CORCEPT THERAPEUTICS INC
Form 10-Q
November 08, 2006
Table of Contents

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2006

or

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

Commission File Number:

000-50679

CORCEPT THERAPEUTICS INCORPORATED

(Exact Name of Corporation as Specified in Its Charter)

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

149 Commonwealth Drive

Menlo Park, CA 94025

(Address of principal executive offices, including zip code)

(650) 327-3270

(Registrant s telephone number, including area code)

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

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

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

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

On November 6, 2006 there were 22,731,766 shares of common stock outstanding at a par value $.001 per share.

Table of Contents

TABLE OF CONTENTS

Table of Contents

CORCEPT THERAPEUTICS INCORPORATED

(A DEVELOPMENT STAGE COMPANY)

CONDENSED BALANCE SHEETS

(In thousands, except share data)

	September 30, 2006 (Unaudited)	December 31, 2005 (See Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 3,296	$ 3,816
Short-term investments	8,738	25,264
Prepaid expenses and other current assets	500	425
Total current assets	12,534	29,505
Long-term investments		539
Property and equipment, net of accumulated depreciation	42	52
Other assets	70	60
Total assets	$ 12,646	$ 30,156
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 2,618	$ 549
Accrued clinical expenses	2,541	2,521
Accrued compensation	153	144
Obligations under capital lease, short-term	13	12
Other accrued liabilities	311	295
Total current liabilities	5,636	3,521
Obligations under capital lease, long-term	32	42
Total liabilities	5,668	3,563
Commitments		
Stockholders equity:		
Preferred stock		
Common stock	23	23
Additional paid-in capital	101,986	101,014
Notes receivable from stockholders	(168)	(168)
Deferred compensation	(293)	(603)
Deficit accumulated during the development stage	(94,562)	(73,565)
Accumulated other comprehensive loss	(8)	(108)

Total stockholders equity	6,978	26,593
Total liabilities and stockholders equity	$ 12,646	$ 30,156

See accompanying notes.

Table of Contents

CORCEPT THERAPEUTICS INCORPORATED

(A DEVELOPMENT STAGE COMPANY)

CONDENSED STATEMENTS OF OPERATIONS

(Unaudited)

(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from inception (May 13, 1998) to September 30,
	2006	2005	2006	2005	2006
Collaboration revenue	$	$	$ 221	$	$ 221
Operating expenses:					
Research and development*	5,147	4,521	17,912	12,560	74,874
General and administrative*	1,402	960	3,900	3,093	23,132
Total operating expenses	6,549	5,481	21,812	15,653	98,006
Loss from operations	(6,549)	(5,481)	(21,591)	(15,653)	(97,785)
Interest and other income, net	154	278	609	842	3,484
Other expense	(8)	(20)	(14)	(35)	(261)
Net loss	$ (6,403)	$ (5,223)	$ (20,996)	$ (14,846)	$ (94,562)
Basic and diluted net loss per share	$ (0.28)	$ (0.23)	$ (0.93)	$ (0.66)	
Shares used in computing basic and diluted net loss per share	22,719	22,621	22,691	22,597	

* Includes non-cash stock-based compensation expense (recovery) consisting of the following:

Research and development	$ 103	$ 53	$ 455	$ (68)	$ 4,451
General and administrative	274	180	803	646	5,594
Total non-cash stock-based compensation	$ 377	$ 233	$ 1,258	$ 578	$ 10,045

See accompanying notes.

Table of Contents

CORCEPT THERAPEUTICS INCORPORATED

(A DEVELOPMENT STAGE COMPANY)

CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Nine Months Ended September 30,		Period from inception (May 13, 1998) to September 30,
	2006	2005	2006
Operating activities			
Net loss	$ (20,996)	$ (14,846)	$ (94,561)
Adjustments to reconcile net loss to net cash used in operations:			
Depreciation and amortization of property and equipment	10	4	71
Expense related to stock options, net of reversals	1,227	496	9,688
Expense related to stock issued for services or in conjunction with license agreement	12	28	75
Expense related to stock issued below fair value	23	51	522
Interest accrued on convertible promissory note			104
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(75)	8	(500)
Other assets	(10)	(29)	(70)
Accounts payable	2,069	283	2,618
Accrued clinical expenses	20	771	2,541
Other liabilities	25	(234)	464
Net cash used in operating activities	(17,695)	(13,468)	(79,048)
Investing activities			
Purchases of property and equipment			(54)
Purchases of short-term and long-term investments	(1,311)	(19,520)	(108,342)
Maturities of short-term and long-term investments	18,476	28,471	99,597
Net cash provided by (used in) investing activities	17,165	8,951	(8,799)
Financing activities			
Proceeds from issuance of common stock, net of cash paid for issuance costs	19	1	49,120
Proceeds from issuance of convertible preferred stock, net of cash paid for issuance costs			40,378
Proceeds from issuance of convertible notes			1,543
Proceeds from repayment of stockholder notes			116
Principal payments of obligations under capital leases	(9)	(2)	(14)
Net cash provided by financing activities	10	(1)	91,143
Net increase (decrease) in cash and cash equivalents	(520)	(4,518)	3,296

Cash and cash equivalents, at beginning of period	3,816	5,930	
Cash and cash equivalents, at end of period	$ 3,296	$ 1,412	$ 3,296

See accompanying notes.

Table of Contents

CORCEPT THERAPEUTICS INCORPORATED

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED 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.

The accompanying unaudited balance sheet as of September 30, 2006, the statements of operations for the three- and nine-month periods ended September 30, 2006 and 2005, and the statements of cash flows for the nine month periods ended September 30, 2006 and 2005 have been prepared in accordance with U.S. generally accepted accounting principles 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 U.S. generally accepted accounting principles 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- and nine-month periods ended September 30, 2006 are not necessarily indicative of the results that may be expected for the year ending December 31, 2006 or any other period. These financial statements and notes should be read in conjunction with the financial statements for the year ended December 31, 2005 included in the Company s Form 10-K. The accompanying balance sheet as of December 31, 2005 has been derived from audited financial statements at that date.

Going Concern

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 accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business.

As reflected in the accompanying financial statements as of September 30, 2006, the Company had cash, cash equivalents and investments balances of $12.0 million, working capital of $6.9 million and an accumulated deficit of $94.6 million. The Company s cash and marketable securities will enable it to complete its current Phase 3 clinical studies evaluating our lead product candidate, CORLUX®, for treating the psychotic features of psychotic major depression (PMD.) The Company expects to report the results of the last of these studies in the first quarter of 2007.

The Company will need to raise additional funds in order to sustain its operations at anticipated levels through at least 2007. 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. If the Company is not able to raise additional funds, it will not be able to continue operations through the second quarter of 2007.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles 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.

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.

Any changes in estimates are recorded in the period of the change.

Table of Contents

CORCEPT THERAPEUTICS INCORPORATED

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS, Continued

Revenue Recognition

Collaboration revenue relates to services rendered in connection with an agreement signed in October 2005 with Eli Lilly and Company (Lilly) in which Lilly agreed to support the Company s proof-of-concept clinical study evaluating the ability of CORLUX, a GR-II antagonist, to mitigate weight gain associated with the use of olanzapine. Under the agreement, Lilly agreed to supply olanzapine and pay for the budgeted costs of the study. Under the agreement, the Company is required to perform specified development activities and the fee paid to us by Lilly is based on the costs associated with the conduct of that trial and the preparation and packaging of clinical trial materials. Revenue is recognized as services are rendered in accordance with the agreement. The cost of providing these research services approximates the revenue recognized. If the costs of the study exceed budgeted amounts, Lilly may not pay for the excess. As of September 30, 2006, the costs have not exceeded the budgeted amounts.

