

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)

☒ **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**

☐ **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**

(State or other jurisdiction of  
incorporation or organization)

**33-0525145**

(IRS Employer Identification No.)

**12790 EL CAMINO REAL  
SAN DIEGO, CALIFORNIA**

(Address of principal executive offices)

**92130**

(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 ☒ 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 ☒

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

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

|   | <b>September<br/>30,<br/>2006</b> | <b>December<br/>31,<br/>2005</b> |
|---|-----------------------------------|----------------------------------|
| <b>ASSETS</b>   |                                   |                                  |
| 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                       |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>   |                                   |                                  |
| 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                          |

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|  |            |            |
|--|------------|------------|
| 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)

|   | <b>Three Months Ended<br/>September 30,</b> |             | <b>Nine Months Ended<br/>September 30,</b> |             |
|---|---|-------------|--|-------------|
|   | <b>2006</b>                                 | <b>2005</b> | <b>2006</b>                                | <b>2005</b> |
| 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)

|  | <b>Nine Months Ended<br/>September 30,</b> |             |
|--|--|-------------|
|  | <b>2006</b>                                | <b>2005</b> |
| <b>CASH FLOW FROM OPERATING ACTIVITIES</b>   |  |             |
| 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)     |
| <b>CASH FLOW FROM INVESTING ACTIVITIES</b>   |  |             |
| 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      |
| <b>CASH FLOW FROM FINANCING ACTIVITIES</b>   |  |             |
| 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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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:

|                                     | <b>Three Months Ended<br/>September 30,</b> |             | <b>Nine Months Ended<br/>September 30,</b> |             |
|-------------------------------------|---|-------------|--|-------------|
|                                     | <b>2006</b>                                 | <b>2005</b> | <b>2006</b>                                | <b>2005</b> |
| 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):

|  | <b>Number</b> | <b>Weighted-<br/>Average<br/>Exercise</b> | <b>Weighted-<br/>Average<br/>Remaining</b> | <b>Aggregate</b> |
|--|---------------|---|--|------------------|
|  | <b>of</b>     | <b>Price</b>                              | <b>Contractual</b>                         | <b>Intrinsic</b> |

|  | <b>Shares</b> | <b>per Share</b> | <b>Term (in<br/>years)</b> | <b>Value</b> |
|--|---------------|------------------|----------------------------|--------------|
| 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      |
|  | 9             |                  |                            |              |

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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):

|                             | <b>Three Months<br/>Ended<br/>September 30,<br/>2005</b> | <b>Nine Months<br/>Ended<br/>September 30,<br/>2005</b> |
|-----------------------------|--|---|
| 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 deferred 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):

| <b>Number<br/>of</b> | <b>Weighted<br/>Average<br/>Grant Date Fair</b> |
|----------------------|---|
|----------------------|---|



|  | 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):

|   | <b>Three months ended<br/>September 30,<br/>2006</b> |             | <b>Nine months ended<br/>September 30,<br/>2006</b> |             |
|---|--|-------------|---|-------------|
|   |  | <b>2005</b> |   | <b>2005</b> |
| Shares used in calculating per share amounts Basic<br>(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<br>income (loss) per share because of their anti-dilutive<br>effect as a result of stock options/warrants which have<br>exercise prices greater than the average market price of<br>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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|                               | <b>Employee<br/>Separation<br/>Costs</b> | <b>Other<br/>Costs</b> | <b>Total</b> |
|-------------------------------|--|------------------------|--------------|
| 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                                   | \$                     | \$ 447       |

During the third quarter of 2006, the Company completed the employee termination activities and no further expenses related to this reduction in workforce are anticipated. However, certain costs are based on estimates, such as participation in certain outplacement services. Pursuant to SFAS No. 146, the Company is required to re-assess estimates on a periodic basis. Accordingly, the Company may revise these estimates in future periods, which could result in additional adjustments. As of September 30, 2006, the Company does not believe that any future changes to these estimates would have a material impact on the Company's financial position, results of operations or cash flows.

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**ITEM 2: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following Management's Discussion and Analysis of Financial Condition and Results of Operations section contains forward-looking statements, which involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below in Part II, Item 1A under the caption Risk Factors. The interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the Financial Statements and Notes thereto for the year ended December 31, 2005 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2005.*

**OVERVIEW**

We discover, develop and intend to commercialize drugs for the treatment of neurological and endocrine-related diseases and disorders. Our 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. We currently have eight programs in various stages of research and development, including six programs in clinical development. While we independently develop many of our product candidates, we are in a collaboration for two of our programs. Our lead clinical development program, indiplon, is a drug candidate for the treatment of insomnia. We submitted two New Drug Applications (NDAs) to the United States Food and Drug Administration (FDA) with respect to indiplon.

On May 15, 2006, we received two complete responses from the FDA regarding our 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 we 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. We 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 we have 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, we have 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 we 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. We 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 discussions, we and the FDA noted positive efficacy data for sleep maintenance with both indiplon capsules and tablets. On the basis of these discussions, we are 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 us and could further delay the approval process.

On June 22, 2006, we and Pfizer agreed to terminate our collaboration and license agreements to develop and co-promote indiplon effective December 19, 2006. As a result, we will reacquire all worldwide rights for indiplon

capsules and tablets. We 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. We will be responsible for any costs associated with additional data or clinical trials that may be required for resubmission of the indiplon NDAs.



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Pursuant to the collaboration agreement with Pfizer, our 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 us that as of July 1, 2006, Pfizer will no longer reimburse or support our sales force.

In July 2006 and August 2006, we announced a restructuring program to prioritize research and development efforts and implement cost containment measures. As a result, we terminated the entire sales force in July 2006 and reduced our research and development, and general and administrative staff in San Diego by approximately 100 employees in August 2006. In connection with the restructuring, we recorded a one-time charge of approximately \$9.5 million in the third quarter of 2006, of which \$2.8 million is included in research and development and \$6.7 million is included sales, general and administrative. Restructuring charges are comprised of salary continuation, outplacement services, and other miscellaneous costs related to these reductions in force. Substantially all of these expenses were paid in cash during the third quarter of 2006. We expect these reductions to reduce expenses by approximately \$50.0 million in 2007.

On September 26, 2006, we 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 options in exchange for a lesser number of new options (a two-for-one exchange ratio) to purchase shares of our 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 our common stock. The Offer was open to eligible employees and active consultants 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 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.

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### **CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

Our discussion and analysis of our financial condition and results of operations is based upon financial statements that we have prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosures. On an on-going basis, we evaluate these estimates, including those related to revenues under collaborative research agreements, clinical trial accruals (which affect research and development expense), share-based compensation, investments and fixed assets. Estimates are based on historical experience, information received from third parties and on various other assumptions that are believed 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. The items in our financial statements requiring significant estimates and judgments are as follows:

Revenues under collaborative research and development agreements are 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. Estimating the duration of the development period includes continual assessment of development stages and regulatory requirements. 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.

