reduction in service of a director, we recorded a reversal of $1.4 million of stock-based compensation expense, which represents 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 options.

We expect that general and administrative expenses will increase during the remainder of 2004 and subsequent years due to increasing payroll and non-cash stock-based compensation as we add additional personnel, support costs for our commercialization efforts, costs associated with growth in our market research activities, 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 and governance activities.

Interest and other income, net. Interest and other income, net, increased approximately $69,000 to $116,000 for the three months ended June 30, 2004, as compared with $47,000 for the three months ended June 30, 2003. The increase was principally attributable to higher average cash, cash equivalents, and investment balances during the six months ended June 30, 2004 as compared to the six months ended June 30, 2003, due to the investment of the net proceeds from the initial public offering in April 2004.

Interest and other income, net, increased approximately $34,000 to $140,000 for the six months ended June 30, 2004 from $106,000 for the six months ended June 30, 2003. The increase was attributable to the investment of the net proceeds from the initial public offering in April 2004.

Interest expense. Interest expense of $5,200 for the three months ended June 30, 2004 and 2003 and $10,400 for the six months ended June 30, 2004 and 2003 represents interest on our convertible note payable to the Institute for the Study of Aging. The note was converted into common stock on June 30, 2004.

Liquidity and Capital Resources

We have incurred operating losses since inception, and at June 30, 2004 we had a deficit accumulated during the development stage of $44.1 million. Since our inception, we have relied primarily on the proceeds from public and private sales of our equity securities to fund our operations.

At June 30, 2004, we had cash and investment balances of $55.2 million, compared to $11.6 million at December 31, 2003. Net cash used in operating activities for the six months ended June 30, 2004 was $5.4 million as compared with $6.6 million for the six months ended June 30, 2003. The use of cash in each period was primarily a result of expenditures associated with our research and development activities and amounts incurred to develop our administrative infrastructure. The decrease in cash used in operating activities was due to the completion of two PMD trials in 2003, which was partially offset by increased spending, particularly in the second quarter of 2004, to prepare for the commencement of pivotal clinical trials for the treatment of the psychotic features of PMD using CORLUX. These trials are expected to commence during the second half of 2004. We expect cash used in operating activities to continue to increase substantially during the remainder of 2004 and later years due to the continuation and expansion of clinical trials, research activities and general and administrative expenses.

In April 2004 we received net proceeds of approximately $49.0 million from the sale of 4,500,000 shares of common stock in our initial public offering. We believe that the net proceeds from this sale, together with our current cash balances and interest thereon, will enable us to complete our ongoing and planned clinical trials reflected in the “Overview” section of this Management’s Discussion and Analysis of Financial Condition and Results of Operation, 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 during this two-year period 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

In March 2004, we signed an agreement for a 2-year rat carcinogenicity study for further development of our lead product, CORLUX™, for the treatment of the psychotic features of psychotic major depression, or PMD. The total commitment under this agreement is $1.6 million with expected payments totaling $614,000 in 2004 and $493,000 per year in 2005 and 2006.

On July 30, 2004 the Company executed a clinical development agreement with a contract research organization to assist us in the oversight of clinical trial activities at various institutions in connection with a planned pivotal trial of CORLUX for the psychotic features of PMD. The total commitment under this agreement is estimated to be $7.6 million with expected payments totaling approximately $2.0 million in 2004, $5.0 million in 2005 and $600,000 in 2006. The agreement may be terminated by us at any time upon thirty days’ written notice.

Critical Accounting Estimates

We believe there have been no significant changes in our critical accounting estimates during the three and six months ended June 30, 2004 as compared to what was previously disclosed in our Form S-1 related to our initial public offering.

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, directors and non-employees.

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.

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. This amount is amortized to expense on a straight-line basis over the vesting period.