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, pre-clinical studies, manufacturing development 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.

Stock-based compensation for employee options

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standard 123 (Revised 2004), *Share-Based Payment* (SFAS 123R), which is a revision of Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation* (SFAS 123 .) SFAS 123R supersedes Accounting Principles Boards Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and amends FASB Statement No. 95, *Statement of Cash Flows.* SFAS 123R 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. SFAS 123R generally eliminates the ability to account for share-based compensation transactions using APB 25, and requires, instead, that such transactions be accounted for using a fair-value based method. In accordance with SFAS 123R, companies are now required to recognize an expense for compensation cost related to share-based payment arrangements with employees and directors, including stock options and employee stock purchase plans.

The Company adopted SFAS 123R as of January 1, 2006 under the modified prospective method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of Statement 123R for all share-based payments granted or modified after the effective date and (b) based on the requirements of Statement 123 for all awards granted to employees prior to the effective date of Statement 123R that remain unvested on the effective date. See Note 2 for a discussion of the Company s stock option plans and the impact of the Company s results from operations due to the implementation of SFAS 123R. Because the Company had used the minimum value method for SFAS 123 pro forma disclosure requirements for options granted prior to the initial public offering of its common stock (IPO) in 2004, we continue to account for the portion of these grants that were non-vested as of January 1, 2006 under the provisions of APB 25 and related Interpretations, with pro forma disclosures under SFAS 123.

2. Stock Option Plans

Stock Option Plans

Under the 2004 Equity Incentive Plan (the 2004 Plan) options, stock purchase and stock appreciation rights and restricted stock awards can be issued to employees, officers, directors and consultants of the Company. The 2004 Plan provides that the exercise price for incentive stock options will be no less than 100% of the fair value of the Company s common stock, as of the date of grant. Generally, options granted under the 2004 Plan have a ten year contractual life and vest over either a four or five year period with 20 or 25% of the underlying shares of common

stock vesting on the first anniversary of the date of grant and the remainder vesting in subsequent equal monthly installments through the remaining vesting period of the grant. The vesting period is equivalent to the requisite service period. Upon exercise, new shares are issued. Prior to the Company s IPO in 2004, options were granted to employees, directors and non-employees under the 2000

Table of Contents

CORCEPT THERAPEUTICS INCORPORATED

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS, Continued

Stock Option Plan (the 2000 Plan). Although options are no longer granted under the 2000 Plan, there are still options outstanding under that plan.

The 2004 Plan provides that the share reserve will be cumulatively increased on January 1 of each year, beginning January 1, 2005 and for nine years thereafter, by a number of shares that is equal to the least of (a) 2% of the number of the Company s shares issued and outstanding at the preceding December 31, (b) 1,000,000 shares and (c) a number of shares set by the board. On March 2, 2006, the board of directors acknowledged and approved the increase in the shares available for grant under the 2004 Plan by 454,073 shares, which represented 2% of the common shares outstanding at December 31, 2005.

During the nine months ended September 30, 2006, options were exercised to purchase approximately 26,000 shares of common stock for aggregate exercise proceeds of approximately $18,800.

Stock-based compensation for employee options

From inception in May 1998 through December 31, 2005, the Company accounted for stock-based compensation for options granted to employees and directors using the intrinsic value method prescribed in APB25 and adopted the disclosure-only alternative of SFAS 123, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure* (SFAS 148). As discussed above, the Company adopted SFAS 123R as of January 1, 2006. Following is a brief synopsis of the implications of adoption of this statement on the Company s accounting practices in regard to stock option grants to employees and directors:

Options granted prior to January 1, 2006:

For options granted prior to the IPO in 2004, the Company is continuing to account for the portion of these grants that were non-vested as of January 1, 2006 under the provisions of APB 25, with pro forma disclosures under SFAS 123. This treatment is being followed because the Company had used the minimum value method for these options under SFAS 123 pro forma disclosure requirements.

For the options granted after the IPO, the Company began, as of January 1, 2006, to record non-cash stock compensation expense in the financial statements in amounts that represent the remaining fair value of the non-vested portion of these grants, utilizing the assumptions and fair value per share information as of the original grant date that the Company has been using for SFAS 123 pro forma disclosure purposes.

For all options granted prior to January 1, 2006, the Company is continuing to utilize the graded-vesting attribution method for amortization of the relevant compensation amounts.

Since the Company has a limited employee base, it does not have sufficient historical information to determine a reasonable forfeiture rate for options that might not vest because of employee terminations. When an employee terminates, the Company will record a change in accounting estimate that represents the difference between the expense recorded under the graded-vesting

method and the expense that would have been recorded based upon the rights to options that vested during the individual s service as an employee.

Options granted or modified on or after January 1, 2006:

Compensation expense is being recorded in the financial statements based on the fair value on the date of grant, in accordance with the provisions and guidelines of SFAS 123R and all relevant Interpretations and SEC Staff Accounting Bulletins.

The grant date fair value for all new grants is being amortized to expense using the straight-line attribution method over the vesting period of the options.

As discussed above, the Company has not determined a forfeiture rate for options that might not vest because of employee terminations. When an employee terminates, we will record a change in accounting estimate that represents the difference between the expense recorded under the straight-line method and the expense that would have been recorded based upon the rights to options that vested during the individual s service as an employee.

Table of Contents

CORCEPT THERAPEUTICS INCORPORATED

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS, Continued

The following table indicates the impact of implementation of SFAS 123R regarding employee options on our statement of operations.

	Three months ended September 30, 2006			Nine months ended September 30, 2006		
Operating Expense Category						
(amounts in thousands)	**Research and development**	**General and administrative**	**Total**	**Research and development**	**General and administrative**	**Total**
Expense under provisions of APB 25	$	$ 81	$ 81	$ 1	$ 309	$ 310
Incremental expense	85	193	278	366	486	852
Expense under provisions of SFAS123R	$ 85	$ 274	$ 359	$ 367	$ 795	$ 1,162

The incremental expense of accounting for stock options to employees and directors under the provisions of SFAS123R represented $0.01 and $0.04 per share for the three- and nine-month periods ended September 30, 2006, respectively. There were no retroactive or non-recurring charges and there was no impact on our statement of financial condition or cash flows as a result of the implementation.

The following table presents the pro forma net loss information required under SFAS 123, as amended by SFAS 148. In the pro forma calculation, amortization related to options to employees and directors that was accounted for under the intrinsic value method prescribed by APB 25 is added back to income and replaced with the expense that would have been reflected in the statements of operations in the respective periods as if the Company had accounted for these options under the fair value method prescribed by SFAS 123. For purposes of this disclosure, the fair value of the stock options is amortized to expense over the vesting periods of the options using the graded-vesting method. The resulting effects on net loss pursuant to SFAS 123 related to these options are not likely to be representative of the effects in future periods or years, due to the decelerating scale of expense recognition under the graded vesting method or the effect of any terminations.

As noted above, the Company estimated the fair value of these options at the date of grant in accordance with SFAS 123, which allowed non-public companies to use the minimum value option pricing model and required the use of a model such as the Black-Sholes 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-Sholes option pricing model for determining the fair value of options granted on or after that date.