Research and development (R&D) expenses include related salaries, contractor fees, facilities costs, administrative expenses and allocations of corporate costs. All such costs are charged to R&D expense as incurred. These expenses result from our independent R&D efforts as well as efforts associated with collaborations, and in-licensing arrangements. In addition, we fund R&D at other companies and research institutions under agreements, which are generally cancelable. We review and accrue clinical trials expenses based on work performed, which relies on estimates of total hours and costs incurred based on patient enrollment, completion of studies and other events. We follow this method because reasonably dependable estimates of the costs applicable to various stages of a research agreement or clinical trial can be made. Accrued clinical costs are subject to revisions as trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

In accordance with Statement of Financial Accounting Standards No. 144 ( SFAS 144 ), Accounting for the Impairment or Disposal of Long-Lived Assets, if indicators of impairment exist, we assess 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, we measure 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. While our current and historical operating and cash flow losses and the action letters from the FDA are indicators of impairment, we believe the future cash flows to be realized from our long-lived assets, i.e. prepaid royalty, will exceed the assets' carrying value, and accordingly we have not recognized any impairment losses through September 30, 2006.

During the second quarter of 2006, we received two letters from the FDA related to our NDA submissions for indiplon. These letters indicated that indiplon capsules were approvable and that indiplon tablets were not approvable. Additionally on June 22, 2006, we announced that we and Pfizer had agreed to terminate our collaboration and license agreements to develop and co-promote indiplon. These two events are indicators of impairment for our prepaid royalty, which is carried as a long-lived asset on our balance sheet. This prepaid royalty arose out of our acquisition, in February 2004, of Wyeth's financial interest in indiplon for approximately \$95.0 million, consisting of \$50.0 million in cash and \$45.0 million in our common stock. This transaction decreased our overall royalty obligation on sales of indiplon from six percent to three and one-half percent. In accordance with SFAS 144 we performed an analysis of the undiscounted cash flows related to this prepaid royalty. Based on our current expectations with respect to FDA

approval, commercialization and our plan to partner indiplon, we have determined that the carrying value of this asset is fully recoverable, and we have not recognized any impairment charge to date. However, events both within and outside of our control, such as competition from other insomnia therapeutic agents, disease prevalence, further FDA actions related to indiplon, our ability to partner indiplon, insomnia market dynamics and general market conditions may have an impact on our ability to recover the carrying value of this asset in the future. In the event that either the tablet or capsule, or both formulations of indiplon or further delayed, are not eventually approved by the FDA or approved by the FDA and not successfully commercialized, an impairment charge would likely occur. We will continue to monitor this long-lived asset on a quarterly basis.

We grant stock options to purchase our common stock to our employees and directors under our 2003 Incentive Stock Plan and grant stock options to certain employees pursuant to Employment Commencement Nonstatutory Stock Option Agreements. We also grant certain employees stock bonuses and restricted stock units under our 2003 Incentive Stock Plan. Additionally, we have outstanding options that were granted under option plans from which we no longer make grants. The benefits provided under all of these plans are subject to the provisions of revised Statement of Financial Accounting Standards No. 123 ( SFAS 123R ), Share-Based Payment, which we adopted effective January 1, 2006. We elected to use the modified prospective application in adopting SFAS 123R and therefore have not restated results for prior periods. The valuation provisions of SFAS 123R apply to new awards and to awards that are outstanding on the adoption date and subsequently modified or cancelled. Our results of operations for fiscal 2006 were impacted by the recognition of non-cash expense related to the fair value of our share-based compensation awards. Share-based compensation expense recognized under SFAS 123R for the three and nine months ended September 30, 2006 was \$3.2 million and \$12.7 million, respectively.

Stock option awards and restricted stock units generally vest over a three to four year period and expense is ratably recognized over those same time periods. However, due to certain retirement provisions in our stock plans, 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

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upon grant of the share-based compensation award. Employees who are age 55 or older and have five or more years of service with us are entitled to accelerated vesting of certain unvested share-based compensation awards upon retirement. This retirement provision leads to variability in the quarterly expense amounts recognized under SFAS 123R, and therefore individual share-based compensation awards may impact earnings disproportionately in any individual fiscal quarter.

The determination of fair value of stock-based payment awards on the date of grant using the Black-Scholes model is affected by our stock price, as well as the input of other subjective assumptions. These assumptions include, but are not limited to, the expected term of stock options and our expected stock price volatility over the term of the awards. Our stock options have characteristics significantly different from those of traded options, and changes in the assumptions can materially affect the fair value estimates.

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. If actual forfeitures vary from our estimates, we will recognize the difference in compensation expense in the period the actual forfeitures occur or when options vest.

At September 30, 2006, total unrecognized, estimated share-based compensation expense related to unvested stock options granted prior to that date was \$11.6 million, which is expected to be recognized over a weighted average period of 2.8 years. As a result of the option repricing and Company restructuring in the third quarter of 2006, more stock options and restricted stock units were cancelled or forfeited than were granted during the first nine months of 2006. Net stock options and restricted stock units, after forfeitures and cancellations, granted during the nine months ended September 30, 2005 represented 3.2% of the outstanding shares as of the beginning of the year. For more information about our accounting for share-based compensation expense, see Note 3 to the Condensed Consolidated Financial Statements in Part I, Item 1.

**RESULTS OF OPERATIONS****THREE MONTHS ENDED SEPTEMBER 30, 2006 AND 2005**

The following table summarizes our primary sources of revenue:

|  | <b>Three Months<br/>Ended September 30,<br/>2006                      2005<br/>(in thousands)</b> |           |
|--|---|-----------|
| Revenues under collaboration agreements: |   |           |
| Pfizer                                   | \$ 1,054  | \$ 64,731 |
| GlaxoSmithKline                          | 20  | 14        |
| Total revenue                            | \$ 1,074  | \$ 64,745 |

Revenues were \$1.1 million for the three months ended September 30, 2006 compared with \$64.7 million for the same period last year. The decrease in revenues for the three months ended September 30, 2006 compared with the same period in 2005 results primarily from a decrease in revenues recognized under our former collaboration agreement with Pfizer, Inc (Pfizer). During the third quarter of 2006, we recognized \$1.1 million of revenue under the Pfizer collaboration agreement, which is comprised of \$0.4 million from Pfizer in the form of sponsored development funding and \$0.7 million resulting from amortization of up-front license fees. During the third quarter of 2005, we recognized \$64.7 million in revenue under the Pfizer collaboration agreement, of which \$1.3 million came from sponsored development funding, \$5.4 million from amortization of up-front license fees, a \$50.0 million milestone related to the FDA's accepting for review our NDA for indiplon tablets, and \$8.0 million related to the sales force allowance.

Research and development expenses decreased to \$25.2 million for the third quarter of 2006 compared with \$26.6 million for the respective period in 2005. The \$1.4 million decrease in research and development expenses is primarily due to lower external development costs for our indiplon clinical program. Indiplon development costs decreased to \$0.7 million in the third quarter of 2006 from \$2.6 million in the third quarter of 2005. Additionally, as a

result of the recent headcount reductions, laboratory costs have decreased by \$1.6 million to \$5.0 million in the third quarter of 2006 compared to \$6.6 million in the same period last year. The decreases in development costs and laboratory costs were partially offset by an increase in personnel expense of \$4.1 million, primarily due to our adoption of SFAS 123R in 2006 and severance costs which were \$1.6 million and \$2.8 million, respectively, in the third quarter of 2006.

