NEUROCRINE BIOSCIENCES INC
Form 10-Q
November 09, 2006

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2006

OR

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

For the transition period from _____ to _____

Commission file number 0-22705

NEUROCRINE BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	**33-0525145**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
12790 EL CAMINO REAL SAN DIEGO, CALIFORNIA	**92130**
(Address of principal executive offices)	(Zip Code)

(858) 617-7600

(Registrant s telephone number, including area code)

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

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

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 þ Accelerated filer o Non-accelerated filer o

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

The number of outstanding shares of the registrant s common stock, par value $0.001 per share, was 37,884,038 as of November 1, 2006.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

NEUROCRINE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except for share information)
(unaudited)

	September 30, 2006	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 75,760	$ 49,948
Short-term investments, available-for-sale	124,018	223,120
Receivables under collaborative agreements	431	858
Other current assets	4,571	5,384
Total current assets	204,780	279,310
Property and equipment, net	93,868	99,307
Restricted cash	5,775	5,775
Prepaid royalty	94,000	94,000
Other non-current assets	5,708	4,731
Total assets	$ 404,131	$ 483,123
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 15,428	$ 21,342
Deferred revenues	976	6,537
Current portion of long-term debt	4,863	5,814
Total current liabilities	21,267	33,693
Long-term debt	50,129	53,590
Other liabilities	6,259	5,736
Total liabilities	77,655	93,019
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued and outstanding		
Common stock, $0.001 par value; 110,000,000 shares authorized; issued and outstanding shares were 37,872,608 as of September 30, 2006 and 37,132,478 as of December 31, 2005	38	37
Additional paid-in capital	719,405	691,717

Accumulated other comprehensive loss	(328)	(1,504)
Accumulated deficit	(392,639)	(300,146)
Total stockholders equity	326,476	390,104
Total liabilities and stockholders equity	$ 404,131	$ 483,123

See accompanying notes to the condensed consolidated financial statements.

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NEUROCRINE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Revenues:				
Sponsored research and development	$ 348	$ 1,297	$ 6,503	$ 8,434
License fees and milestones	726	55,448	6,811	87,344
Sales force allowance		8,000	16,480	14,000
Total revenues	1,074	64,745	29,794	109,778
Operating expenses:				
Research and development	25,223	26,627	79,070	81,863
Sales, general and administrative	16,047	12,997	47,778	28,393
Total operating expenses	41,270	39,624	126,848	110,256
(Loss) income from operations	(40,196)	25,121	(97,054)	(478)
Other income and (expenses):				
Interest income	2,442	2,080	7,862	5,394
Interest expense	(917)	(1,024)	(2,829)	(3,162)
Other expense, net	(472)	(26)	(472)	(37)
Total other income, net	1,053	1,030	4,561	2,195
Net (loss) income	$(39,143)	$26,151	$ (92,493)	$ 1,717
Net (loss) income per common share:				
Basic	$ (1.03)	$ 0.71	$ (2.46)	$ 0.05
Diluted	$ (1.03)	$ 0.68	$ (2.46)	$ 0.05
Shares used in the calculation of net (loss) income per common share:				
Basic	37,868	36,707	37,664	36,685
Diluted	37,868	38,406	37,664	37,992

See accompanying notes to the condensed consolidated financial statements.

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NEUROCRINE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2006	**2005**
CASH FLOW FROM OPERATING ACTIVITIES		
Net (loss) income	$ (92,493)	$ 1,717
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation and amortization	7,987	7,491
Deferred revenues	(5,561)	(16,778)
Loss on disposal of fixed assets	476	
Loan forgiveness on notes receivable from stockholder	50	50
Share-based compensation expense	12,666	421
Change in operating assets and liabilities:		
Accounts receivable and other current assets	1,240	5,896
Other non-current assets	(889)	(437)
Accounts payable and accrued liabilities	(5,914)	(7,146)
Other non-current liabilities	(97)	896
Net cash used in operating activities	(82,535)	(7,890)
CASH FLOW FROM INVESTING ACTIVITIES		
Purchases of short-term investments	(62,521)	(49,522)
Sales/maturities of short-term investments	162,661	73,493
Restricted cash		(525)
Purchases of property and equipment	(3,024)	(4,262)
Net cash provided by investing activities	97,116	19,184
CASH FLOW FROM FINANCING ACTIVITIES		
Issuance of common stock	15,643	8,196
Principal payments on debt	(4,412)	(5,133)
Net cash provided by financing activities	11,231	3,063
Net increase in cash and cash equivalents	25,812	14,357
Cash and cash equivalents at beginning of the period	49,948	61,027
Cash and cash equivalents at end of the period	$ 75,760	$ 75,384

See accompanying notes to the condensed consolidated financial statements.