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except per share data)	**2006**	**2005**	**2006**	**2005**
Net loss as reported	$ (6,403)	$ (5,223)	$ (20,996)	$ (14,846)
Adjustments to net loss related to stock awards to employees and directors accounted for under the intrinsic value method:				
Add back amortization of deferred compensation	81	181	310	689
Deduct stock-based employee compensation expense determined under SFAS 123	(110)	(556)	(411)	(1,997)
Pro forma net loss	$ (6,432)	$ (5,598)	$ (21,097)	$ (16,154)

Net loss per share

As reported basic and diluted	$ (0.28)	$ (0.23)	$ (0.93)	$ (0.66)
Pro forma basic and diluted	$ (0.28)	$ (0.25)	$ (0.93)	$ (0.71)

Table of Contents

CORCEPT THERAPEUTICS INCORPORATED

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS, Continued

The following table summarizes the weighted-average assumptions and resultant fair value for options granted to employees and directors during the first nine months of 2006 and 2005.

	Nine Months Ended September 30,	
	2006	2005
Weighted average assumptions for stock options granted:		
Risk-free rate	4.98%	4.09%
Expected term	6.0 years	9.3 years
Expected volatility of stock price	78.6%	72.8%
Dividend rate	0%	0%
Weighted average fair value of grants issued	$ 3.09	$ 3.87

The expected term for options granted during 2006 is based on the simple method prescribed by the SEC in Staff Accounting Bulletin 107, and considers the weighted average of the vesting period and contractual life of the options. For options granted during the nine-month period ended September 30, 2005 the expected term was based on the contractual life of the options. There has been no adjustment made to the expected term to adjust for employees expected exercise and expected post-vesting termination behavior because the Company has a limited employee base and does not have sufficient historical information to determine such an adjustment.

The expected volatility of the Company s stock used in determining the fair value of option grants is based on a weighted-average combination of the volatility of the Company s own stock price and that of a group of peer companies since the Company does not have sufficient historical data from which to base an appropriate valuation assumption.

Non-employees

Options granted to non-employees 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. Expense related to options and other stock compensation issued to non-employees was approximately $18,000 and $51,000 for the three-month periods ended September 30, 2006 and 2005, respectively, and $88,000 and $138,000 for the nine-month periods ended September 30, 2006 and 2005, respectively.

Option activity during 2006

The following is a summary of option activity for the nine months ended September 30, 2006. (Shares and intrinsic value data are in thousands.)

	Share Data		Weighted-Average		
				Remaining Contractual Life	
	Shares Available	Options Outstanding	Exercise Price	(in years)	Aggregate Intrinsic Value
Balance at December 31, 2005	2,770	1,335	$ 6.41	8.1	$ 3,031
Increase in shares authorized under 2004 Plan	454				
Shares granted	(637)	637	$ 4.33		
Shares exercised		(26)	$ 0.73		$ 360

Shares issued for services	(2)		$ 4.86		
Shares cancelled and forfeited under 2004 Plan	32	(32)	$ 4.47		
Shares cancelled and forfeited under 2000 Plan		(13)	$ 12.13		
Balance at September 30, 2006	2,617	1,901	$ 5.79	8.2	$ 2,670
Options exercisable and expected to become exercisable at September 30, 2006		1,901	$ 5.79	8.2	$ 2,670
Options exercisable at September 30, 2006		658	$ 6.40	7.0	$ 1,674

Table of Contents

CORCEPT THERAPEUTICS INCORPORATED

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS, Continued

The following table presents the total fair value of options to employees that vested during the three-month and nine-month periods ended September 30, 2006. All amounts are in thousands.

	Three Months Ended September 30, 2006	Nine Months Ended September 30, 2006
Pre-IPO options, using minimum value method	$ 347	$ 1,051
Options granted after IPO through 2005, using fair value under SFAS 123	202	642
Options granted during 2006, using fair values under SFAS 123R	48	48
Total	$ 597	$ 1,741

As of September 30, 2006, the Company had the following amounts of unrecognized compensation expense for employee options outstanding as of that date.

	Amount (in thousands)	Weighted-average period (in years)
Remaining deferred compensation related to options granted prior to the IPO, to be expensed under the provisions of APB 25	$ 293	2.3
Remaining fair value to be expensed		
Options granted after IPO through 2005, using fair value under SFAS 123	927	3.1
Options granted during 2006, using fair value under SFAS 123R	1,815	3.6
Total	$ 3,035	

The following is a summary of options outstanding and options exercisable at September 30, 2006.

	Options Outstanding			Options Exercisable	
(in thousands, except per share and year data)	Options Outstanding	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Options Exercisable	Weighted Average Exercise Price
$ 0.10 $ 0.75	65	4.5	$ 0.45	65	$ 0.44
$ 4.00 $ 7.73	1,700	8.4	$ 5.50	529	$ 6.43
$ 10.06 $ 15.00	136	7.6	$ 12.07	64	$ 12.16
	1,901	8.2	$ 5.79	658	$ 6.40

3. Commitments

During the first quarter of 2006, the Company entered into agreements with a contract research organization (CRO) to assist in the conduct of a cardiac study being performed in 2006 for a commitment of approximately $2.5 million. The master agreement with this CRO provides for termination by the Company with ninety days notice.

In March 2006, the Company signed an amendment to our agreement with the CRO that assists us in the conduct of European clinical trial activities to add five European sites to our U.S.-based Phase 3 trials. The preparatory work for this effort had begun in late 2005 under a letter of intent with the CRO. The total commitment under this amendment is approximately 818,000 Euros, or approximately $975,000 based on the conversion rate at the time of signing, of which approximately $65,000 had been committed previously under the letter of intent signed during 2005. In addition, approximately $495,000 of this commitment relates to per patient costs that will replace the commitments related to these costs under agreements signed during 2004 and 2005 with the other CROs that are enrolling patients for these trials at clinical sites in the United States. The net amount of the incremental commitment related to this amendment is approximately $415,000 in excess of the amount of clinical trial commitments as of December 31, 2005.

During the course of 2006, the Company modified the projected time table for the completion of enrollment of Study 06, one of its U.S.-based phase 3 trials. The extension in time to complete this trial is expected to increase projected costs by approximately $1.0 million in excess of the amounts previously reported as commitments for this trial.

Table of Contents

CORCEPT THERAPEUTICS INCORPORATED

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED FINANCIAL STATEMENTS, Continued

4. 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. All figures are in thousands.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
	(in thousands)			
Net loss as reported	$ (6,403)	$ (5,223)	$ (20,996)	$ (14,846)
Change in unrealized gain (loss)	37	(14)	100	(58)
Comprehensive net loss	$ (6,366)	$ (5,237)	$ (20,896)	$ (14,904)

5. Net Loss Per Share

Basic and diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding during the period less outstanding shares subject to repurchase. Outstanding shares subject to repurchase are not included in the computation of basic net loss per share until the Company s time-based repurchase rights have lapsed.

	Three Months ended September 30,		Nine Months ended September 30,	
	2006	2005	2006	2005
	(In thousands, except per share amounts)			
Net loss (numerator)	$ (6,403)	$ (5,223)	$ (20,996)	$ (14,846)
Shares used in computing historical basic and diluted net loss per share (denominator)				
Weighted-average common shares outstanding	22,732	22,703	22,720	22,697
Less weighted-average shares subject to repurchase	(13)	(82)	(29)	(100)
Denominator for basic and diluted net loss per share	22,719	22,621	22,691	22,597
Basic and diluted net loss per share	$ (0.28)	$ (0.23)	$ (0.93)	$ (0.66)

The following table presents information on securities outstanding as of the end of each period that could potentially dilute the per share data in the future.