Sales, general and administrative expenses increased to \$16.0 million for the third quarter of 2006 compared with \$13.0 million during the same period last year. The \$3.0 million increase in expenses from 2005 to 2006 resulted primarily from severance costs of \$6.7 million. The severance costs are partially offset by savings from headcount reduction in personnel costs of approximately \$2.4 million and other sales force related costs of approximately \$0.9 million. Additionally, the adoption of SFAS 123R in 2006 resulted in additional expense of approximately \$1.6 million.

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Net loss for the third quarter of 2006 was \$39.1 million, or \$1.03 loss per share, compared to net income of \$26.2 million, or \$0.71 net income per basic share, for the same period in 2005. The primary reason for the increase in net loss is the recognition of a \$50.0 million milestone under the Pfizer collaboration agreement in 2005. Additionally, the adoption of SFAS 123R and restructuring costs resulted in expenses of \$3.2 million and \$9.5 million, respectively, in the third quarter of 2006.

**NINE MONTHS ENDED SEPTEMBER 30, 2006 AND 2005**

The following table summarizes our primary sources of revenue:

|  | <b>Nine Months<br/>Ended September 30,<br/>2006                      2005<br/>(in thousands)</b> |            |
|--|--|------------|
| Revenues under collaboration agreements: |  |            |
| Pfizer                                   | \$ 28,747  | \$ 108,305 |
| GlaxoSmithKline                          | 1,047  | 1,473      |
| Total revenues                           | \$ 29,794  | \$ 109,778 |

Revenues were \$29.8 million for the nine months ended September 30, 2006 compared with \$109.8 million for the respective period last year. The decrease in revenues during the first nine months of 2006, compared with the respective period in 2005, resulted primarily from the achievement of \$70.0 million in milestones under our former collaboration agreement with Pfizer related to the FDA's accepting for review our NDA's for indiplon capsules and tablets in 2005. During the first nine months of 2006, we recognized \$28.7 million in revenue from Pfizer, comprised of \$6.4 million in the form of sponsored development funding, \$5.8 million resulting from amortization of up-front license fees, and \$16.5 million related to the sales force allowance for operating our sales force. During the first nine months of 2005, we recognized \$108.3 million in revenue from Pfizer, comprised of \$8.0 million in the form of sponsored development funding, \$16.3 million resulting from amortization of up-front license fees, \$70.0 million of milestones, and \$14.0 million related to the sales force allowance received from Pfizer. Under our GSK collaboration agreement, we recognized a \$1.0 million milestone during the first nine months of 2006 for progress related to the CRF program. During the first nine months of 2005, we recognized \$1.5 million in revenue under the GSK collaboration agreement, which included a \$1.0 million milestone for successful completion of the research portion of our collaboration agreement.

Research and development expenses were \$79.1 million for the first nine months of 2006 and \$81.9 million for the respective period in 2005. This decrease in research and development expenses resulted from a decrease in external development costs of \$11.1 million. External development costs incurred related to indiplon for the first nine months of 2006 were \$1.2 million compared to \$11.7 million for the same period last year. This decrease in indiplon external development costs was offset by fluctuations in other external development programs. External development costs for our GnRH compound for endometriosis increased to \$8.4 million in the first nine months of 2006 from \$7.4 million in the same period last year and external development costs related to the SNRI program increased by \$2.1 million in the first nine months of 2006. External development costs related to our terminated APL programs decreased to \$2.8 million in the first nine months of 2006 from \$6.5 million in the first nine months of 2005. The decrease in development expenses is offset by \$5.5 million in expense related to the adoption of SFAS 123R and \$2.8 million in severance costs in 2006.

Sales, general and administrative expenses increased to \$47.8 million for the nine months ended September 30, 2006 compared with \$28.4 million during the same period last year. The \$19.4 million increase in expenses from 2005 to 2006 resulted primarily from adoption of SFAS 123R and restructuring costs, which resulted in expense of approximately \$7.2 million and \$6.7 million, respectively, during the first nine months of 2006. Additionally, direct costs (excluding severance costs) related to our sales force increased to \$16.7 million in the first nine months of 2006 compared to \$12.1 million during the same period in 2005. This increase in sales force costs was offset by revenue

recognized under our sales force allowance from Pfizer.

Other income was \$4.6 million for the first nine months of 2006 compared to \$2.2 million during the first nine months of 2005. The increase resulted primarily from increased interest income due to higher rates of return on our investments.

Net loss for the first nine months of 2006 was \$92.5 million, or \$2.46 loss per share, compared to net income of \$1.7 million, or \$0.05 net income per basic share, for the same period in 2005. The primary reason for the \$94.2 million increase in net loss is the achievement of \$70.0 million in milestones under our Pfizer collaboration during the first nine months of 2005. Additionally, the adoption of SFAS 123R and restructuring costs in the first nine months of 2006 resulted in additional expense of \$12.7 million and \$9.5 million, respectively.

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To date, our revenues have come from funded research and development, achievements of milestones under corporate collaborations, licensing of product candidates, and from the sales force allowance from Pfizer. The nature and amount of these revenues from period to period may lead to substantial fluctuations in the results of quarterly revenues and earnings. Accordingly, results and earnings of one period are not predictive of future periods. Collaborations accounted for 100% of our revenues for the nine months ended September 30, 2006 and 2005.

We expect to incur a net loss of approximately \$115.0 million during fiscal 2006, which includes approximately \$9.5 million in expense related to our reduction in force during the third quarter of 2006 and various non-cash expenses such as those associated with our adoption of FAS 123R and depreciation. Additionally, we expect to incur operating losses for the foreseeable future because of the decrease in revenues we will experience as a result of the termination of the Pfizer collaboration agreement and because of the expenses we expect to incur for the clinical trials and other costs related to refiling of the indiplon NDAs as well as costs to progress other programs through our pipeline. Future profitability is dependent upon the approval of our NDAs for indiplon by the FDA and upon acceptance of indiplon by prescribers and consumers.

### **LIQUIDITY AND CAPITAL RESOURCES**

At September 30, 2006, our cash, cash equivalents, and short-term investments totaled \$199.8 million compared with \$273.1 million at December 31, 2005. The decrease in cash balances at September 30, 2006 resulted primarily from our net loss of \$92.5 million offset by an increase in additional paid in capital of \$15.6 million primarily from stock option exercises.

Net cash used in operating activities during the first nine months of 2006 was \$82.5 million compared with \$7.9 million during the same period last year. This fluctuation resulted from our net loss of \$92.5 million for the first nine months of 2006 compared to our net income of \$1.7 million for the same period in 2005. The increase in our net loss during the first nine months of 2006 is primarily due to the decrease in revenue recognized under our former collaboration agreement with Pfizer, which decreased to \$28.7 million from \$108.3 million for the nine months ended September 30, 2006 and 2005, respectively.

Net cash provided by investing activities during the first nine months of 2006 was \$97.1 million compared to \$19.2 million for the first nine months of 2005. The fluctuation in net cash provided by investing activities resulted primarily from the timing differences in investment purchases, sales and maturities, and the fluctuation of our portfolio mix between cash equivalents and short-term investment holdings to fund operations.

