

NEUROCRINE BIOSCIENCES INC

Form 10-Q

October 29, 2010

[Table of Contents](#)

**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 EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2010

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 0-22705

**NEUROCRINE BIOSCIENCES, INC.**

(Exact name of registrant as specified in its charter)

Edgar Filing: NEUROCRINE BIOSCIENCES INC - Form 10-Q

|                                                                                                                 |                                                           |
|-----------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|
| <b>DELAWARE</b><br>(State or other jurisdiction of<br>incorporation or organization)                            | <b>33-0525145</b><br>(IRS Employer<br>Identification No.) |
| <b>12780 EL CAMINO REAL,</b><br><br><b>SAN DIEGO, CALIFORNIA</b><br>(Address of principal executive office)     | <b>92130</b><br>(Zip Code)                                |
| <b>(858) 617-7600</b><br><br>(Registrant's telephone number, including area code)                               |                                                           |
| <b>Not Applicable</b><br><br>(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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

|                                                                                              |                                                       |
|----------------------------------------------------------------------------------------------|-------------------------------------------------------|
| Large accelerated filer <input type="checkbox"/>                                             | Accelerated filer <input checked="" type="checkbox"/> |
| Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company) | Smaller reporting company <input type="checkbox"/>    |

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

The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 54,862,463 as of October 25, 2010.

**Table of Contents**

**NEUROCRINE BIOSCIENCES, INC.**

**FORM 10-Q INDEX**

|                                                                                                                        | <b>PAGE</b> |
|------------------------------------------------------------------------------------------------------------------------|-------------|
| <b>PART I. FINANCIAL INFORMATION</b>                                                                                   |             |
| <u>ITEM 1: Financial Statements</u>                                                                                    | 3           |
| <u>Condensed Consolidated Balance Sheets as of September 30, 2010 and December 31, 2009</u>                            | 3           |
| <u>Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2010 and 2009</u> | 4           |
| <u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2010 and 2009</u>           | 5           |
| <u>Notes to the Condensed Consolidated Financial Statements</u>                                                        | 6           |
| <u>ITEM 2: Management's Discussion and Analysis of Financial Condition and Results of Operations</u>                   | 16          |
| <u>ITEM 3: Quantitative and Qualitative Disclosures About Market Risk</u>                                              | 22          |
| <u>ITEM 4: Controls and Procedures</u>                                                                                 | 22          |
| <b>PART II. OTHER INFORMATION</b>                                                                                      |             |
| <u>ITEM 1A: Risk Factors</u>                                                                                           | 22          |
| <u>ITEM 6: Exhibits</u>                                                                                                | 31          |
| <u>Signatures</u>                                                                                                      | 32          |

**Table of Contents****PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****NEUROCRINE BIOSCIENCES, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS****(in thousands, except for share information)****(unaudited)**

|                                                                                                                                                                               | <b>September 30,<br/>2010</b> | <b>December 31,<br/>2009</b> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|------------------------------|
| <b>ASSETS</b>                                                                                                                                                                 |                               |                              |
| Current assets:                                                                                                                                                               |                               |                              |
| Cash and cash equivalents                                                                                                                                                     | \$ 77,330                     | \$ 37,329                    |
| Short-term investments                                                                                                                                                        | 47,641                        | 16,135                       |
| Accounts receivable                                                                                                                                                           | 5,219                         |                              |
| Other current assets                                                                                                                                                          | 1,402                         | 1,923                        |
| Total current assets                                                                                                                                                          | 131,592                       | 55,387                       |
| Property and equipment, net                                                                                                                                                   | 1,827                         | 2,695                        |
| Long-term investments                                                                                                                                                         | 10,181                        | 6,411                        |
| Restricted cash                                                                                                                                                               | 6,333                         | 6,325                        |
| Total assets                                                                                                                                                                  | \$ 149,933                    | \$ 70,818                    |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>                                                                                                                                   |                               |                              |
| Current liabilities:                                                                                                                                                          |                               |                              |
| Accounts payable                                                                                                                                                              | \$ 912                        | \$ 2,188                     |
| Accrued liabilities                                                                                                                                                           | 8,334                         | 6,240                        |
| Current portion of deferred revenues                                                                                                                                          | 36,960                        | 2,941                        |
| Current portion of cease-use liability                                                                                                                                        | 4,047                         | 4,289                        |
| Current portion of deferred gain on sale of real estate                                                                                                                       | 2,931                         | 2,867                        |
| Other liabilities                                                                                                                                                             |                               | 1,436                        |
| Total current liabilities                                                                                                                                                     | 53,184                        | 19,961                       |
| Deferred revenues                                                                                                                                                             | 46,400                        | 8,757                        |
| Deferred gain on sale of real estate                                                                                                                                          | 27,790                        | 29,999                       |
| Deferred rent                                                                                                                                                                 | 1,425                         | 906                          |
| Cease-use liability                                                                                                                                                           | 4,487                         | 7,241                        |
| Total liabilities                                                                                                                                                             | 133,286                       | 66,864                       |
| 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 54,849,697 as of September 30, 2010 and 43,991,565 as of December 31, 2009 | 55                            | 44                           |
| Additional paid-in capital                                                                                                                                                    | 780,652                       | 757,002                      |