	September 30,	
	2006	2005
	(in thousands)	
Shares subject to repurchase	5	73

Stock options outstanding	1,288	1,286
Total	1,293	1,359

Table of Contents

ITEM 2

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 Risk Factors section of this Form 10-Q. 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. All statements contained in this Form 10-Q other than statements of historical fact are forward-looking statements. When used in this report or elsewhere by management from time to time, the words believe, anticipate, intend, plan, estimate, expect, and similar expressions are forward-looking statements. Such forward-looking statements are based on current expectations, but the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements made in this Form 10-Q include, but are not limited to, statements about:

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

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

OVERVIEW

We are a pharmaceutical company engaged in the development of medications for the treatment of severe psychiatric and neurological diseases. Since our inception in May 1998, we have been developing our lead product, CORLUX®, targeted for the treatment of the psychotic features of psychotic major depression, or PMD, under an exclusive patent license from Stanford University. The United States Food and Drug Administration, or FDA, has granted fast track status to evaluate the safety and efficacy of CORLUX for the treatment of the psychotic features of PMD. In September and October 2004, we initiated two Phase 3 clinical trials in the United States to support a planned New Drug Application, or NDA. These trials are referred to herein as Study 07 and Study 06, respectively. Both of these trials are covered by Special Protocol Assessments, or SPAs, from the FDA. In addition, in May 2005, we initiated a third Phase 3 clinical trial (Study 09) in Europe. In all three of these trials CORLUX is being evaluated for treating the psychotic features of PMD.

In August and September 2006 we announced the results of Studies 07 and 09. Study 07 was a randomized, double-blind, placebo-controlled study. 257 patients were enrolled in this trial. The primary endpoint, a responder analysis, was the proportion of patients with at least a 50 percent improvement in the Brief Psychiatric Rating Scale Positive Symptom Subscale (BPRS PSS) score at both Day 7 and Day 56. The BPRS is an 18-item rating instrument used to assess psychopathology, and the PSS is a subset of four items in the BPRS that specifically measure psychosis. In this study, 30.5 percent of the patients receiving CORLUX and 28.6 percent of the patients receiving placebo met the primary endpoint. This was not a statistically significant difference in response rate. The two key secondary endpoints of Study 07 also failed to achieve statistical significance. There was an unusually high placebo response rate in this trial. At Day 56, for example, approximately 80 percent of the patients in both of the arms of the study were responders as measured by a 50 percent improvement in BPRS PSS score.

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

Table of Contents

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

The enrollment in Study 07 did not have an even pace. 150 patients were enrolled in the first 480 days of the study (September 2004 through December 2005) and 107 patients in the last 120 days. An analysis of the results of the first 150 patients revealed a statistically significant difference on the primary endpoint favoring patients who took CORLUX compared to those who did not. Most of the clinical sites enrolling patients during this time had participated in the conduct of our double-blinded Phase 2 trial, Study 03, which had been the basis for the design of all three of our Phase 3 trials.

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

A second interesting item from Study 07 derives from a post hoc analysis of the relationship between the concentration of CORLUX in patients blood at Day 7 and the degree of change from baseline in their BPRS PSS scores at Day 56. A post hoc analysis examines the data for relationships not designated before the study began. These data revealed a statistically significant correlation between plasma levels achieved during treatment and clinical outcome at Day 56 as measured by the BPRS PSS. Higher plasma concentrations of CORLUX were associated with greater reduction of symptoms. Also, the response rate on the primary endpoint among patients with CORLUX plasma levels higher than 1800 nanograms per milliliter was statistically significantly greater than the response rates observed in patients who received placebo. The response rate on the primary endpoint in patients with plasma concentrations of CORLUX of less than 1800 nanograms per milliliter did not statistically separate from the response rates observed in patients who received placebo.

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

Results from Study 06 are anticipated in the first quarter of 2007.

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

In October 2005, we announced that we had signed an agreement with Eli Lilly and Company, or Lilly, in which Lilly agreed to support our proof-of-concept clinical study evaluating the ability of CORLUX to mitigate weight gain associated with the use of olanzapine. This study in healthy male volunteers was initiated during the first quarter of 2006. We are relocating this study to a new site in India and have made minor changes in the protocol. We are in the process of filing for

13

Table of Contents

regulatory approval in India to begin enrolling patients and expect to report the results of this study in the second quarter of 2007.

Our activities to date have included:

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

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

We are in the development stage and have incurred significant losses since our inception because we had not generated any revenue through 2005, and do not expect to generate significant revenue for the foreseeable future. As of September 30, 2006, we had an accumulated deficit of approximately $94.6 million. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for CORLUX, discovery research, non-clinical activities such as toxicology and carcinogenicity studies, manufacturing process development and regulatory activities, as well as general and administrative expenses. We expect to continue to incur net losses over at least the next several years as we continue 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 securing financing, uncertainties associated with obtaining and enforcing patents, our investment in manufacturing set-up, the lengthy and expensive regulatory approval process and competition from other products. Our ability to successfully generate revenues in the foreseeable future is dependent upon our ability, alone or with others, to finance our operations and develop, obtain regulatory approval for, manufacture and market our lead product.

Results Of Operations

Three- and Nine-Month Periods Ended September 30, 2006 and 2005

Collaboration revenue Collaboration revenue relates to services rendered in connection with our agreement with Lilly discussed above. Under the agreement, Lilly will supply olanzapine and pay for the budgeted costs of the study. Under the agreement, we are required to perform specified development activities and the fee paid to us by Lilly is based on the costs associated with the conduct of that trial and the preparation and packaging of clinical trial materials. Revenue is recognized as services are rendered in accordance with the agreement. The cost of providing these research services approximates the revenue recognized. If the costs of the study exceed budgeted amounts, Lilly may not pay for the excess. As of September 30, 2006, the costs have not exceeded the budgeted amounts.

During the nine-month period ended September 30, 2006, we recognized approximately $221,000 of revenue under this agreement. We did not recognize any revenue during the third quarter of 2006. No such revenue was recorded during 2005 as the study did not commence until early 2006. Total revenues from this collaboration are expected to be between $500,000 and $1.0 million over the course of this study.

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

Research and development expenses increased 14% to $5.1 million for the three-month period ended September 30, 2006, from $4.5 million for the three-month period ended September 30, 2005. For the nine months ended September 30, 2006, research and development expenses increased 43% to $17.9 million from $12.6 million for the nine months ended September 30, 2005. The increases in expenses between years reflect clinical trial cost increases of approximately $870,000 and $6.5 million respectively, for the current quarter and year-to-date periods, primarily related to clinical trial expenses for PMD. The costs of our clinical program also reflected decreases of approximately $285,000 and $625,000 for the current quarter and year-to-date periods from the conclusion of our study in mild to moderate Alzheimer s disease in 2005. Research

Table of Contents

expenses related to the further development of our new chemical entities increased by $40,000 in the third quarter of 2006 compared with the same period in 2005. Research expenses decreased by $450,000 in the first nine months of 2006 versus the same period in 2005 because a major phase of our drug discovery program concluded in this period of 2005. This was due to the successful conclusion in early 2005 of a program focusing on the discovery of our new chemical entities. In addition, during the three- and nine-month periods ended September 30, 2006, as compared to the similar periods in 2005, there were decreases in pre-clinical studies of approximately $20,000 and $305,000, decreases in travel, consulting and other expenses of $115,000 and $270,000 and increases in staffing expenses of approximately $120,000 and $500,000, respectively. The increases in staffing expenses were primarily due to higher non-cash stock-based compensation expense. See the discussion below under the caption Stock-based compensation for options to employees impact of adopting SFAS 123R regarding the impact of adoption in January 2006.