Net cash provided by financing activities during the first nine months of 2006 was \$11.2 million compared with \$3.1 million for the respective period last year. This fluctuation resulted primarily from cash proceeds from the issuance of common stock pursuant to stock option exercises which increased by \$7.4 million in the first nine months of 2006 compared to the same period last year. We expect similar fluctuations to occur throughout the year, as the amount and frequency of stock-related transactions are dependent upon the market performance of our common stock.

We believe that our existing capital resources, together with interest income and future payments due under our strategic alliances, will be sufficient to satisfy our current and projected funding requirements for at least the next 12 months. However, we cannot guarantee that these capital resources and payments will be sufficient to conduct all of our research and development programs as planned. The amount and timing of expenditures will vary depending upon a number of factors, including progress of our research and development programs and the extent to which additional clinical trials are necessary in connection with the resubmissions of our NDAs for indiplon capsules and tablets.



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We will require additional funding to continue our research and product development programs, to conduct preclinical studies and clinical trials, for operating expenses, to pursue regulatory approvals for our product candidates, for the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims, if any, the cost of product in-licensing and any possible acquisitions, and we may require additional funding to establish manufacturing and marketing capabilities in the future. We intend to seek additional funding through strategic alliances, and may seek additional funding through public or private sales of our securities, including equity securities. In addition, we have financed capital purchases and may continue to pursue opportunities to obtain additional debt financing in the future. However, additional equity or debt financing might not be available on reasonable terms, if at all. Any additional equity financings will be dilutive to our stockholders and any additional debt financings may involve operating covenants that restrict our business. If adequate funds are not available, we may be required to curtail significantly one or more of our research or development programs or obtain funds through arrangements with collaborators or others. This may require us to relinquish rights to certain of our technologies or product candidates. To the extent that we are unable to obtain third-party funding for such expenses, we expect that increased expenses will result in increased losses from operations. We cannot assure you that we will be successful in the development of our product candidates, or that, if successful; any products marketed will generate sufficient revenues to enable us to earn a profit.

### **CAUTION ON FORWARD-LOOKING STATEMENTS**

Our business is subject to significant risks, including but not limited to, the risks inherent in our research and development activities, including the successful continuation of our strategic collaborations, the successful completion of clinical trials, the lengthy, expensive and uncertain process of seeking regulatory approvals, uncertainties associated both with the potential infringement of patents and other intellectual property rights of third parties, and with obtaining and enforcing our own patents and patent rights, uncertainties regarding government reforms and of product pricing and reimbursement levels, technological change and competition, manufacturing uncertainties and dependence on third parties. Even if our product candidates appear promising at an early stage of development, they may not reach the market for numerous reasons. Such reasons include the possibilities that the product will be ineffective or unsafe during clinical trials, will fail to receive necessary regulatory approvals, will be difficult to manufacture on a large scale, will be uneconomical to market or will be precluded from commercialization by proprietary rights of third parties. For more information about the risks we face, see **Risk Factors** included in Part II, Item 1A of this report.

### **INTEREST RATE RISK**

We are exposed to interest rate risk on our short-term investments. The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in highly liquid and high quality government and other debt securities. To minimize our exposure due to adverse shifts in interest rates, we invest in short-term securities and ensure that the maximum average maturity of our investments does not exceed 40 months. If a 10% change in interest rates were to have occurred on September 30, 2006, this change would not have had a material effect on the fair value of our investment portfolio as of that date. Due to the short holding period of our investments, we have concluded that we do not have a material financial market risk exposure.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

A discussion of our exposure to, and management of, market risk appears in Part I, Item 2 of this Quarterly Report on Form 10-Q under the heading **Interest Rate Risk**.

### **ITEM 4. CONTROLS AND PROCEDURES**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the timelines specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decision regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of

possible controls and procedures.

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As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the quarter covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

There has been no change in our internal controls over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

## **PART II: OTHER INFORMATION**

### **ITEM 1A. RISK FACTORS**

The following risk factors do not reflect any material changes to the Risk Factors set forth in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2006, except as follows:

We revised the first risk factor to reflect the fact that we held two end-of-review meetings with the United States Food and Drug Administration (FDA) related to indiplon capsules & tablets, and the impact on the indiplon development program;

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report and those we may make from time to time. If any of the following risks actually occur, our business, operating results, prospects or financial condition could be harmed. Additional risks not presently known to us, or that we currently deem immaterial, may also affect our business operations.

#### **Risks Related to Our Company**

**Our near-term success is dependent on the success of our lead product candidate, indiplon, and we may not receive regulatory approvals for it or our other product candidates or approvals may be delayed.**

Based on the results of preclinical studies and Phase I, Phase II and Phase III clinical trials on indiplon, as well as a non-clinical data package related to indiplon manufacturing, formulation and commercial product development, we assembled and filed with the FDA New Drug Applications (NDAs) for both indiplon capsules and indiplon tablets. On May 15, 2006, we received two complete responses from the FDA regarding our 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 we 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. We 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 we have 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, we have 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 we 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. We 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 discussions, we 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.

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If we are unable to perform the required analyses or conduct the clinical trials or if these data analyses or clinical trials do not demonstrate the safety and efficacy of indiplon capsules or indiplon tablets, we may not be able to resubmit the NDA for either or both formulations. If we do obtain positive results from these data analyses and clinical trials, we would then refile the NDAs. The process of preparing and resubmitting the NDAs will require significant resources and could be time consuming and subject to unanticipated delays and cost. Upon resubmission, the FDA could again refuse to approve one or both NDAs, or could still require additional data analysis or clinical trials, which would require substantial expenditures by us and could further delay the approval process. Even if our indiplon NDAs are approved, the FDA may determine that our data do not support elements of the labeling we have requested. In such a case, the labeling actually granted by the FDA could limit the commercial success of the product. The FDA could also require Phase IV, or post-marketing, trials to study the long-term effects of indiplon and could withdraw its approval based on the results of those trials. We face the risk that for any of the reasons described above, as well as other reasons set forth herein, indiplon may never be approved by the FDA or commercialized anywhere in the world.

If we are unable to refile one or both NDAs, or the FDA refuses to accept or approve the resubmitted NDAs for any reason or we experience a significant delay in approval and subsequent commercialization of indiplon, our business and reputation would be harmed and our stock price would decline.

***If we cannot raise additional funding, we may be unable to complete development of our product candidates.***

We may require additional funding to continue our research and product development programs, including preclinical testing and clinical trials of our product candidates, for operating expenses and to pursue regulatory approvals for product candidates, such as indiplon. We also may require additional funding to establish manufacturing and marketing capabilities in the future. We believe that our existing capital resources, together with interest income, and future payments due under our strategic alliances, will be sufficient to satisfy our current and projected funding requirements for at least the next 12 months. However, these resources might be insufficient to conduct research and development programs as planned. If we cannot obtain adequate funds, we may be required to curtail significantly one or more of our research and development programs or obtain funds through additional arrangements with corporate collaborators or others that may require us to relinquish rights to some of our technologies or product candidates.