## Edgar Filing: NEUROCRINE BIOSCIENCES INC - Form 10-Q

|                                            |            |           |
|--------------------------------------------|------------|-----------|
| Accumulated other comprehensive income     | 696        | 1,209     |
| Accumulated deficit                        | (764,756)  | (754,301) |
| Total stockholders' equity                 | 16,647     | 3,954     |
| Total liabilities and stockholders' equity | \$ 149,933 | \$ 70,818 |

See accompanying notes to the condensed consolidated financial statements.

**Table of Contents****NEUROCRINE BIOSCIENCES, INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****(in thousands, except loss per share data)****(unaudited)**

|                                                                       | <b>Three Months Ended<br/>September 30,</b> |             | <b>Nine Months Ended<br/>September 30,</b> |             |
|-----------------------------------------------------------------------|---------------------------------------------|-------------|--------------------------------------------|-------------|
|                                                                       | <b>2010</b>                                 | <b>2009</b> | <b>2010</b>                                | <b>2009</b> |
| Revenues:                                                             |                                             |             |                                            |             |
| Sponsored research and development                                    | \$ 5,210                                    | \$ 3        | \$ 6,519                                   | \$ 23       |
| License fees and milestones                                           | 9,238                                       | 730         | 13,325                                     | 2,190       |
| Total revenues                                                        | 14,448                                      | 733         | 19,844                                     | 2,213       |
| Operating expenses:                                                   |                                             |             |                                            |             |
| Research and development                                              | 8,227                                       | 7,401       | 23,086                                     | 29,057      |
| General and administrative                                            | 3,635                                       | 2,966       | 9,950                                      | 11,988      |
| Cease use expense                                                     | 120                                         | 89          | 401                                        | 5,858       |
| Total operating expenses                                              | 11,982                                      | 10,456      | 33,437                                     | 46,903      |
| Income (loss) from operations                                         | 2,466                                       | (9,723)     | (13,593)                                   | (44,690)    |
| Other income:                                                         |                                             |             |                                            |             |
| Gain on sale/disposal of assets                                       | 34                                          | 571         | 202                                        | 733         |
| Deferred gain on real estate                                          | 715                                         | 694         | 2,145                                      | 2,084       |
| Investment income and (expense), net                                  | 118                                         | 161         | 732                                        | (1,637)     |
| Other income, net                                                     |                                             | 120         | 59                                         | 388         |
| Total other income                                                    | 867                                         | 1,546       | 3,138                                      | 1,568       |
| Net income (loss)                                                     | \$ 3,333                                    | \$ (8,177)  | \$ (10,455)                                | \$ (43,122) |
| Net income (loss) per common share:                                   |                                             |             |                                            |             |
| Basic                                                                 | \$ 0.06                                     | \$ (0.21)   | \$ (0.20)                                  | \$ (1.11)   |
| Diluted                                                               | \$ 0.06                                     | \$ (0.21)   | \$ (0.20)                                  | \$ (1.11)   |
| Shares used in the calculation of net income (loss) per common share: |                                             |             |                                            |             |
| Basic                                                                 | 54,844                                      | 39,096      | 52,130                                     | 38,938      |
| Diluted                                                               | 55,648                                      | 39,096      | 52,130                                     | 38,938      |

See accompanying notes to the condensed consolidated financial statements.