Clinical trials. We recorded accruals for estimated preclinical and clinical study costs of approximately $334,000 as of December 31, 2003 and $484,000 as of June 30, 2004. 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

On March 31, 2004, the FASB issued an Exposure Draft, "Share-Based Payment - An Amendment of FASB Statements No. 123 and 95." The proposed Statement addresses the accounting for transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise's equity instruments or that may be settled by the issuance of such equity instruments. The proposed Statement would eliminate the ability to account for share-based compensation transactions using APB 25, and generally would require instead that such transactions be accounted for using a fair-value based method. As proposed, companies would be required to recognize an expense for compensation cost related to share-based payment arrangements including stock options and employee stock purchase plans. As proposed, the new rules would be applied on a modified prospective basis as defined in the exposure draft, and would be effective for public companies for fiscal years beginning after December 15, 2004. The Company is in the process of assessing the impact that this proposed Standard may have on its future financial condition and results of operations.

FACTORS THAT MAY AFFECT FUTURE RESULTS

Set forth below and elsewhere in this report, as well as in our prospectus dated April 14, 2004 are risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements contained in this report.

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. As of June 30, 2004, we had an accumulated deficit of approximately $44.1 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 CORLUX and 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, 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 at least two pivotal clinical trials in the United States 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 pre-clinical or clinical development programs;
- 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;
- 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, pre-clinical or manufacturing studies. These studies 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 have submitted the protocols for our first two pivotal clinical trials to the FDA for a special protocol assessment, or SPA, pursuant to which the FDA will assess whether the protocols are adequate to meet the scientific and regulatory requirements necessary to support marketing approval of CORLUX for the treatment of the psychotic features of PMD. We are in active dialogue with the FDA concerning the design of these trials. In connection with the assessment, we may decide, or the FDA may require us, to modify one or both of the protocols by, for example, changing the proposed primary endpoint, other endpoints, 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 rely on clinical investigators and clinical sites to enroll patients and other third parties to manage our trials and to perform related data collection and analysis. However, we may not be able to control the amount and timing of resources that the clinical sites that conduct the clinical testing may devote to our pivotal clinical trials. If these clinical 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 monitor clinical site performance and to perform investigator supervision, data collection and analysis in our pivotal clinical trials. In addition, we have identified approximately 50 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 FDA may not find that the candidate is safe;
- the FDA may not find data from the clinical or preclinical testing to be sufficient; or
- the FDA may not approve our or our third party manufacturers' processes or facilities.

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

If we receive regulatory approval for our product candidates, including CORLUX, we will also be subject to ongoing FDA obligations and continued regulatory oversight and review, such as continued safety reporting requirements; and we may also be subject to additional FDA post-marketing obligations. If we are not able to maintain regulatory compliance, we may not be permitted to market our 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 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 develop our products in the clinic in order to obtain foreign regulatory approvals on a timely basis, if at all.

Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our 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;
- 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 identified an alternative tablet manufacturer but have not yet entered into an agreement with this potential supplier. 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.

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 issued U.S. patents and have exclusively licensed three issued U.S. patents, in each case along with a number of corresponding foreign patents or patent applications. We also have nine U.S. method of use patent applications for GR-II antagonists and 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 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 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 two of our 11 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.

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 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 costs and timing of our clinical trials;
- the results of our research efforts and clinical trials;
- the timing of the approval by the FDA, if any, to market CORLUX for the treatment of the psychotic features of PMD;
- developments or disputes concerning patents or proprietary rights, including announcements of claims of infringement, interference or litigation against us or our licensors;
- actual or anticipated fluctuations in our operating results;
- changes in our growth rates;
- the timing of commercialization of CORLUX and future product candidates; and
- changes in the reimbursement policies of third-party insurance companies or government agencies.

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 to insure that the drug is not administered to pregnant women. The failure to observe these precautions could result in significant product claims.

We have only limited product liability insurance coverage, with limits customary for a development stage company. We intend to expand our product liability insurance coverage to any 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 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 size and composition of our management team;
- develop our administrative, accounting and management information systems and controls; and
- hire and train additional qualified personnel.