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NEUROCRINE BIOSCIENCES, INC.
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. ORGANIZATION AND SUMMARY OF BUSINESS

Neurocrine Biosciences, Inc. (the Company or Neurocrine) was incorporated in California in 1992 and reincorporated in Delaware in 1996. The Company discovers, develops and intends to commercialize drugs for the treatment of neurological and endocrine-related diseases and disorders. The Company s product candidates address some of the largest pharmaceutical markets in the world, including insomnia, anxiety, depression, endometriosis, irritable bowel syndrome, pain, Parkinson s disease, and other neurological and endocrine related diseases and disorders. The Company currently has eight programs in various stages of research and development, including six programs in clinical development. While the Company independently develops many of its product candidates, they are in a collaboration for two of its programs. The lead clinical development program, indiplon, is a drug candidate for the treatment of insomnia. The Company submitted two New Drug Applications (NDAs) to the United States Food and Drug Administration (FDA) with respect to indiplon.

On May 15, 2006, the Company received two complete responses from the FDA regarding the indiplon capsule and tablet NDAs. These responses indicated that indiplon 5 mg and 10 mg capsules were approvable (FDA Approvable Letter) and that the 15 mg tablets were not approvable (FDA Not Approvable Letter).

The FDA Approvable Letter requested that the Company reanalyze data from certain preclinical and clinical studies to support approval of indiplon 5 mg and 10 mg capsules for sleep initiation and middle of the night dosing. The FDA Approvable Letter also requested reexamination of the safety analysis for the elderly population. The Company held an end-of-review meeting with FDA related to the FDA Approvable Letter in August 2006. This meeting was specifically focused on determining the actions needed to bring indiplon capsules from Approvable to Approval in the resubmission of the NDA for indiplon capsules. At the meeting the FDA requested that the resubmission include further analyses and modifications of analyses previously submitted to address questions raised by the FDA in the initial review. This reanalysis is ongoing. The FDA also requested, and the Company has completed, a supplemental pharmacokinetic/food effect profile of indiplon capsules including several meal types. While the FDA has not requested any additional clinical studies for the indiplon capsules resubmission, the Company has elected to conduct an additional 3-month safety and efficacy study to supplement the reanalysis and provide additional support for the resubmission. The NDA for indiplon capsules is targeted to be resubmitted to the FDA during summer 2008.

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

The process of preparing and resubmitting the tablet NDA will require significant resources and is subject to unanticipated delays and cost. Upon resubmission of both NDAs, the FDA may still require additional data analysis or clinical trials, which would require substantial expenditures by the Company and could further delay the approval process.

On June 22, 2006, Pfizer and the Company agreed to terminate their collaboration and license agreements to develop and co-promote indiplon effective December 19, 2006. As a result, the Company will reacquire all worldwide rights for indiplon capsules and tablets. The Company will receive reimbursement of certain indiplon expenses incurred or committed prior to the June 22, 2006 notice date as well as certain ongoing expenses until December 19,

2006, the effective date of termination. The Company will be responsible for any costs associated with additional data or clinical trials that may be required for resubmission of the indiplon NDAs.

Pursuant to the Company s collaboration agreement with Pfizer, the Company s sales force ceased detailing Pfizer s antidepressant Zoloft® to psychiatrists as of June 30, 2006, the date of expiration of Zoloft® patent exclusivity. Pfizer notified the Company that as of July 1, 2006, Pfizer will no longer reimburse or support the Company s sales force.

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In July 2006 and August 2006, the Company announced a restructuring program to prioritize research and development efforts and implement cost containment measures. As a result, the Company terminated the entire sales force in July 2006 and reduced its research and development, and general and administrative staff in San Diego by approximately 100 employees in August 2006. In connection with the restructuring, the Company recorded a one-time charge of approximately $9.5 million in the third quarter of 2006 for salary continuation, outplacement services, and other costs related to these reductions in force. Substantially all of these expenses were paid out in cash during the third quarter of 2006 (See Note 11 Severance Costs).