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

|                                                                                           | <b>Nine Months Ended<br/>September 30,</b> |             |
|-------------------------------------------------------------------------------------------|--------------------------------------------|-------------|
|                                                                                           | <b>2010</b>                                | <b>2009</b> |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES</b>                                               |                                            |             |
| Net loss                                                                                  | \$ (10,455)                                | \$ (43,122) |
| Adjustments to reconcile net loss to net cash provided by (used in) operating activities: |                                            |             |
| Depreciation and amortization                                                             | 1,132                                      | 2,609       |
| Gain on sale of assets                                                                    | (203)                                      | (732)       |
| Fair value adjustment for trading auction rate security rights                            | 1,206                                      | 665         |
| Loss on sale of investments                                                               | 186                                        | 1,073       |
| Fair value adjustment trading for auction rate securities                                 | (1,206)                                    | 482         |
| Realized gain on sale of auction rate securities                                          | (626)                                      |             |
| Cease-use expense                                                                         | 401                                        | 5,858       |
| Deferred gain on sale of real estate                                                      | (2,145)                                    | (2,084)     |
| Deferred revenues                                                                         | (13,338)                                   | (2,197)     |
| Deferred rent                                                                             | 519                                        | 596         |
| Share-based compensation expense                                                          | 2,277                                      | 4,610       |
| Amortization of premiums on short term-investments                                        | 451                                        | (3)         |
| Change in operating assets and liabilities:                                               |                                            |             |
| Proceeds from sale of trading securities                                                  | 12,775                                     |             |
| Accounts receivable and other current assets                                              | (4,713)                                    | (122)       |
| Other assets                                                                              |                                            | 1,993       |
| Accounts payable and accrued liabilities                                                  | 818                                        | (3,133)     |
| Upfront licensing fees                                                                    | 85,000                                     |             |
| Cease-use liability                                                                       | (3,397)                                    | (3,979)     |
| Other liabilities                                                                         | (1,436)                                    | (1,636)     |
| Net cash provided by (used in) operating activities                                       | 67,246                                     | (39,122)    |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES</b>                                               |                                            |             |
| Purchases of investments                                                                  | (58,592)                                   | (16,065)    |
| Sales/maturities of investments                                                           | 10,032                                     | 21,030      |
| Deposits and restricted cash                                                              | (8)                                        | 87          |
| Proceeds from sales of property and equipment                                             | 242                                        | 954         |
| Purchases of property and equipment, net                                                  | (303)                                      | (35)        |
| Net cash (used in) provided by investing activities                                       | (48,629)                                   | 5,971       |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES</b>                                               |                                            |             |
| Issuance of common stock                                                                  | 21,384                                     |             |
| Net cash provided by financing activities                                                 | 21,384                                     |             |
| Net increase (decrease) in cash and cash equivalents                                      | 40,001                                     | (33,151)    |
| Cash and cash equivalents at beginning of the period                                      | 37,329                                     | 68,467      |

## Edgar Filing: NEUROCRINE BIOSCIENCES INC - Form 10-Q

|                                                |           |           |
|------------------------------------------------|-----------|-----------|
| Cash and cash equivalents at end of the period | \$ 77,330 | \$ 35,316 |
|------------------------------------------------|-----------|-----------|

See accompanying notes to the condensed consolidated financial statements.



---

**Table of Contents**

**NEUROCRINE BIOSCIENCES, INC.**

**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(unaudited)**

**1. 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 period 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 financial statements and notes thereto for the year ended December 31, 2009 and the three and six months ended March 31 and June 30, 2010, respectively, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2009 and the Company's Quarterly Reports on Form 10-Q for the three and six months ended March 31 and June 30, 2010, respectively, filed with the SEC.

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

**2. ORGANIZATION AND SUMMARY OF BUSINESS**

Neurocrine Biosciences, Inc. 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 endometriosis, anxiety, depression, pain, diabetes, irritable bowel syndrome, insomnia 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 own product candidates, Neurocrine is in collaborations with pharmaceutical companies for four of its programs. The Company's lead clinical development program, *elagolix*, is a drug candidate for the treatment of endometriosis.

**3. IMPACT OF RECENTLY ISSUED ACCOUNTING STANDARDS**

In April 2010, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2010-17, *Revenue Recognition (Topic 605), Milestone Method of Revenue Recognition* (ASU 2010-17) and Accounting Standards Codification (ASC) Subtopic 605-28, *Revenue Recognition - Milestone Method* (ASC 605-28), which covers research and development milestone recognition. This guidance is not required and does not represent the only acceptable method of revenue recognition. This guidance is effective for milestones achieved in fiscal years and interim periods beginning on or after June 15, 2010 and will not have a material impact on the Company's results of operations as it is consistent with the Company's historical practice of milestone revenue recognition.

In February 2010, the FASB issued amended guidance on subsequent events. Under this amended guidance, SEC filers are no longer required to disclose the date through which subsequent events have been evaluated in originally issued and revised financial statements. This guidance was effective immediately and the Company adopted these new requirements upon issuance of this guidance.