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

If 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 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' Clozaril, Pfizer's Geodon and Navane, Ortho-McNeil's Haldol, Janssen Pharmaceutica's Risperdal, AstraZeneca's Seroquel, GlaxoSmithKline's Stelazine and Thorazine, Mylan's thioridazine, Schering Corporation's Trilafon and Eli Lilly's Zyprexa. CORLUX may not compete effectively with these established treatments. 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 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 Our Stock

The market price of our common stock may be highly volatile. We cannot assure you that an active trading market for our common stock will exist at any time. Holders of our common stock may not be able to sell shares quickly or at the market price if trading in our common stock is not active. Since initial trading of our stock began on April 14, 2004 through August 4, 2004 our average daily trading volume has been approximately 65,000 shares and our price has ranged from $12.65 to $4.90. The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

- actual or anticipated results of our clinical trials;
- actual or anticipated regulatory approvals of our products or of competing products;
- changes in laws or regulations applicable to our products or our competitors' products;
- changes in the expected or actual timing of our development programs or our competitors' potential development programs;
- actual or anticipated variations in quarterly operating results;
- announcements of technological innovations by us, our collaborators or our competitors;
- new products or services introduced or announced by us or our competitors;
- changes in financial estimates or recommendations by securities analysts;
- conditions or trends in the biotechnology and pharmaceutical industries;
- changes in the market valuations of similar companies;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- additions or departures of key personnel;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- developments concerning our collaborations;
- trading volume of our common stock; and
- sales of our common stock by us or our stockholders.

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

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. If securities analysts do not cover our common stock, 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 by the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts who elects to cover us downgrades our stock, our stock price would likely decline rapidly. If one or more of these analysts ceases coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline. In addition, 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 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 million additional shares of common stock eligible for sale beginning October 11, 2004 upon the expiration of lock-up arrangements between our stockholders and the underwriters associated with our recently completed initial public offering.

Our officers, directors and principal stockholders control 73% of our common stock after our initial public offering in April 2004 and will be able to significantly influence corporate actions.

After the completion of our initial public offering of common stock on April 14, 2004, our officers, directors and principal stockholders control approximately 73% 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 may delay or prevent an acquisition of us or a change in our management. Some of these provisions divide our board into three classes with only a portion of our directors subject to election at each annual meeting, allow us to issue preferred stock without any vote or further action by the stockholders, require advance notification of stockholder proposals and nominations of candidates for election as directors and prohibit stockholders from acting by written consent. In addition, a supermajority vote of stockholders is required to amend our bylaws. Our bylaws provide that special meetings of the stockholders may be called only by our Chairman, President or the board of directors and that the authorized number of directors may be changed only by resolution of the board of directors. These provisions may prevent or delay a change in our board of directors or our management, which is appointed by our board of directors. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law. Section 203 may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us. These provisions in our charter, bylaws and under Delaware law could reduce the price that investors might be willing to pay for shares of our common stock in the future and result in the market price being lower than it would be without these provisions.

ITEM 3 - 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 June 30, 2004, our cash and cash equivalents and short-term and long-term investments consisted of money market funds maintained at major U.S. financial institutions, commercial paper, government agency obligations, and corporate bonds with a credit quality of A2/A or higher. To minimize our exposure to interest rate market risk, we have limited the weighted average maturity of our fixed rate investments to less than eighteen months. 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 June 30, 2004.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures. Based on their evaluation as of June 30, 2004, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) were sufficiently effective to ensure that the information required to be disclosed by us in this Quarterly Report on Form 10-Q was recorded, processed, summarized and reported within the time periods specified in the SEC's rules and Form 10-Q.

Changes in internal controls. There were no changes in our internal controls over financial reporting during the quarter ended June 30, 2004 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the effectiveness of controls. Our management, including our chief executive officer and chief financial officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our chief executive officer and chief financial officer have concluded, based on their evaluation, that our disclosure controls and procedures were sufficiently effective as of June 30, 2004 to provide reasonable assurance that the objectives of our disclosure control system were met.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently involved in any material legal proceedings.

ITEM 2. CHANGES IN SECURITIES, USE OF PROCEEDS AND ISSUER PURCHASES OF EQUITY SECURITIES

(d) Proceeds from Sale of Registered Securities.