2. BASIS OF PRESENTATION

The condensed consolidated financial statements included herein are unaudited. These statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions of the Securities and Exchange Commission (SEC) on Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, these financial statements include all adjustments (consisting of normal recurring adjustments) necessary for a fair presentation of the financial position, results of operations, and cash flows for the periods presented. The results of operations for the interim periods shown in this report are not necessarily indicative of results expected for the full year. These financial statements should be read in conjunction with the Management s Discussion and Analysis of Financial Condition and Results of Operations, Quantitative and Qualitative Disclosures About Market Risk and the audited financial statements and notes thereto for the year ended December 31, 2005 included in our Annual Report on Form 10-K for the year ended December 31, 2005, filed with the SEC.

The terms Company and we and our are used in this report to refer collectively to Neurocrine Biosciences, Inc. and its subsidiaries.

3. SHARE-BASED COMPENSATION

The Company grants stock options, restricted stock units and stock bonuses (collectively, share-based compensation) to its employees and directors under the 2003 Incentive Stock Plan, as amended (the 2003 Plan) and grants stock options to certain employees pursuant to Employment Commencement Nonstatutory Stock Options. Until June 30, 2006, eligible employees could also purchase shares of our common stock at 85% of the fair market value on the last day of each six-month offering period under our Amended and Restated Employee Stock Purchase Plan. The benefits provided under these Plans are share-based compensation subject to the provisions of Statement of Financial Accounting Standards (SFAS) 123 (revised 2004), Share-Based Payment (SFAS 123R).

Prior to January 1, 2006, the Company accounted for share-based compensation under the recognition and measurement principles of Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB 25). Therefore, the Company measured compensation expense for its share-based compensation using the intrinsic value method, that is, as the excess, if any, of the fair market value of the Company s stock at the grant date over the amount required to be paid to acquire the stock, and provided the disclosures required by SFAS 123, Accounting for Stock-Based Compensation (SFAS 123) and SFAS 148, Accounting for Stock-Based Compensation-Transition and Disclosure (SFAS 148).

Effective January 1, 2006, the Company began recording compensation expense associated with stock options and other equity-based compensation in accordance with SFAS 123R, using the modified prospective transition method and therefore has not restated results for prior periods. Under the modified prospective transition method, share-based compensation expense for 2006 includes 1) compensation expense for all share-based awards granted on or after January 1, 2006 as determined based on the grant-date fair value estimated in accordance with the provisions of SFAS 123R and 2) compensation expense for share-based compensation awards granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS 123. The Company recognizes compensation expense on a straight-line basis over the requisite service period of the award, which is generally four years; however, certain provisions in the Company s equity compensation plans provide for shorter vesting periods under certain circumstances.

On September 26, 2006, the Company completed a Tender Offer (Offer) to holders of outstanding options to purchase its common stock under the 2003 Plan, 1992 Incentive Stock Plan (the 1992 Plan) and 2001 Stock Option

Plan, as amended (the 2001 Plan). The Offer was for holders of options under the 2003 Plan to cancel their

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options in exchange for a lesser number of new options (a two-for-one exchange ratio) to purchase shares of the Company s common stock issued under the 2003 Plan and for holders of options under the 1992 Plan and 2001 Plan to cancel one-half of their options and amend their remaining options to purchase shares of the Company s common stock. The Offer was open to eligible employees and active consultants of the Company who held options with an exercise price of $20.00 or higher per share as of September 25, 2006. Certain executives and members of the Board of Directors were not eligible to participate in the Offer. Approximately 2.0 million options were exchanged or amended resulting in approximately 1.0 million new or amended option grants and approximately 1.0 million cancelled option grants at the completion of the Offer. New or amended options under the Offer vest annually over a period of three years and have a weighted average exercise price of $10.90. Share based compensation expense related to the Offer totaled approximately $6.3 million and will be amortized over 3 years.