Our future capital requirements will depend on many factors, including:

- continued scientific progress in our research and development programs;

- the magnitude of our research and development programs;

- progress with preclinical testing and clinical trials;

- the time and costs involved in obtaining regulatory approvals;

- the costs involved in filing and pursuing patent applications and enforcing patent claims;

- competing technological and market developments;

- the establishment of additional strategic alliances;

- the cost of commercialization activities and arrangements, including manufacturing of our product candidates; and

- the cost of product in-licensing and any possible acquisitions.

We intend to seek additional funding through strategic alliances, and may seek additional funding through public or private sales of our securities, including equity securities. In addition, we have financed capital purchases and may continue to pursue opportunities to obtain additional debt financing in the future. However, additional equity or debt financing might not be available on reasonable terms, if at all. Any additional equity financings will be dilutive to our

stockholders and any additional debt financings may involve operating covenants that restrict our business.

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***Because of the termination of our collaboration with Pfizer to develop and co-promote indiplon, we must identify a new partner and enter into a collaboration agreement with them or develop, commercialize, market and sell indiplon by ourselves.***

On June 22, 2006, we announced that the Company and Pfizer had agreed to terminate our collaboration and license agreements to develop and co-promote indiplon. Under the collaboration, Pfizer had agreed to:

fund substantially all third-party costs related to future indiplon development, manufacturing and commercialization activities;

fund a 200-person Neurocrine sales force that would initially promote Zoloft® and, upon approval of the indiplon NDAs, co-promote indiplon in the United States;

be responsible for obtaining all regulatory approvals outside of the United States and regulatory approvals in the United States after approval of the first indiplon NDA; and

be responsible for sales and marketing of indiplon worldwide.

As a result of termination of this collaboration, we will reacquire all worldwide rights for indiplon capsules and tablets. We 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. We will be responsible for any costs associated with additional data or clinical trials that may be required for resubmission of the indiplon NDAs.

We will seek another partner or partners, at an appropriate time, to assist us in the worldwide development and commercialization of indiplon or develop, commercialize, market and sell indiplon by ourselves. We face competition in our search for partners with whom we may collaborate. As a result, we may not be successful in finding another collaboration partner on favorable terms, or at all, and any failure to obtain a new partner on favorable terms could adversely affect indiplon development, commercialization and future sales, which would harm our business. Identifying a new partner and entering into a collaboration agreement with them or developing the necessary infrastructure to commercialize, market and sell indiplon ourselves could cause delays in obtaining regulatory approvals and commercialization of indiplon, which would negatively impact our business. If we choose to commercialize, market and sell indiplon ourselves, we will be required to substantially increase our internal sales, distribution and marketing capabilities. The development of the infrastructure necessary to commercialize, market and sell indiplon will require substantial resources and may divert the attention of our management and key personnel and negatively impact our other product development efforts. Moreover, we may not be able to hire a sales force that is sufficient in size or has adequate expertise.

Pursuant to the collaboration agreement with Pfizer, our 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 us that as of July 1, 2006, Pfizer will no longer reimburse or support our sales force. Consequently, we terminated the entire sales force in July 2006 and incurred expenses of approximately \$5.9 million in the third quarter of 2006 related to salary continuation, outplacement services, and other costs related to eliminating the sales force. We cannot assure you that we will be able to successfully rebuild the sales force in a timely manner, or at all, should indiplon be approved by the FDA.

***We may become involved in securities class action litigation that could divert management's attention and harm our business.***

The market price of our common stock has declined significantly since our May 16, 2006 announcement of the FDA's action letters with respect to indiplon. In the past, following periods of volatility in the market price of a particular company's securities, securities class action litigation has often been brought against the company. We may become involved in this type of litigation in the future, which would be expensive and divert management's attention and resources from operating the business. Additionally, we may not be successful in having any such suit dismissed or settled within the limits of our insurance.

***Even if we ultimately receive an approval letter for indiplon or any other product, we may be unable to commercialize such products immediately upon receipt of such letter.***

Commercialization of a product for which we have received an approval letter from the FDA could be delayed for a number of reasons, some of which are outside of our control, including delays in the FDA's issuance of approvals for our trademarks or delays in the completion of required procedures by agencies other than the FDA, such as the Drug Enforcement Administration (DEA). For example, one of our competitors received an approval letter from the FDA for its proprietary product. In connection with the approval, the FDA recommended that the competitor's product be classified as a Schedule IV controlled substance by the DEA.



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However, because the Federal government's administrative process for formally classifying the product as a Schedule IV controlled substance was not yet complete, the competitor's product launch was delayed several months. Indiplon, like the competitor's product, and like all non-benzodiazepine hypnotics, is expected to be a Schedule IV controlled substance requiring classification by the DEA. There can be no assurance that we will receive DEA scheduling promptly. If we receive an approval letter for indiplon and are unable to commercialize indiplon promptly thereafter, our business and financial position may be materially adversely affected due to reduced revenue from product sales during the period that commercialization is delayed. In addition, the exclusivity period, or the time during which the FDA will prevent generic pharmaceuticals from introducing a generic copy of the product, begins to run upon receipt of the approval letter from the FDA and, therefore, to the extent we are unable to commercialize a product upon receipt of an approval letter, our long-term product sales and revenues could be adversely affected.

***Our clinical trials may fail to demonstrate the safety and efficacy of our product candidates, which could prevent or significantly delay their regulatory approval.***

Any failure or substantial delay in completing clinical trials for our product candidates may severely harm our business. Before obtaining regulatory approval for the sale of any of our potential products, we must subject these product candidates to extensive preclinical and clinical testing to demonstrate their safety and efficacy for humans. Clinical trials are expensive, time-consuming and may take years to complete.

In connection with the clinical trials of indiplon and our other product candidates, we face the risks that:

the product may not prove to be effective;

we may discover that a product candidate may cause harmful side effects;

the results may not replicate the results of earlier, smaller trials;

we or the FDA may suspend the trials;

the results may not be statistically significant;

patient recruitment may be slower than expected; and

patients may drop out of the trials.

For example, we announced in 2006 that the results of our Phase II clinical trial using our altered peptide ligand (APL) technology for diabetes did not meet its primary endpoint and demonstrate efficacy, although the product was safe and well tolerated. Based on these results, we discontinued the development of our APL-Diabetes program.

Late stage clinical trials are often conducted with patients having the most advanced stages of disease. During the course of treatment, these patients can die or suffer other adverse medical effects for reasons that may not be related to the pharmaceutical agent being tested but which can nevertheless adversely affect clinical trial results.

***We have a history of losses and expect to incur losses and negative operating cash flows for the near future, and we may never achieve sustained profitability.***

Since our inception, we have incurred significant net losses, including net losses of \$22.2 million and \$45.8 million for the years ended December 31, 2005 and 2004, respectively. As a result of ongoing operating losses, we had an accumulated deficit of \$300.1 million and \$278.0 million as of December 31, 2005 and 2004, respectively. We do not expect to be profitable for the year ended December 31, 2006. Additionally, we will be responsible for any costs associated with additional data or clinical trials that may be required for resubmission of the indiplon NDAs.