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

Project	Three Months Ended September 30, 2006	2005	Nine Months Ended September 30, 2006	2005
	(in thousands)		*(in thousands)*	
CORLUX for the treatment of the psychotic features of PMD	$ 4,918	$ 4,050	$ 17,000	$ 11,081
CORLUX for other clinical programs	3	362	205	844
Drug discovery research	123	56	252	703
Stock-based compensation	103	53	455	(68)
Total research and development expense	$ 5,147	$ 4,521	$ 17,912	$ 12,560

We expect that research and development expenditures will decrease during the fourth quarter of 2006 because many of the clinical trials we have been conducting are in the process of being concluded or will soon conclude. Research and development expenses in 2007 will be largely dependent on the availability of additional funds to finance clinical development plans based on our experience from prior trials. See also, the Liquidity and Capital Resources section in this Form 10Q.

Many factors can affect the cost and timing of our trials including inconclusive results requiring additional clinical trials, slow patient enrollment, adverse side effects in study patients, insufficient supplies for our clinical trials and real or perceived lack of effectiveness or safety of the drug in our trials. In addition, the development of all of our 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 46% to $1.4 million for the three-month period ended September 30, 2006, from $1.0 million for the three-month period ended September 30, 2005. For the nine months ended September 30, 2006, general and administrative expenses increased 26% to $3.9 million from $3.1 million for the nine months ended September 30, 2005. These increases were primarily due to increases in staffing costs of approximately $155,000 and $330,000 during the three- and nine-month periods ended September 30, 2006, respectively, as compared with the similar periods in 2005 and increases in professional fees of approximately $260,000 and $475,000 during the three- and nine-month periods ended September 30, 2006, respectively, as compared with the similar periods in 2005. See discussion below under the caption Stock-based compensation for options to employees impact of adopting SFAS 123R regarding the impact of adoption in January 2006.

We expect that general and administrative expenses for the fourth quarter of 2006 will remain about the same level as prior quarters in 2006. The amount of general and administrative expenses in 2007 will be largely dependent on our assessment of the staff necessary to support our continued clinical development activities and the availability of additional funds. See also, the Liquidity and Capital Resources section in this Form 10Q.

Non-operating income, net

Interest and other income, net. Interest and other income, net, decreased to approximately $154,000 for the three months ended September 30, 2006 and $609,000 for the nine months ended September 30, 2006 from $278,000 and $842,000, respectively, for the same periods in 2005. The change was principally attributable to decreased earnings due to

15

Table of Contents

lower average balance of invested funds that were partially offset by higher yields on the investment portfolios during the 2006 period as compared to the 2005 period.

Other expense. Other expense was $8,000 and $14,000, respectively, for the three- and nine-month periods ended September 30, 2006, compared to $20,000 and $35,000, respectively, for the same periods in 2005. Other expense represents state tax and interest expense on capitalized leases entered into during the second quarter of 2005.

Liquidity and Capital Resources

We have incurred operating losses since inception, and at September 30, 2006, we had a deficit accumulated during the development stage of $94.6 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 September 30, 2006, we had cash, cash equivalents and investments balances of $12.0 million, compared to $29.6 million at December 31, 2005. Net cash used in operating activities for the nine-month periods ended September 30, 2006 and 2005, were $17.7 and $13.5 million, respectively. The use of cash in each period was primarily a result of net losses associated with our research and development activities and amounts incurred to develop our administrative infrastructure.

Our cash and marketable securities will enable us to complete the third of our three Phase 3 clinical studies evaluating our lead product candidate, CORLUX, for treating the psychotic features of PMD. We expect to report the results of this study in the first quarter of 2007. However, we do not have sufficient funds to maintain our current infrastructure through the completion and reporting of results of the proof-of-concept weight-gain mitigation study. If we are not able to raise additional funds, we will not be able to continue operations through the second quarter of 2007.

It is highly likely that we will have to perform additional efficacy trials prior to submission of an NDA for CORLUX for the treatment of the psychotic features of PMD. We will need to raise additional funds to complete the development of CORLUX for the treatment of PMD and other indications, to prepare for its commercialization and to conduct other research activities. The additional funds will be used to fund increases in our research and development and general and administrative activities in 2007 and subsequent years.

We believe that funds should be available for these purposes if the results of our Phase 3 trials are sufficiently encouraging. However, the first two of our three Phase 3 trials failed to meet their primary and key secondary endpoints. We cannot be certain that additional funding will be available on acceptable terms or at all. Further, any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or to obtain funds through collaborations with others that are on unfavorable terms or that may require us to relinquish certain rights to our technologies or products, including potentially our lead product, that we would otherwise seek to develop on our own; or we may be required to discontinue operations.

Contractual Obligations and Commercial Commitments

During the first quarter of 2006, we entered into agreements with a contract research organization, or CRO, to assist in the conduct of a cardiac study being performed in 2006 for a total commitment of approximately $2.5 million. The master agreement with this CRO provides for termination by us with ninety days notice.

In March 2006, we signed an amendment to our agreement with the CRO that assists us in the conduct of European clinical trial activities to add five European sites to our U.S.-based Phase 3 trials. The preparatory work for this effort had begun in late 2005 under a letter of intent with the CRO. The total commitment under this amendment is approximately 818,000 Euros, approximately $975,000 based on the conversion rate at the time of signing, of which approximately $65,000 had been committed previously under a letter of intent signed during 2005. In addition, approximately $495,000 of this commitment relates to per patient costs that will replace the commitments related to these costs under agreements signed during 2004 and 2005 with the other CROs that are enrolling patients for these trials at clinical sites in the United States. The net amount of the incremental commitment related to this amendment is approximately $415,000 in excess of the amount of clinical trial commitments as of December 31, 2005.

During the course of 2006, we modified the projected time table for the completion of enrollment of Study 06, one of our U.S.-based phase 3 trials. The extension in time to complete this trial is expected to increase projected costs by approximately $1.0 million in excess of the amounts previously reported as commitments for this trial.

16

Table of Contents

Critical Accounting Policies and Estimates

We believe there have been no significant changes in our critical accounting policies and estimates during the nine months ended September 30, 2006 as compared to what was previously disclosed in our Form 10-K for the year ended December 31, 2005, except for the changes discussed below regarding the adoption of a revenue recognition policy and the implementation of SFAS 123R.

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

Revenue recognition Collaboration revenue Collaboration revenue relates to services rendered in connection with our agreement signed in October 2005 with Lilly under which Lilly supplies olanzapine and pays for the budgeted costs of the study. We are required to perform development activities as specified in this agreement and the fee that we are paid for these services is based on the costs associated with the conduct of the trial and the preparation and packaging of clinical trial materials. Revenue is recognized as services are rendered in accordance with the agreement. The cost of providing these research services approximates the revenue recognized. If the costs of the study exceed budgeted amounts, Lilly may not pay for the excess.

Accruals of Research and Development Costs. We recorded accruals for estimated costs of research, pre-clinical and clinical studies, and manufacturing development of approximately $2.5 million as of September 30, 2006 and December 31, 2005. These 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 and service providers. 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.

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

Employees and directors

In December 2004, the Financial Accounting Standard Board, or FASB, issued Statement of Financial Accounting Standard 123 (Revised 2004), *Share-Based Payment*, or SFAS 123R, which is a revision of Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation,* or SFAS123. SFAS 123R supersedes Accounting Principles Boards Opinion No. 25, *Accounting for Stock Issued to Employees*, or APB 25, and amends FASB Statement No. 95, *Statement of Cash Flows.* SFAS 123R 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. SFAS 123R generally eliminates the ability to account for share-based compensation transactions using APB 25, and requires, instead, that such transactions be accounted for using a fair-value based method. In accordance with SFAS 123R, companies are now required to recognize an expense for compensation cost related to share-based payment arrangements, including stock options to employees and directors and employee stock purchase plans.