As a result of the adoption of SFAS 123R, the Company s net loss for the three and nine months ended September 30, 2006 includes $3.2 million and $12.7 million, respectively, of compensation expense related to the Company s share-based compensation awards. The compensation expense related to the Company s share-based compensation arrangements is recorded as components of sales, general and administrative expense ($1.6 million and $7.2 million for the three and nine months ended September 30, 2006, respectively) and research and development expense ($1.6 million and $5.5 million for the three and nine months ended September 30, 2006, respectively). SFAS 123R requires that cash flows resulting from tax deductions in excess of the cumulative compensation cost recognized for options exercised (excess tax benefits) be classified as cash inflows provided by financing activities and cash outflows used in operating activities. Due to the Company s net loss position, no tax benefits have been recognized in the cash flow statement.

The Company issues new shares upon the exercise of stock options and the issuance of stock bonus awards.

Share-Based Compensation Plans

Since 1992, the Company has authorized a total of 13.7 million shares of common stock for issuance pursuant to its 1992 Plan, 1996 Director Option Plan, 1997 Northwest Neurologic, Inc. Restated Incentive Stock Plan, 2001 Plan, several Employment Commencement Nonstatutory Stock Option Agreements and the 2003 Plan (collectively, the Option Plans). The Option Plans provide for the grant of stock options, restricted stock, restricted stock units, and stock bonuses to officers, directors, employees, and consultants of the Company. Currently, all new grants of stock options are made from the 2003 Plan or through Employment Commencement Nonstatutory Stock Option Agreements. As of September 30, 2006, of the 13.7 million shares reserved for issuance under the Option Plans, 1.4 million of these shares were originally reserved for issuance pursuant to the terms of the Company s 1992 Plan, 1996 Director Stock Option Plan and 2001 Plan and would currently be available for issuance but for the Company s determination in 2003 not to make further grants under these plans; 5.6 million were issued upon exercise of stock options previously granted or pursuant to restricted stock or stock bonus awards; 5.7 million were subject to outstanding options and restricted stock units; and 1.0 million remained available for future grant under the 2003 Plan. Share awards made under the 2003 Plan that are later cancelled due to forfeiture or expiration return to the pool available for future grants.

Vesting Provisions of Share-Based Compensation

Stock options granted under the Option Plans primarily have terms of up to ten years from the date of grant, and generally vest over a three to four-year period. Stock bonuses granted under the Option Plans generally have vesting periods ranging from two to four years. Restricted stock units granted under the Option Plans have vesting periods of three years. The expense recognized under SFAS 123R is generally recognized ratably over the vesting period. However, certain retirement provisions in the Option Plans provide that employees who are age 55 or older and have five or more years of service with the Company will be entitled to accelerated vesting of all of the unvested share-based compensation awards upon retirement from the Company. In these cases, share-based compensation expense may be recognized over a shorter period of time, and in some cases the entire share-based compensation expense may be recognized upon grant of the share-based compensation award. Effective January 1, 2006, the maximum contractual term for all options granted from the 2003 Incentive Stock Plan was reduced to seven years.

On November 7, 2005, the Company accelerated vesting of all unvested stock options to purchase shares of common stock that were held by then-current employees and had an exercise price per share equal to or greater than

$50.00. Stock options to purchase approximately 472,000 shares of common stock were subject to this acceleration. The exercise prices and number of shares subject to the accelerated stock options were unchanged. The acceleration was effective November 7, 2005, and the expense was included in the pro forma results of operations for the fourth quarter of 2005 which were disclosed in the notes to Company s consolidated financial statements for the year ended December 31, 2005 pursuant to SFAS 123. The acceleration of these stock options was undertaken to eliminate the future compensation expense of approximately $10.5 million that the Company would have otherwise recognized under SFAS 123R in its future consolidated statements of operations.

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Stock Options

The exercise price of all options granted during the nine months ended September 30, 2006 and 2005 was equal to the market value on the date of grant and, accordingly, no share-based compensation expense for such options is reflected in net income for the first nine months of fiscal year 2005 in accordance with APB 25. The estimated fair value of each option award granted was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions for option grants during the three and nine months ended September 30, 2006 and 2005:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	**2005**	**2006**	**2005**
Risk-free interest rate	4.55%	4.18%	4.56%	4.18%
Expected volatility of common stock	66.00%	34.00%	62.52%	34.00%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Expected option term	4.2 years	5.8 years	4.3 years	5.8 years