In January 2010, the FASB issued ASU No. 2010-06, *Improving Disclosures about Fair Value Measurements* (ASU 2010-06). This guidance requires the disclosure of separate amounts of significant transfers in and out of Level 1 and Level 2 fair value measurements and the reason for such transfers. ASU 2010-06 also requires information related to purchases, sales, issuances, and settlements of Level 3 financial assets and liabilities to be presented separately in the reconciliation of fair value measurements for the period presented. In addition, ASU 2010-06 clarifies existing disclosure guidance with respect to the level of disaggregation for classes of financial assets and liabilities as well as valuation techniques and inputs used for both recurring and nonrecurring fair value measurements of Level 2 and Level 3 assets and liabilities. The Company has provided the additional required disclosures effective January 1, 2010.



**Table of Contents****NEUROCRINE BIOSCIENCES, INC.****NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(unaudited)****4. USE OF ESTIMATES**

The preparation of condensed consolidated 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 condensed consolidated financial statements and the accompanying notes. Actual results could differ from those estimates.

**5. INVESTMENTS**

Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in comprehensive income (loss). 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 other 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.

Investments consist of the following (in thousands):

|                                                                 | <b>September 30,<br/>2010</b> | <b>December 31,<br/>2009</b> |
|-----------------------------------------------------------------|-------------------------------|------------------------------|
| Certificates of deposit                                         | \$ 958                        | \$ 3,360                     |
| Commercial paper                                                | 26,116                        |                              |
| Corporate bonds                                                 | 25,470                        |                              |
| U.S. Federal agency notes/bonds                                 | 2,500                         |                              |
| Auction rate securities, available-for-sale, long-term (Note 6) | 2,778                         | 6,411                        |
| Auction rate securities, trading (Note 6)                       |                               | 11,569                       |
| Auction rate security rights, trading (Note 6)                  |                               | 1,206                        |
| Ending balance                                                  | \$ 57,822                     | \$ 22,546                    |

The following is a summary of investments classified as available-for-sale securities (in thousands):

|                                 | <b>Amortized<br/>Cost</b> | <b>Gross<br/>Unrealized<br/>Gains(1)</b> | <b>Gross<br/>Unrealized<br/>Losses(1)</b> | <b>Aggregate<br/>Estimated<br/>Fair<br/>Value</b> |
|---------------------------------|---------------------------|------------------------------------------|-------------------------------------------|---------------------------------------------------|
| <b>September 30, 2010</b>       |                           |                                          |                                           |                                                   |
| Certificates of deposit         | \$ 960                    | \$                                       | \$ (2)                                    | \$ 958                                            |
| Commercial paper                | 26,150                    |                                          | (34)                                      | 26,116                                            |
| Corporate bonds                 | 25,479                    | 4                                        | (13)                                      | 25,470                                            |
| U.S. Federal agency notes/bonds | 2,500                     |                                          |                                           | 2,500                                             |
| Auction rate securities         | 2,037                     | 741                                      |                                           | 2,778                                             |

# Edgar Filing: NEUROCRINE BIOSCIENCES INC - Form 10-Q

|                                     |           |        |         |           |
|-------------------------------------|-----------|--------|---------|-----------|
| Total available-for-sale securities | \$ 57,126 | \$ 745 | \$ (49) | \$ 57,822 |
|-------------------------------------|-----------|--------|---------|-----------|

## December 31, 2009

|                         |          |       |        |          |
|-------------------------|----------|-------|--------|----------|
| Certificates of deposit | \$ 3,360 | \$ 1  | \$ (1) | \$ 3,360 |
| Auction rate securities | 5,031    | 1,380 |        | 6,411    |

|                                     |          |          |        |          |
|-------------------------------------|----------|----------|--------|----------|
| Total available-for-sale securities | \$ 8,391 | \$ 1,381 | \$ (1) | \$ 9,771 |
|-------------------------------------|----------|----------|--------|----------|

- (1) Unrealized gains and losses are included in other comprehensive income.

**Table of Contents****NEUROCRINE BIOSCIENCES, INC.****NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(unaudited)**

The amortized cost and estimated fair value of debt securities classified as available-for-sale by contractual maturity are presented below (in thousands):