We have not yet obtained regulatory approvals of any products and, consequently, have not generated revenues from the sale of products. Even if we succeed in developing and commercializing one or more of our drugs, we may not be profitable. We also expect to continue to incur significant operating and capital expenditures as we:

seek regulatory approvals for our product candidates;

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develop, formulate, manufacture and commercialize our drugs;

in-license or acquire new product development opportunities;

implement additional internal systems and infrastructure; and

hire additional clinical, scientific and marketing personnel.

We also expect to experience negative cash flow for the near future as we fund our operating losses, in-licensing or acquisition opportunities, and capital expenditures. We will need to generate significant revenues to achieve and maintain profitability and positive cash flow. We may not be able to generate these revenues, and we may never achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the market price of our common stock. Even if we become profitable, we cannot assure you that we would be able to sustain or increase profitability on a quarterly or annual basis.

***Because our operating results may vary significantly in future periods, our stock price may decline.***

Our quarterly revenues, expenses and operating results have fluctuated in the past and are likely to fluctuate significantly in the future. Our revenues are unpredictable and may fluctuate, among other reasons, due to our achievement of product development objectives and milestones, clinical trial enrollment and expenses, research and development expenses and the timing and nature of contract manufacturing and contract research payments. A high portion of our costs are predetermined on an annual basis, due in part to our significant research and development costs. Thus, small declines in revenue could disproportionately affect operating results in a quarter. Because of these factors, our operating results in one or more future quarters may fail to meet the expectations of securities analysts or investors, which could cause our stock price to decline.

***We depend on continuing our current collaboration and developing additional collaborations to develop and commercialize our product candidates.***

Our strategy for developing and commercializing our products is dependent upon maintaining our current arrangements and establishing new arrangements with research collaborators, corporate collaborators and others. We have an active collaboration agreement with GlaxoSmithKline and previously have had collaborations with Pfizer, Wyeth, Johnson & Johnson, and Eli Lilly and Company. We historically have been dependent upon these corporate collaborators to provide adequate funding for a number of our programs. Under these arrangements, our corporate collaborators are typically responsible for:

selecting compounds for subsequent development as drug candidates;

conducting preclinical studies and clinical trials and obtaining required regulatory approvals for these drug candidates; and

manufacturing and commercializing any resulting drugs.

Because we expect to continue to rely heavily on corporate collaborators, the development of our projects would be substantially delayed if one or more of our current or future collaborators:

failed to select a compound that we have discovered for subsequent development into marketable products;

failed to gain the requisite regulatory approvals of these products;

did not successfully commercialize products that we originate;

did not conduct its collaborative activities in a timely manner;

did not devote sufficient time and resources to our partnered programs or potential products;

terminated its alliance with us;

developed, either alone or with others, products that may compete with our products;

disputed our respective allocations of rights to any products or technology developed during our collaborations;  
or

merged with a third party that wants to terminate the collaboration.

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These issues and possible disagreements with current or future corporate collaborators could lead to delays in the collaborative research, development or commercialization of many of our product candidates. Furthermore, disagreements with these parties could require or result in litigation or arbitration, which would be time-consuming and expensive. If any of these issues arise, it may delay the development and commercialization of drug candidates and, ultimately, our generation of product revenues.

***We license some of our core technologies and drug candidates from third parties. If we default on any of our obligations under those licenses, we could lose our rights to those technologies and drug candidates.***

We are dependent on licenses from third parties for some of our key technologies. These licenses typically subject us to various commercialization, reporting and other obligations. If we fail to comply with these obligations, we could lose important rights. For example, we have licensed indiplon from DOV Pharmaceutical. In addition, we license some of the core technologies used in our collaborations from third parties, including the CRF receptor we license from The Salk Institute and use in our CRF program, Urocortin 2, which we license from Research Development Foundation and the adenosine 2A receptor antagonist we license from Almirall Prodesfarma, S.A. Other in-licensed technologies, such as the GnRH receptor we license from Mount Sinai School of Medicine, will be important for future collaborations for our GnRH program. If we were to default on our obligations under any of our product licenses, we could lose some or all of our rights to develop, market and sell the product. Likewise, if we were to lose our rights under a license to use proprietary research tools, it could adversely affect our existing collaborations or adversely affect our ability to form new collaborations. We also face the risk that our licensors could, for a number of reasons, lose patent protection or lose their rights to the technologies we have licensed, thereby impairing or extinguishing our rights under our licenses with them.

***Because the development of our product candidates is subject to a substantial degree of technological uncertainty, we may not succeed in developing any of our product candidates.***

All of our product candidates are in research, clinical development or in registration with the FDA. Only a small number of research and development programs ultimately result in commercially successful drugs. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons. These reasons include the possibilities that the potential products may:

be found ineffective or cause harmful side effects during preclinical studies or clinical trials;

fail to receive necessary regulatory approvals on a timely basis or at all;

be precluded from commercialization by proprietary rights of third parties;

be difficult to manufacture on a large scale; or

be uneconomical or fail to achieve market acceptance.

If any of our products encounters any of these potential problems, we may never successfully market that product.

Since indiplon is our most advanced product program, our business and reputation would be particularly harmed, and our stock price likely would be harmed, if we fail to receive necessary regulatory approvals on a timely basis or achieve market acceptance.

***We have limited marketing experience, sales force or distribution capabilities, and if our products are approved, we may not be able to commercialize them successfully.***

Although we do not currently have any marketable products, our ability to produce revenues ultimately depends on our ability to sell our products if and when they are approved by the FDA. We currently have limited experience in marketing and selling pharmaceutical products. If we fail to establish successful marketing and sales capabilities or fail to enter into successful marketing arrangements with third parties, our product revenues will suffer.

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***The independent clinical investigators and contract research organizations that we rely upon to conduct our clinical trials may not be diligent, careful or timely, and may make mistakes, in the conduct of our trials.***

We depend on independent clinical investigators and contract research organizations, or CROs, to conduct our clinical trials under their agreements with us. The investigators are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If independent investigators fail to devote sufficient time and resources to our drug development programs, or if their performance is substandard, it will delay the approval of our FDA applications and our introduction of new drugs. The CROs we contract with for execution of our clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Failure of the CROs to meet their obligations could adversely affect clinical development of our products. Moreover, these independent investigators and CROs may also have relationships with other commercial entities, some of which may compete with us. If independent investigators and CROs assist our competitors at our expense, it could harm our competitive position.

***We have no manufacturing capabilities. If third-party manufacturers of our product candidates fail to devote sufficient time and resources to our concerns, or if their performance is substandard, our clinical trials and product introductions may be delayed and our costs may rise.***

We have in the past utilized, and intend to continue to utilize, third-party manufacturers to produce the drug compounds we use in our clinical trials and for the potential commercialization of our future products. We have no experience in manufacturing products for commercial purposes and do not currently have any manufacturing facilities. Consequently, we depend on several contract manufacturers for all production of products for development and commercial purposes. If we are unable to obtain or retain third-party manufacturers, we will not be able to commercialize our products. The manufacture of our products for clinical trials and commercial purposes is subject to specific FDA regulations. Our third-party manufacturers might not comply with FDA regulations relating to manufacturing our products for clinical trials and commercial purposes or other regulatory requirements now or in the future. Our reliance on contract manufacturers also exposes us to the following risks:

contract manufacturers may encounter difficulties in achieving volume production, quality control and quality assurance, and also may experience shortages in qualified personnel. As a result, our contract manufacturers might not be able to meet our clinical schedules or adequately manufacture our products in commercial quantities when required;

switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly on acceptable terms, or at all;

our contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store or distribute our products; and

drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the DEA, and corresponding state agencies to ensure strict compliance with good manufacturing practices and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

Our current dependence upon third parties for the manufacture of our products may harm our profit margin, if any, on the sale of our future products and our ability to develop and deliver products on a timely and competitive basis.