The risk-free interest rate assumption is based upon observed interest rates appropriate for the expected term of the Company s employee stock options. The expected volatility is based on the historical volatility of the Company s stock. The Company has not paid any dividends on common stock since its inception and does not anticipate paying dividends on its common stock in the foreseeable future. Except for options issued in the Offer, the computation of the expected option term is based on a weighted-average calculation combining the average life of options that have already been exercised or cancelled with the estimated life of all unexercised options. Per Staff Accounting Bulletin 107 (SAB 107), the Company used the simplified method to compute the expected option term for all options granted in the Offer. The simplified method was used because the contractual life of the amended or exchanged options varied from approximately three to seven years due to the terms of the Offer. The decrease in the expected option term from 2005 to 2006 is due to the decrease in the maximum term of the options granted after January 1, 2006 from ten years to seven years.

Share-based compensation expense recognized in the Condensed Consolidated Statement of Operations for the nine months ended September 30, 2006 is based on awards ultimately expected to vest, net of estimated forfeitures. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Pre-vesting forfeitures for awards with monthly vesting terms were estimated to be 0% in 2006 based on historical experience. The effect of pre-vesting forfeitures for awards with monthly vesting terms has historically been negligible on the Company s recorded expense. Pre-vesting forfeitures for awards with annual vesting terms were estimated at 10% in 2006 based on historical employee turnover experience. The effect of the restructuring has been excluded from the historical review of employee turnover because it was a one-time event and also included minimal pre-vesting forfeitures. In the Company s pro forma information required under SFAS 123 for the periods prior to fiscal 2006, the Company accounted for forfeitures as they occurred. The Company s determination of fair value is affected by the Company s stock price as well as a number of assumptions that require judgment. The weighted-average fair value of options granted during the nine months ended September 30, 2006 and 2005, estimated as of the grant date using the Black-Scholes option valuation model, was $9.83 per option and $16.36 per option, respectively.

A summary of the status of the Company s stock option plans as of September 30, 2006 and of changes in options outstanding under the plans during the nine months ended September 30, 2006 is as follows (in thousands, except for weighted average exercise price and weighted average remaining contractual term data):

	Number of	**Weighted-Average Exercise Price**	**Weighted-Average Remaining Contractual**	**Aggregate Intrinsic**

	Shares	per Share	Term (in years)	Value
Options outstanding at December 31, 2005	6,544	$ 38.32		
Options granted/amended	1,581	$ 17.01		
Options exercised	(544)	$ 27.87		
Options forfeited or expired	(2,788)	$ 43.15		
Options outstanding at September 30, 2006	4,793	$ 29.67	5.8	$2,135
Options vested and exercisable at September 30, 2006	3,415	$ 35.20	5.4	$2,126

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For the three and nine months ended September 30, 2006, share-based compensation expense related to stock options was $2.8 million and $12.0 million, respectively. As of September 30, 2006, there was approximately $11.6 million of unamortized compensation cost related to unvested stock option awards, which is expected to be recognized over a remaining weighted-average vesting period of 2.8 years. The total intrinsic value of stock option exercises during the nine months ended September 30, 2006, was $18.0 million. Cash received from stock option exercises for the nine months ended September 30, 2006 and 2005 was $15.2 million and $7.2 million, respectively. For the three months ended September 30, 2006, the weighted average fair value of options exercised was $4.11.

For stock options granted prior to the adoption of SFAS 123R, the following table illustrates the pro forma effect on net income and earnings per common share as if the Company had applied the fair value recognition provisions of SFAS 123 in determining stock-based compensation (in thousands, except income (loss) per share data):

	Three Months Ended September 30, 2005	Nine Months Ended September 30, 2005
Net income, as reported	$ 26,151	$ 1,717
Stock option expense	(6,156)	(16,628)
Pro forma net income (loss)	$ 19,995	$ (14,911)
Income (loss) per share:		
Basic as reported	$ 0.71	$ 0.05
Diluted as reported	$ 0.68	$ 0.05
Basic proforma	$ 0.54	$ (0.41)
Diluted proforma	$ 0.52	$ (0.41)