We adopted SFAS 123R as of January 1, 2006 under the modified prospective method, in which compensation cost is recognized beginning with the effective date (a) based on the requirements of Statement 123R for all share-based payment arrangements with employees granted or modified after the effective date and (b) based on the requirements of Statement 123 for all awards granted to employees and directors prior to the effective date of Statement 123R that remain non-vested on the effective date. Because we had used the minimum value method for options granted prior to the IPO in 2004 for SFAS 123 pro forma disclosure requirements, we continue to account for the portion of these grants that were non-vested as of January 1, 2006 under the provisions of APB 25 and related Interpretations, with pro forma disclosures under SFAS 123.

Table of Contents

Following is a brief synopsis of the implications of adoption of this statement on our accounting practices and the estimates and judgments that are considered in determining fair value in regard to stock option grants to employees and directors:

The grant date fair value for all new grants issued after January 1, 2006 is being amortized to expense using the straight-line method over the vesting period of the options.

The expected term used in determining the fair value for options is based on the simple method prescribed by the SEC in Staff Accounting Bulletin 107, and considers the weighted average of the vesting period and contractual life of the options. There has been no adjustment made to the expected term to adjust for employees expected exercise and expected post-vesting termination behavior because we have a limited employee base and do not have sufficient historical information to determine such an adjustment.

The expected volatility of our common stock used in determining the fair value of option grants is based on a weighted-average combination of the volatility of our own stock price and that of a group of peer companies since we do not have sufficient historical data from which to base an appropriate volatility assumption.

Since we have a limited employee base, at this time we do not have sufficient historical information to determine a reasonable forfeiture rate for options that might not vest because of employee terminations. When an employee terminates, we will record a change in accounting estimate that represents the difference between the expense recorded under the straight-line method and the expense that would have been recorded based upon the rights to options that vested during the individual s service as an employee.

Non-employees

Stock-based compensation related to option grants to non-employees is charged to expense on a straight line basis over the vesting period of the options, based on the fair value of the options, which approximates the period over which the related services are rendered, using the Black-Sholes option pricing model. The assumptions used in these calculations are similar to those used for the SFAS 123 disclosures for options granted to employees, with the exception that, for non-employee options, we are required to use the remaining contractual term as the life of the option and the fair value related to unvested non-employee options is remeasured quarterly, based on the then current stock price as reflected on the Nasdaq Stock Market.

Stock-based compensation for options to employees impact of adopting SFAS 123R

The following table indicates the impact of implementation of SFAS 123R for employee options on our statement of operations.

	Three months ended September 30, 2006			Nine months ended September 30, 2006		
Operating Expense Category						
(amounts in thousands)	**Research and development**	**General and administrative**	**Total**	**Research and development**	**General and administrative**	**Total**
Expense under provisions of APB 25	$	$ 81	$ 81	$ 1	$ 309	$ 310
Incremental expense	85	193	278	366	486	852
Expense under provisions of SFAS123R	$ 85	$ 274	$ 359	$ 367	$ 795	$ 1,162

The table below provides an estimate of the amounts that we will record as operating expense in our statement of operations for the remainder of 2006, based on the non-vested portion of options granted prior to the January 1, 2006 that remained non-vested as of September 30, 2006. There will be no impact on our financial condition or cash flow as these charges are all non-cash amounts. It should be noted that the amounts actually recorded during the remainder of 2006 may differ from the figures presented in this table due to the issuance of any new grants or employee terminations during the remainder of the year. These amounts may not be indicative of the level of expense that will be recorded in future years

due to the decelerating scale of expense recognition under the graded vesting method used to amortize the cost of options granted prior to January 1, 2006 and due to the possible issuance of any new grants or employee terminations.

	Remainder of 2006		
Operating Expense Category			
(amounts in thousands)	**Research and development**	**General and administrative**	**Total**
Expense under provisions of APB 25	$	$ 64	$ 64
Incremental expense	101	191	292
Expense under provisions of SFAS123R	$ 101	$ 255	$ 356

Table of Contents

As of September 30, 2006, the Company had the following amounts of unrecognized compensation expense for employee options outstanding as of that date.

	Amount *(in thousands)*	Weighted-average period *(in years)*
Remaining deferred compensation related to options granted prior to the IPO, to be expensed under the provisions of APB 25	$ 293	2.3
Remaining fair value to be expense		
Options granted after IPO through 2006, using fair value under SFAS 123	927	3.1
Options granted during 2006, using fair value under SFAS 123R	1,815	3.6
Total	$ 3,035	

ITEM 3 - QUANTITATIVE AND QUALITATIVE DISCLOSURES

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 September 30, 2006, our cash and cash equivalents consisted primarily of money market funds maintained at major U.S. financial institutions, and the short-term investments consist of corporate debt securities and U.S. government obligations. To minimize our exposure to interest rate market risk, we have limited the maturities of our investments to less than two years with an average maturity not to exceed one year. Due to the short-term nature of these instruments, a 1% increase or decrease in market interest rates would not have a material adverse impact on the total value of our portfolio as of September 30, 2006.

Currency Risk

In 2004, we signed a master agreement with a CRO to assist us in the conduct of clinical trials in Europe. The costs of these trials are denominated in Euros, which the vendor converts into U.S. dollars for invoicing as costs are incurred, generally on a monthly basis. Thus, we may bear some currency rate exposure for the costs of these trials. As of December 31, 2005, we had executed amendments to this agreement that included Euro-denominated commitments of approximately 6.0 million Euros. In March 2006, we signed an additional amendment to our agreement with this CRO to add five European sites to our U.S.-based Phase 3 trials. The preparatory work for this effort had begun in late 2005 under a letter of intent with the CRO. The total commitment under this amendment is approximately 818,000 Euros, approximately $975,000 based on the conversion rate at the time of signing, of which approximately $65,000 (53,000 Euros) had been committed previously under the letter of intent.

Approximately 1.5 million Euros of the contractual commitments had not been expended or accrued as of September 30, 2006, which is equivalent to approximately $2.0 million, using the exchange rate as of that date. A 1% increase or decrease in the currency rate of exchange between the U.S. Dollar and the Euro would have an impact of approximately $20,000 on the unexpended cost of these trials based on the original commitments. The timing of payments for these trials will depend upon various factors including the pace of site selection, patient enrollment, and other trial activities. The master agreement with this CRO provides for termination by us with forty-five days notice.

These trials were originally expected to be conducted through the third quarter of 2007. In late October 2006, we notified the CRO of our intent to terminate Study 13, the retreatment study. Of the two remaining Euro-denominated trials, one phase 3 trial (Study 09) has completed enrollment and remaining activities should be completed by the end of 2006. The efforts under the March 2006 amendment to add enrollment at European sites to Study 06, another of our phase 3 trials, are continuing and we expect to report the results of this trial in the first quarter of 2007.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures. Based on their evaluation as of September 30, 2006, 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 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. Our

disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met.

Changes in internal controls. There were no changes in our internal controls over financial reporting during the quarter ended September 30, 2006 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently involved in any material legal proceedings.

ITEM 1A RISK FACTORS

In addition to other information in this report, the following factors should be considered carefully in evaluating our company.

The risk factors set forth below contain a number of changes relative to those set forth in the RISK FACTORS section of our annual report on Form 10-K for the year ended December 31, 2005. The material changes relate primarily to the progress of clinical trials for our lead product CORLUX® for the treatment of the psychotic features of Psychotic Major Depression (PMD) and our liquidity position and funding requirements. Additional risks and uncertainties of which we are unaware or currently deem less material may also become important factors that may harm our business.