***Potential future impairments under SFAS 144 could adversely affect our future results of operations and financial position.***

In accordance with Statement of Financial Accounting Standards No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, we assess our long-lived assets for impairment quarterly or whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If indicators of impairment exist, we assess 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 the carrying amount is not recoverable, we measure the amount of any impairment by comparing the carrying value of the asset to the present

value of the expected future cash flows (fair value) associated with the use of the asset. If the carrying amount of the asset were determined to be impaired, an impairment loss to write-down the carrying value of the asset to fair value would be required.

For example, our September 30, 2006 balance sheet reflects \$94.0 million of prepaid royalties related to our acquisition in February 2004 of Wyeth's financial interest in indiplon for approximately \$95.0 million, consisting of \$50.0 million in cash and \$45.0 million in our common stock. This transaction decreased our overall royalty obligation on sales of indiplon from six percent to three and one-half percent.

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This transaction has been recorded as a long-term asset and will be amortized over the commercialization period of indiplon, based primarily upon indiplon sales. Given the FDA letters we received on our NDA submissions for indiplon and the subsequent cancellation of the collaboration agreement with Pfizer, we determined that indicators of impairment existed. We performed the undiscounted cash flow analysis and determined that the carrying value of the prepaid royalty was recoverable as of September 30, 2006. However, events both within and outside of our control, such as competition from other insomnia therapeutic agents, disease prevalence, further FDA actions related to indiplon, our ability to partner indiplon, insomnia market dynamics and general market conditions may have an impact on our ability to recover the carrying value of this asset in the future.

If we determine that the sum of the expected future undiscounted cash flows relating to this prepaid royalty is less than the carrying amount of the asset, the asset would be impaired, and we would be required to take an impairment loss to write-down the carrying value of the asset to fair value. A material reduction in earnings resulting from such a charge could cause us to fail to be profitable in the period in which the charge is taken or otherwise to fail to meet the expectations of investors and securities analysts, which could cause the price of our stock to decline.

***If we are unable to retain and recruit qualified scientists or if any of our key senior executives discontinues his or her employment with us, it may delay our development efforts.***

We are highly dependent on the principal members of our management and scientific staff. The loss of any of these people could impede the achievement of our development objectives. Furthermore, recruiting and retaining qualified scientific personnel to perform research and development work in the future is critical to our success. We may be unable to attract and retain personnel on acceptable terms given the competition among biotechnology, pharmaceutical and health care companies, universities and non-profit research institutions for experienced scientists. In addition, we rely on a significant number of consultants to assist us in formulating our research and development strategy. All of our consultants are employed by employers other than us. They may have commitments to, or advisory or consulting agreements with, other entities that may limit their availability to us.

***We may be subject to claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.***

As is commonplace in the biotechnology industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

***Governmental and third-party payors may impose sales and pharmaceutical pricing controls on our products that could limit our product revenues and delay profitability.***

The continuing efforts of government and third-party payors to contain or reduce the costs of health care through various means may reduce our potential revenues. These payors' efforts could decrease the price that we receive for any products we may develop and sell in the future. In addition, third-party insurance coverage may not be available to patients for any products we develop. If government and third-party payors do not provide adequate coverage and reimbursement levels for our products, or if price controls are enacted, our product revenues will suffer.

***If physicians and patients do not accept our products, we may not recover our investment.***

The commercial success of our products, if they are approved for marketing, will depend upon the acceptance of our products as safe and effective by the medical community and patients.

The market acceptance of our products could be affected by a number of factors, including:

the timing of receipt of marketing approvals;

the safety and efficacy of the products;

the success of existing products addressing our target markets or the emergence of equivalent or superior products; and

the cost-effectiveness of the products.



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In addition, market acceptance depends on the effectiveness of our marketing strategy, and, to date, we have very limited sales and marketing experience or capabilities. If the medical community and patients do not ultimately accept our products as being safe and effective, we may not recover our investment.

***Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses.***

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and Nasdaq rules, are creating uncertainty for companies such as ours. These new or changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, our efforts to comply with evolving laws, regulations and standards have resulted in, and are likely to continue to result in, increased general and administrative expenses and management time related to compliance activities. In particular, our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 and the related regulations regarding our required assessment of our internal controls over financial reporting and our external auditors' audit of that assessment requires the commitment of significant financial and managerial resources. We expect these efforts to require the continued commitment of significant resources. If we fail to comply with new or changed laws, regulations and standards, our reputation may be harmed and we might be subject to sanctions or investigation by regulatory authorities, such as the Securities and Exchange Commission. Any such action could adversely affect our financial results and the market price of our common stock.

***The price of our common stock is volatile.***

The market prices for securities of biotechnology and pharmaceutical companies historically have been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Over the course of the last 12 months, the price of our common stock has ranged from approximately \$8 per share to approximately \$73 per share. The market price of our common stock may fluctuate in response to many factors, including:

- developments related to the FDA approval process for indiplon;

- the results of our clinical trials;

- developments concerning our strategic alliance agreements;

- announcements of technological innovations or new therapeutic products by us or others;

- developments in patent or other proprietary rights;

- future sales of our common stock by existing stockholders;

- comments by securities analysts;

- general market conditions;

- fluctuations in our operating results;

- government regulation;

- health care reimbursement;

- failure of any of our product candidates, if approved, to achieve commercial success; and

public concern as to the safety of our drugs.

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### **Risks Related to Our Industry**

#### ***We may not receive regulatory approvals for our product candidates or approvals may be delayed.***

Regulation by government authorities in the United States and foreign countries is a significant factor in the development, manufacture and marketing of our proposed products and in our ongoing research and product development activities. Any failure to receive the regulatory approvals necessary to commercialize our product candidates would harm our business. The process of obtaining these approvals and the subsequent compliance with federal and state statutes and regulations require spending substantial time and financial resources. If we fail or our collaborators or licensees fail to obtain or maintain, or encounter delays in obtaining or maintaining, regulatory approvals, it could adversely affect the marketing of any products we develop, our ability to receive product or royalty revenues, our recovery of prepaid royalties, and our liquidity and capital resources. All of our products are in research and development, and we have not yet received regulatory approval to commercialize any product from the FDA or any other regulatory body. In addition, we have limited experience in filing and pursuing applications necessary to gain regulatory approvals, which may impede our ability to obtain such approvals.