Restricted Stock Units

Beginning in January 2006, certain employees are eligible to receive restricted stock units under the 2003 Plan. In accordance with SFAS 123R, the fair value of restricted stock units is estimated based on the closing sale price of the Company s common stock on the Nasdaq Global Select Market on the date of issuance. The total number of restricted stock awards expected to vest is adjusted by estimated forfeiture rates, which has been estimated at 0% based on historical experience of stock bonus awards. Based upon the Company s closing stock price as of September 30, 2006, there is approximately $9.0 million of unamortized compensation cost related to restricted stock units, which is expected to be recognized over a remaining weighted-average vesting period of 2.8 years. The restricted stock units may, at the election of eligible employees, be subject to deterred delivery arrangements and recorded as other long-term liabilities in the consolidated balance sheet. For the three and nine months ended September 30, 2006, the adjustment to share-based compensation expense related to restricted stock units was $0.4 million and $0.6 million, respectively.

A summary of the status of the Company s restricted stock units as of September 30, 2006 and of changes in restricted stock units outstanding under the plan during the nine months ended September 30, 2006 is as follows (in thousands, except for weighted average grant date fair value per unit):

	Number of	Weighted Average Grant Date Fair

	Shares	Value per Unit
Restricted stock units outstanding at December 31, 2005		$
Restricted stock units granted	895	13.14
Restricted stock units outstanding at September 30, 2006	895	$ 13.14
Restricted stock units vested at September 30, 2006	9	$ 60.95

Stock Bonus Awards

The Company granted approximately 39,000 shares of its common stock pursuant to stock bonus awards between 2003 and 2005 from the 2003 Plan. Based upon the Company s closing stock price as of September 30, 2006, there was approximately $63,000 of unamortized compensation cost related to these stock bonus awards, representing approximately 5,800 shares of common stock, which is expected to be recognized over a remaining weighted-average vesting period of approximately 1.5 years. The common stock related to these awards has been placed into the Company s deferred compensation plan and recorded as other long-term liabilities in the consolidated balance sheet. Once in the deferred compensation plan, the related liability and expense for these stock bonus awards is adjusted to reflect the market value of the Company s stock for each reporting period.

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Employee Stock Purchase Plan

As of June 30, 2006, the Company had reserved 725,000 shares of common stock for issuance under the Amended and Restated Employee Stock Purchase Plan (the Purchase Plan). Effective January 1, 2006, the Purchase Plan was amended such that the purchase price of common stock would be at 85% of the fair market value per share of common stock on the date on which the shares are purchased. As of June 30, 2006, 640,000 shares had been issued pursuant to the Purchase Plan. Cash received from employee stock purchases under the Purchase Plan for the nine months ended September 30, 2006 and 2005 was $0.4 million and $1.0 million, respectively.

The Purchase Plan had a six-month contribution period with purchase dates of June 30 and December 31 each year. The Company recognized approximately $77,000 in share-based compensation expense related to the purchase on June 30, 2006.

Effective July 1, 2006, the Company terminated the Purchase Plan. The termination was a result of a review of the Purchase Plan s effectiveness in providing long-term share ownership to the Company s employees. In addition, the Purchase Plan had an insufficient amount of shares available to allow full participation by employees.

4. USE OF ESTIMATES

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

5. SHORT-TERM INVESTMENTS AVAILABLE-FOR-SALE

Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in comprehensive income. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest income. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in interest income or expense. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

6. IMPAIRMENT OF LONG-LIVED ASSETS

In accordance with SFAS 144, Accounting for the Impairment or Disposal of Long-Lived Assets, if indicators of impairment exist, the Company assesses the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, the Company measures the amount of such impairment by comparing the carrying value of the asset to the estimated fair value of the related asset, which is generally determined based on the present value of the expected future cash flows. The Company carries as a long-lived asset on its balance sheet a prepaid royalty arising from its acquisition in February 2004 of Wyeth s financial interest in indiplon. The Company s current and historical operating and cash flow losses and the action letters from the FDA are indicators of impairment for the prepaid royalty. However, the Company believes the future cash flows to be realized from the prepaid royalty will exceed the asset s carrying value. The Company intends to pursue approvals of indiplon for both sleep onset and maintenance and to seek a commercialization partner. Accordingly, the Company has not recognized any impairment losses through September 30, 2006. However, events both within and outside of the Company s control, such as competition from other insomnia therapeutic agents, disease prevalence, further FDA actions related to indiplon, the Company s ability to partner indiplon, insomnia market dynamics and general market conditions may have an impact on the Company s ability to recover the carrying value of this asset in the future.