If any of the risks or uncertainties described in this Form 10-Q or in our annual report on Form 10-K for the year ended December 31, 2005 actually occurs, our business, results of operations or financial condition could be materially adversely affected. The risks and uncertainties described in this Form 10-Q are not the only ones facing the company. Except as required by law, we undertake no obligations to update any risk factors.

Risks Related to Our Business

Our current capital is sufficient to fund operations only into the second quarter of 2007. We need additional capital in order to continue operations and capital may not be available to us at all or on favorable terms.

Without additional funding we will not be able to continue the company s operations through the second quarter of 2007. Our cash and marketable securities will enable us to complete the third of our three Phase 3 clinical studies evaluating our lead product candidate, CORLUX, for treating the psychotic features of PMD. However, we do not have sufficient funds to maintain our current infrastructure through the completion and reporting of results of the proof-of-concept weight-gain mitigation study. We believe that our ability to secure substantial additional funding will depend largely on the results of our ongoing Phase 3 clinical trial, expected in the first quarter of 2007. The first two of our three Phase 3 trials failed to meet their primary and key secondary endpoints. We cannot be certain that additional funding will be available on acceptable terms or at all.

Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or to obtain funds through collaborations with others that are on unfavorable terms or that may require us to relinquish certain rights to our technologies or products, including potentially our lead product, that we would otherwise seek to develop on our own; or we may be required to discontinue operations.

We currently have no credit facility or committed sources of capital.

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

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

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

be solely dependent on the successful development, approval and commercialization of CORLUX. We have completed two Phase 3 clinical trials and are conducting a third trial the results of

Table of Contents

which are expected in the first quarter of 2007. All three trials are for the evaluation of CORLUX for the treatment of the psychotic features of PMD. Neither of the first two trials met its primary or key secondary endpoints.

While we expect that the initial results of Study 06 are expected to be reported in the first quarter of 2007, we cannot assure you that this will occur. Even though Study 06 is covered by a Special Protocol Assessment, or SPA, we may decide, or the FDA may require us, to pursue additional clinical trials to demonstrate the safety and/or efficacy of CORLUX or to pursue additional supportive studies. This is highly likely to be the case because the FDA requires at least two positive Phase 3 studies prior to the submission of a New Drug Application (NDA).

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

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

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

To gain regulatory approval from the FDA to market CORLUX for the treatment of the psychotic features of PMD, our Phase 3 clinical trials must demonstrate the safety and efficacy of CORLUX for this treatment. The first two of our three Phase 3 studies did not meet their primary of key secondary endpoints. The third study is in progress with results expected in the first quarter of 2007. In addition to our clinical trials, we are conducting, or plan to conduct, carcinogenicity studies, toxicology tests and other studies in support of a potential NDA. Clinical development is a long, expensive and uncertain process and is subject to delays, and data obtained from clinical trials and supportive studies are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Favorable results of preclinical studies and initial clinical trials of CORLUX are not necessarily indicative of the results we will obtain in later clinical trials. While we obtained favorable results in some of our Phase 2 clinical trials, these results were not replicated in Study 07 or Study 09 and are not sufficient to support an application for FDA approval. Study 06, the Phase 3 clinical trial we are currently conducting, may not be successful. In addition, we cannot assure you that supportive studies and tests will produce favorable results.

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

During the development of CORLUX, we have been engaged in dialogue with the FDA to determine an acceptable development plan which would enable the Agency to complete its review in a satisfactory manner. Even though our ongoing Phase 3 trial is covered by an SPA, we may decide, or the FDA may require us, to pursue additional clinical trials to demonstrate the safety and/or efficacy of CORLUX. This is highly likely to be the case because the FDA requires at least two positive Phase 3 studies prior to the submission of an NDA. In addition, the FDA may require us to pursue additional supportive studies. Recently, the FDA recommended that we conduct a dose proportionality study and other studies to determine whether there are interactions between CORLUX and some commonly used drugs. We are continuing our dialogue with the FDA to define any additional data needed to complete an NDA. Although our cash and marketable securities will enable us to complete our ongoing Phase 3 trial, we will need to raise additional funds for our research and development and general and administrative activities in 2007 and subsequent years. We believe that our ability to secure substantial additional funding in the near term will depend largely on the result of our ongoing Phase 3 clinical trial. Our inability to raise capital will result in a delay of the performance of these activities and harm our business and product development efforts. Without additional funding we will not be able to continue the company s operations through the second quarter of 2007.

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

Table of Contents

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

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

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

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

We are a development stage company with no current source of product revenue. We have a limited history of operations and have focused primarily on clinical trials, and if the outcome of our clinical trials supports it, we plan to seek FDA regulatory clearance to market CORLUX for the treatment of the psychotic features of PMD. Historically, we have funded our operations primarily from the sale of our equity securities. We have incurred losses in each year since our inception in 1998. As of September 30, 2006, we had an accumulated deficit of approximately $94.6 million. We do not know when or if we will generate product revenue. Subject to our ability to raise additional funds, we expect our research and development expenses to increase in connection with the clinical trials and other development activities for CORLUX and for other product candidates. We expect to incur significant expenses related to the preparation for commercializing CORLUX and for the product s launch, if the FDA approves our NDA. As a result, we expect that our losses will increase for the foreseeable future. We are unable to predict the extent of any future losses or whether or when we will become profitable.

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

We rely on clinical investigators and clinical sites to enroll patients and other third parties to manage our trials and to perform related data collection and analysis. However, we may not be able to control the amount and timing of resources that the clinical sites that conduct the clinical testing may devote to our clinical trials. For example, we reported in September 2005 that, due to a slower than anticipated pace of patient enrollment, we had revised the date by which we expect to report the results of Study 06, one of our three Phase 3 efficacy studies. Prior to the September announcement, we had expected to report results from this clinical trial in the first half of 2006. We now expect to report these results in the first quarter of 2007. There can be no assurance that the steps we are taking to increase the pace of enrollment will be successful. If our clinical investigators and clinical sites fail to enroll a sufficient number of patients in our clinical trials or fail to enroll them on our planned schedules, we will be unable to complete our trials or to complete them as planned, which could delay or prevent us from completing the clinical development of CORLUX.

We have contracted with Premier Research (formerly Scirex Corporation), PPD Development, LP, (PPD), and i3 Research, an Ingenix Company (i3), to monitor clinical site performance and to perform investigator supervision, data collection and analysis in Study 06. We may not be able to maintain these relationships with Premier Research, PPD or i3 or with the clinical sites without undue delays or excessive expenditures. Our agreements with clinical investigators and clinical sites for clinical testing and with Premier Research, PPD and i3 for trial management services place substantial responsibilities on these parties, which could result in delays in, or termination of Study 06 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, Study 06 may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for, or successfully commercialize, CORLUX.

Table of Contents

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

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

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

If we are unable to obtain or maintain regulatory approval, we will be limited in our ability to commercialize our 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 approval process for human medicines. The FDA can deny, delay or limit approval of a product candidate for many reasons including:

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

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

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

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

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

We intend to commercialize our products in international markets. Outside the United States, we can commercialize a product only if we receive a marketing authorization and, in some cases, pricing approval, from the appropriate regulatory authorities. This foreign regulatory approval process includes all of the risks associated with the FDA approval process, and, in some cases, additional risks. The approval procedure varies

among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. We have not taken any actions to

Table of Contents

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

If a human medicine is intended for the treatment of a serious or life-threatening condition and the medicine demonstrates the potential to address unmet medical needs for this condition, the sponsor of an Investigational New Drug Application, or IND, may apply for FDA fast track designation for a particular indication. Marketing applications submitted by sponsors of 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 applications considered for approval under conventional FDA procedures. In addition, the FDA may withdraw our fast track designation at any time. If we lose our fast track designation, the approval process may be delayed. In addition, our fast track designation does not guarantee that we will qualify for or be able to take advantage of the expedited review procedures and does not increase the likelihood that CORLUX will receive regulatory approval for the treatment of the psychotic features of PMD.