In particular, human therapeutic products are subject to rigorous preclinical testing and clinical trials and other approval procedures of the FDA and similar regulatory authorities in foreign countries. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertising, promotion, sale and distribution of biopharmaceutical products. Securing FDA approval requires the submission of extensive preclinical and clinical data and supporting information to the FDA for each indication to establish the product candidate's safety and efficacy. The approval process may take many years to complete and may involve ongoing requirements for post-marketing studies. Any FDA or other regulatory approval of our product candidates, once obtained, may be withdrawn. If our potential products are marketed abroad, they will also be subject to extensive regulation by foreign governments.

#### ***We face intense competition, and if we are unable to compete effectively, the demand for our products, if any, may be reduced.***

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition in the development and marketing of our product candidates from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies.

Competition may also arise from, among other things:

- other drug development technologies;

- methods of preventing or reducing the incidence of disease, including vaccines; and

- new small molecule or other classes of therapeutic agents.

Developments by others may render our product candidates or technologies obsolete or noncompetitive.

We are performing research on or developing products for the treatment of several disorders including insomnia, anxiety, depression, endometriosis, irritable bowel syndrome, pain, Parkinson's Disease, and other neuro-endocrine related diseases and disorders, and there are a number of competitors to products in our research pipeline. If one or more of our competitors' products or programs are successful, the market for our products may be reduced or eliminated.

Compared to us, many of our competitors and potential competitors have substantially greater:

- capital resources;

- research and development resources, including personnel and technology;

- regulatory experience;

- preclinical study and clinical testing experience;

- manufacturing and marketing experience; and

production facilities.

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***If we are unable to protect our intellectual property, our competitors could develop and market products based on our discoveries, which may reduce demand for our products.***

Our success will depend on our ability to, among other things:

obtain patent protection for our products;

preserve our trade secrets;

prevent third parties from infringing upon our proprietary rights; and

operate without infringing upon the proprietary rights of others, both in the United States and internationally.

Because of the substantial length of time and expense associated with bringing new products through the development and regulatory approval processes in order to reach the marketplace, the pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Accordingly, we intend to seek patent protection for our proprietary technology and compounds. However, we face the risk that we may not obtain any of these patents and that the breadth of claims we obtain, if any, may not provide adequate protection of our proprietary technology or compounds.

We also rely upon unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, through confidentiality agreements with our commercial collaborators, employees and consultants. We also have invention or patent assignment agreements with our employees and some, but not all, of our commercial collaborators and consultants. However, if our employees, commercial collaborators or consultants breach these agreements, we may not have adequate remedies for any such breach, and our trade secrets may otherwise become known or independently discovered by our competitors.

In addition, although we own a number of patents, the issuance of a patent is not conclusive as to its validity or enforceability, and third parties may challenge the validity or enforceability of our patents. We cannot assure you how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court or in other proceedings. It is possible that a competitor may successfully challenge our patents or that challenges will result in limitations of their coverage. Moreover, competitors may infringe our patents or successfully avoid them through design innovation. To prevent infringement or unauthorized use, we may need to file infringement claims, which are expensive and time-consuming. In addition, in an infringement proceeding a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. Interference proceedings declared by the United States Patent and Trademark Office (USPTO) may be necessary to determine the priority of inventions with respect to our patent applications or those of our licensors. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and be a distraction to management. We cannot assure you that we will be able to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

***The technologies we use in our research as well as the drug targets we select may infringe the patents or violate the proprietary rights of third parties.***

We cannot assure you that third parties will not assert patent or other intellectual property infringement claims against us or our collaboration partners with respect to technologies used in potential products. We are aware of a patent application controlled by another company, which if granted in its broadest scope and held to be valid, could impact the commercialization of our indiplon tablets in the United States unless we obtain a license, which may not be available to us. Based on information available from the USPTO, we have learned that the USPTO has examined the pending claims of this application two times and that both times it has rejected all the pending claims. We are also aware that the corresponding patent application in Europe has issued as a patent, and we have filed an opposition against the issued European patent. Even if we were to prevail, any litigation could be costly and time-consuming and could divert the attention of our management and key personnel from our business operations. If a patent infringement suit were brought against us or our collaboration partners, we or our collaboration partners could be forced to stop or delay developing, manufacturing or selling potential products that are claimed to infringe a third party's intellectual

property unless that party grants us or our collaboration partners rights to use its intellectual property. In such cases, we could be required to obtain

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licenses to patents or proprietary rights of others in order to continue to commercialize our products. However, we may not be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all. Even if our collaboration partners or we were able to obtain rights to the third party's intellectual property, these rights may be non-exclusive, thereby giving our competitors access to the same intellectual property. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations as a result of patent infringement claims, which could severely harm our business.

### ***We face potential product liability exposure far in excess of our limited insurance coverage.***

The use of any of our potential products in clinical trials, and the sale of any approved products, may expose us to liability claims. These claims might be made directly by consumers, health care providers, pharmaceutical companies or others selling our products. We have obtained limited product liability insurance coverage for our clinical trials in the amount of \$10 million per occurrence and \$10 million in the aggregate. However, our insurance may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, juries have awarded large judgments in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us would decrease our cash reserves and could cause our stock price to fall.

### ***Our activities involve hazardous materials, and we may be liable for any resulting contamination or injuries.***

Our research activities involve the controlled use of hazardous materials. We cannot eliminate the risk of accidental contamination or injury from these materials. If an accident occurs, a court may hold us liable for any resulting damages, which may harm our results of operations and cause us to use a substantial portion of our cash reserves, which would force us to seek additional financing.

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**ITEM 6. EXHIBITS**

- 3.1 Restated Certificate of Incorporation (1)
- 3.2 Certificate of Amendment to Certificate of Incorporation (2)
- 3.3 Bylaws (1)
- 3.4 Certificate of Amendment of Bylaws (1)
- 3.5 Certificate of Amendment of Bylaws dated May 28, 2004 (3)
- 10.1 Amended and Restated Employment Agreement dated September 18, 2006 between the Company and Paul W. Hawran (4)
- 10.2 Employment Agreement dated September 18, 2006 between the Company and Timothy P. Coughlin (4)
- 10.3 Form of Restricted Stock Unit Agreement
- 31.1 Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934.
- 31.2 Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934.
- 32\* Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- (1) Incorporated by reference to the Company's Registration Statement on Form S-1 (Registration No. 333-03172)
- (2) Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed on August 9, 2006
- (3) Incorporated by reference to the Company's Quarterly



Report on Form  
10-Q filed on  
August 9, 2004

- (4) Incorporated by  
reference to the  
Company's  
Current Report  
on Form 8-K  
filed on  
September 19,  
2006

\* These  
certifications are  
being furnished  
solely to  
accompany this  
quarterly report  
pursuant to 18.  
U.S.C.  
Section 1350,  
and are not  
being filed for  
purposes of  
Section 18 of  
the Securities  
Exchange Act of  
1934 and are not  
to be  
incorporated by  
reference into  
any filing of  
Neurocrine  
Biosciences,  
Inc., whether  
made before or  
after the date  
hereof,  
regardless of  
any general  
incorporation  
language in such  
filing.

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**SIGNATURES**

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

Dated: November 8, 2006

/s/ Timothy P. Coughlin  
Timothy P. Coughlin  
Vice President and  
Chief Financial Officer  
(Duly authorized officer and  
Principal Financial Officer)

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