7. INCOME (LOSS) PER COMMON SHARE

The Company computes net income (loss) per share in accordance with SFAS 128, Earnings Per Share. Under the provisions of SFAS 128, basic net income (loss) per share is computed by dividing the net income (loss) for the period by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share is computed by dividing the net income (loss) for the period by the weighted average number of common and common equivalent shares outstanding during the period. Additionally, potentially dilutive securities, composed of incremental common shares issuable upon the assumed exercise of stock options and warrants, are excluded from historical diluted income (loss) per share because of their anti-dilutive effect. Potentially dilutive securities totaled 0.4 million and 0.8 million for the three months and nine months ended September 30, 2006.

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Shares used in calculating basic and diluted earnings per share were as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2006	2005	2006	2005
Shares used in calculating per share amounts Basic (Weighted average common shares outstanding)	37,868	36,707	37,664	36,685
Net effect of dilutive common share equivalents		1,699		1,307
Shares used in calculating per share amounts Diluted	37,868	38,406	37,664	37,992
Potentially dilutive shares excluded from basic and diluted income (loss) per share because of their anti-dilutive effect as a result of stock options/warrants which have exercise prices greater than the average market price of the common shares	400	1,722	800	2,377

8. COMPREHENSIVE INCOME (LOSS)

Comprehensive income (loss) is calculated in accordance with SFAS 130, Comprehensive Income. SFAS 130 requires the disclosure of all components of comprehensive income (loss), including net income (loss) and changes in equity during a period from transactions and other events and circumstances generated from non-owner sources. The Company s components of comprehensive income (loss) consist of the net income (loss) and unrealized gains and losses on short-term investments. For the three months ended September 30, 2006 and 2005, comprehensive (loss) income was $(38.2) million and $26.0 million, respectively. For the nine months ended September 30, 2006 and 2005, comprehensive (loss) income was $(91.3) million and $1.3 million, respectively.

9. REVENUE RECOGNITION

Revenue under collaborative research and development agreements and grants is recognized as costs are incurred over the period specified in the related agreement or as the services are performed. These agreements are on a best-efforts basis and do not require scientific achievement as a performance obligation, and provide for payment to be made when costs are incurred or the services are performed. All fees are nonrefundable to the collaborators. Up-front, nonrefundable payments for license fees and advance payments for sponsored research revenues received in excess of amounts earned are classified as deferred revenue and recognized as income over the contract or development period. Milestone payments are recognized as revenue upon achievement of pre-defined scientific events which require substantive effort and for which achievement of the milestone was not readily assured at the inception of the agreement. Revenue related to the sales force allowance is recognized based on the related costs incurred to build and operate the sales function.

10. RESEARCH AND DEVELOPMENT EXPENSES

Research and development (R&D) expenses are recognized as incurred and include related salaries, contractor fees, facilities costs, administrative expenses and allocations of certain other costs. All such costs are charged to R&D expenses as incurred. These expenses result from the Company s independent R&D efforts as well as efforts associated with collaborations and in-licensing arrangements. In addition, the Company funds R&D, conducted on its behalf, at other companies and research institutions under agreements, which are generally cancelable. The Company reviews and accrues clinical trials expense based on work performed. Accrued clinical costs are subject to revisions as trials progress to completion. Revisions to accruals are recorded in the period in which the facts that give rise to the revision become known.

11. SEVERANCE COSTS

During the third quarter of 2006, the Company eliminated its entire sales force and also reduced its research and development and general and administrative staff in San Diego by approximately 100 employees. Pursuant to SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities, the Company recorded a one-time charge

of approximately $9.5 million in the third quarter of 2006 related to this reduction in workforce, of which $2.8 million is included in research and development and $6.7 million is included in sales, general and administrative expense. The following table sets forth the activity in the severance reserves during the nine months ended September 30, 2006 (in thousands):

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	Employee Separation Costs	Other Costs	Total
Balance at December 31, 2005	$	$	$
Accrued and expensed	8,443	1,027	9,470
Cash payments	(7,996)	(472)	(8,468)
Non-cash expenses		(555)	(555)
Balance at September 30, 2006	$ 447		