On April 19, 2004, we completed an initial public offering of 4,500,000 shares our common stock. The managing underwriters in the offering were Thomas Weisel Partners LLC, Piper Jaffray & Co. and Legg Mason Wood Walker, Incorporated. The shares of common stock sold in the offering were registered under the Securities Act of 1933, as amended, on a Registration Statement on Form S-1 (the "Registration Statement") (Reg. No. 333-112676) that was declared effective by the SEC on April 14, 2004. The offering commenced on April 14, 2004. All 4,500,000 shares of common stock registered under the Registration Statement were sold at a price of $12.00 per share. The aggregate price was $54,000,000. In connection with the offering, we paid an aggregate of $3,780,000 in underwriting discounts and commissions to the Underwriters. In addition, the following table sets forth the approximate expenses incurred in connection with the offering, other than underwriting discounts and commissions.

SEC registration fee	$ 10,000
NASD filing fee	10,000
Nadaq National Market listing fee	100,000
Blue sky qualification fees and expenses	15,000
Printing and engraving expenses	65,500
Legal fees and expenses we need revised number here	539,400
Accounting fees and expenses	210,000
Transfer Agent fees	1,800
Travel and other miscellaneous	248,300
Total	$ 1,200,000

After deducting the underwriting discounts and commissions and the estimated offering expenses described above, we received net proceeds from the offering of approximately $49.0 million. During the quarter ended June 30, 2004, approximately $2.0 million of the net proceeds was used for research and development activities and approximately $600,000 was used for general and administrative activities with the balance being placed in temporary investments for future use as needed.

Our Series A Preferred Stock, Series B Preferred Stock, Series BB Preferred Stock and Series C Preferred Stock converted to common stock in April 2004 in connection with our initial public offering.

On June 30, 2004, the Company converted the note payable to the Institute for the Study of Aging into common stock. Under the terms of the note, the principal amount plus any unpaid interest could be converted into common stock of the Company upon completion of the initial public offering of the Company's stock at the offering price. At the date of conversion, the principal and accrued interest aggregating $534,105 was converted into 44,508 shares of common stock.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

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

None.

ITEM 5. OTHER INFORMATION

None

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

The exhibits listed on the accompanying index to exhibits are filed or incorporated by reference (as stated therein) as part of this Quarterly Report on Form 10-Q.

(b) Reports on Form 8-K

On May 28, 2004 we filed a report on Form 8-K to report the release of financial results for the quarter ended March 31, 2004.

(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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CORCEPT THERAPEUTICS INCORPORATED

Date: Aug. 12, 2004

/s/ JOSEPH K. BELANOFF

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

Date: Aug. 12, 2004

/s/ Fred Kurland

Fred Kurland
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit Index

Exhibit Number	Description of Document
31.1	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Joseph K. Belanoff, M.D.
31.2	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Fred Kurland.
32.1	Certification pursuant to 18 U.S.C. Section 1350 of Joseph K. Belanoff, M.D.
32.2	Certification pursuant to 18 U.S.C. Section 1350 of Fred Kurland.

Exhibit 31.1

CERTIFICATION

I, Joseph K. Belanoff, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2004 of Corcept Therapeutics Incorporated;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) [Paragraph omitted pursuant to SEC Release 33-8238];
   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ JOSEPH K. BELANOFF

Joseph K. Belanoff, M.D.
Chief Executive Officer
August 12, 2004

Exhibit 31.2

CERTIFICATION

I, Fred Kurland, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2004 of Corcept Therapeutics Incorporated;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) [Paragraph omitted pursuant to SEC Release 33-8238];
   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

/s/ Fred Kurland

Fred Kurland
Chief Financial Officer
August 12, 2004

Exhibit 32.1

Corcept Therapeutics Incorporated

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Corcept Therapeutics Incorporated (the "Company") on Form 10-Q for the period ended June 30, 2004, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joseph K. Belanoff, M.D., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

/s/ JOSEPH K. BELANOFF

Joseph K. Belanoff, M.D.
Chief Executive Officer
August 12, 2004

Exhibit 32.2

Corcept Therapeutics Incorporated

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Corcept Therapeutics Incorporated (the "Company") on Form 10-Q for the period ended June 30, 2004, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Fred Kurland, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

/s/ Fred Kurland

Fred Kurland
Chief Financial Officer
August 12, 2004