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

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

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

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

the rate of adoption of CORLUX by physicians and by target patient population; and

negative publicity concerning CORLUX, RU-486 or mifepristone.

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

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

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

Table of Contents

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

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

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

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

Failure of our third party suppliers and manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our 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 may require us to conduct a study to demonstrate that the tablets used in our clinical trials are equivalent to the final commercial product. If we are unable to establish that the tablets are equivalent or if the FDA disagrees with the results of our study, commercial launch of CORLUX would be delayed.

If we or others identify side effects after our 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 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

Table of Contents

protect our intellectual property, competitors may be able to use our intellectual property and erode our competitive advantage.

To date, we own three 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 ten U.S. method of use patent applications for GR-II antagonists and three composition of matter patent applications covering specific GR-II antagonists. We have applied, and will continue to apply, for patents covering our product candidates as we deem appropriate.

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

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

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

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

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, targeted for the treatment of PMD. A method of use patent covers only a specified use of a particular compound, not a particular composition of matter. All of our issued patents and all but three of our 13 U.S. patent applications relate to use patents. Because none of our issued patents covers the composition of mifepristone or any other

Table of Contents

compound, we cannot prevent others from commercializing mifepristone or any other GR-II antagonist. If others receive approval to manufacture and market mifepristone or any other GR-II antagonist, physicians could prescribe mifepristone or any other GR-II antagonist for PMD patients instead of CORLUX. Although any such off-label use would violate our licensed patent, effectively monitoring compliance with our licensed patent may be difficult and costly. In addition, if others develop a treatment for PMD that works through a mechanism which does not involve the GR-II receptor, physicians could prescribe that treatment instead of CORLUX.

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

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

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

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

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

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

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

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

Table of Contents

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 for CORLUX or other product candidates, 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 some cases, less common adverse effects of a pharmaceutical product are not known until long after the FDA approves the product for marketing. The active ingredient in CORLUX is used to terminate pregnancy. Therefore, necessary and strict precautions must be taken by clinicians using the medicine in our clinical trials and, if approved by the FDA, physicians prescribing the medicine to women with childbearing potential, to insure that the medicine is not administered to pregnant women. The failure to observe these precautions could result in significant product claims.

We have only limited product liability insurance coverage, with limits customary for a development stage company. We intend to expand our product liability insurance coverage to any 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 staff and limited marketing activities and will need to develop sales and marketing capabilities to successfully commercialize CORLUX and any future uses of GR-II antagonists.

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

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

If resources are made available to continue operations through and beyond the second quarter of 2007, we plan to use those resources to expand our research and development efforts and develop a sales and marketing organization when appropriate. In that event, we expect to experience growth, which may strain our operations, product development and other managerial and operating resources. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. To date, we have relied on a small management team, including a number of part-time contributors. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to manage any future growth effectively.

To that end, we must be able to:

- manage our research and development efforts effectively;
- manage our clinical trials effectively;
- integrate additional management, administrative and sales and marketing personnel;
- expand the size and composition of our management team;

develop our administrative, accounting and management information systems and controls; and

hire and train additional qualified personnel.

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

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

There is significant uncertainty related to the availability of insurance coverage and reimbursement for newly approved medications. The commercial success of our potential medications in both domestic and international markets is dependent

Table of Contents

on whether third-party coverage and reimbursement is available for them. Medicare, Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new medicines, and, as a result, they may not cover or provide adequate payment for our medications. The continuing efforts of 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 medicinal therapy.

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

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

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.

Table of Contents

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

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

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

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

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

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

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

Table of Contents

Risks Related to Our Stock

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

We cannot assure you that an active trading market for our common stock will exist at any time. Holders of our common stock may not be able to sell shares quickly or at the market price if trading in our common stock is not active. During the 52-week period ended November 6, 2006, our average daily trading volume has been approximately 125,000 shares and the intra-day sales prices per share of our common stock ranged from $0.68 to $6.15. The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

- our cash and short-term investment position;
- actual or anticipated timing and results of our clinical trials;
- actual or anticipated regulatory approvals of our 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;

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

sales of our common stock by us or our stockholders.

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

Our stock could be delisted by the Nasdaq Global Market. If delisting occurs, our business will be harmed.

The closing price of our common stock on the Nasdaq Global Market has been less than $1.00 since September 29, 2006. If the closing price of our common stock is less than $1.00 for 30 consecutive business days, our common stock will be out of compliance with the minimum closing bid price requirement for continued listing on the Nasdaq Global Market. Although Nasdaq provides listed companies a 180-day grace period to regain compliance with the minimum closing bid price requirement, there is no guarantee that the Company could regain compliance within this period, and as a result the Company could be delisted from the Nasdaq Global Market. In the event our common stock is delisted from the Nasdaq Global Market, there would be a number of negative implications, including reduced liquidity in our common stock , the loss of Form S-3 eligibility, the loss of federal preemption of state securities laws and the potential loss of confidence by suppliers and employees, as well as the potential loss of analyst coverage and institutional investor interest, fewer business development opportunities and greater difficulty in obtaining financing.

Table of Contents

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

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

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

Sales of a substantial number of shares of our common stock in the public market could harm the market price of our common stock. As additional shares of our common stock become available for resale in the public market, the supply of our common stock will increase, which could decrease the price. Substantially all of the shares of our common stock are eligible for sale, subject to applicable volume and other resale restrictions.

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

As of November 6, 2006, our officers, directors and principal stockholders control a majority of our common stock. As a result, these stockholders, acting together, will be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders and may prevent or delay a change in control. This concentration of ownership may have the effect of delaying or preventing a change in control and might adversely affect the market price of our common stock. In addition, this significant concentration of share ownership may adversely affect the trading price of our common stock because investors often perceive disadvantages to owning stock in companies with controlling stockholders.

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

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

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

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

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

with an

Table of Contents

unqualified report as to the effectiveness of our internal controls over financial reporting as the required deadline and future year ends, investors could lose confidence in the reliability of our financial reporting.

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

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

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

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

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIESAND USE OF PROCEEDS

Proceeds from Sale of Registered Securities.

On April 19, 2004, we completed an initial public offering of 4,500,000 shares of our common stock. The shares of common stock sold in the offering were registered under the Securities Act of 1933, as amended, on a Registration Statement on Form S-1 (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. 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 September 30, 2006, approximately $4.4 million of the net proceeds was used for research and development activities and approximately $1.0 million was used for general and administrative activities. Between the effective date of the Registration Statement and September 30, 2006, approximately $37.3 million of the net proceeds was used for research and development activities and approximately $8.5 million was used for general and administrative activities. The remaining proceeds from the offering have been placed in temporary investments of marketable securities for future use as needed.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

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

None.

33

Table of Contents

ITEM 5. OTHER INFORMATION

None.

ITEM 6. 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.

Table of Contents

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: November 8, 2006

/s/ JOSEPH K. BELANOFF
Joseph K. Belanoff, M.D.

Chief Executive Officer

Date: November 8, 2006

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

Table of Contents

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.