|                                                          | <b>Maturing<br/>in less than<br/>12 months</b> |                                     | <b>Maturing<br/>in more than<br/>12 Months</b> |                                     |
|----------------------------------------------------------|------------------------------------------------|-------------------------------------|------------------------------------------------|-------------------------------------|
|                                                          | <b>Amortized<br/>Cost</b>                      | <b>Estimated<br/>Fair<br/>Value</b> | <b>Amortized<br/>Cost</b>                      | <b>Estimated<br/>Fair<br/>Value</b> |
| <b>September 30, 2010</b>                                |                                                |                                     |                                                |                                     |
| Certificates of deposit                                  | \$ 720                                         | \$ 718                              | \$ 240                                         | \$ 240                              |
| Commercial paper                                         | 26,150                                         | 26,116                              |                                                |                                     |
| U.S. Federal agency notes/bonds                          |                                                |                                     | 2,500                                          | 2,500                               |
| Corporate bonds                                          | 20,811                                         | 20,807                              | 4,668                                          | 4,663                               |
| Auction rate securities classified as available-for-sale |                                                |                                     | 2,037                                          | 2,778                               |
| <b>Total available-for-sale securities</b>               | <b>\$ 47,681</b>                               | <b>\$ 47,641</b>                    | <b>\$ 9,445</b>                                | <b>\$ 10,181</b>                    |
| <b>December 31, 2009</b>                                 |                                                |                                     |                                                |                                     |
| Certificates of deposit                                  | \$ 3,360                                       | \$ 3,360                            | \$                                             | \$                                  |
| Auction rate securities classified as available-for-sale |                                                |                                     | 5,031                                          | 6,411                               |
| <b>Total available-for-sale securities</b>               | <b>\$ 3,360</b>                                | <b>\$ 3,360</b>                     | <b>\$ 5,031</b>                                | <b>\$ 6,411</b>                     |

The following table presents certain information related to sales and maturities of investments (in thousands):

|                                                                                          | <b>Three Months<br/>Ended<br/>September 30,</b> |             | <b>Nine Months Ended<br/>September 30,</b> |             |
|------------------------------------------------------------------------------------------|-------------------------------------------------|-------------|--------------------------------------------|-------------|
|                                                                                          | <b>2010</b>                                     | <b>2009</b> | <b>2010</b>                                | <b>2009</b> |
| Proceeds from sales/maturities of available-for-sale securities                          | \$ 3,872                                        | \$ 7,830    | \$ 10,032                                  | \$ 21,030   |
| Gross realized gains on sales of available-for-sale securities                           | 35                                              | 53          | 626                                        | 53          |
| Gross realized losses on sales of available-for-sale securities                          |                                                 |             |                                            |             |
| Gains reclassified out of accumulated other comprehensive income into earnings           | 24                                              | 24          | 566                                        | 24          |
| Unrealized gains recognized during the period in accumulated other comprehensive income  | 73                                              | 73          | 24                                         | 1,485       |
| Unrealized losses recognized during the period in accumulated other comprehensive income | (45)                                            | (1)         | (141)                                      | (26)        |

The following table presents information about investments in an unrealized loss position (in thousands):

|                           | Less Than 12 Months  |                   | 12 Months or Greater |                   | Total                |                   |
|---------------------------|----------------------|-------------------|----------------------|-------------------|----------------------|-------------------|
|                           | Estimated Fair Value | Unrealized Losses | Estimated Fair Value | Unrealized Losses | Estimated Fair Value | Unrealized Losses |
| <b>September 30, 2010</b> |                      |                   |                      |                   |                      |                   |
| Certificates of deposit   | \$ 958               | \$ (2)            | \$                   | \$                | \$ 958               | \$ (2)            |
| Commercial paper          | 26,116               | (34)              |                      |                   | 26,116               | (34)              |
| Corporate bonds           | 20,850               | (13)              |                      |                   | 20,850               | (13)              |
| Total                     | \$ 47,924            | \$ (49)           | \$                   | \$                | \$ 47,924            | \$ (49)           |
| <b>December 31, 2009</b>  |                      |                   |                      |                   |                      |                   |
| Certificates of deposit   | \$ 1,439             | \$ (1)            | \$                   | \$                | \$ 1,439             | \$ (1)            |
| Total                     | \$ 1,439             | \$ (1)            | \$                   | \$                | \$ 1,439             | \$ (1)            |

#### 6. AUCTION RATE SECURITIES

The Company's investments at September 30, 2010 included an auction rate security which had a par value of \$3.1 million. This auction rate security was treated as an available-for-sale security and carried as a long-term investment on the Company's condensed consolidated balance sheet with an estimated fair value of \$2.8 million at September 30, 2010.

**Table of Contents**

**NEUROCRINE BIOSCIENCES, INC.**

**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(unaudited)**

This auction rate security is secured by student loans, which are backed by the full faith and credit of the federal government (up to approximately 98% of the value of the student loans). This security continues to pay interest according to its stated terms with interest rates resetting every 28 days. While it is not the Company's intent to hold this security until its stated maturity date, this investment is scheduled to ultimately mature in 2045.

During the three months ended March 31, 2010, the Company sold one auction rate security which had a par value of \$4.0 million for approximately \$3.1 million. As part of this sale, the Company recognized a one-time gain on sale of approximately \$0.5 million in the Company's condensed consolidated statement of operations.

During the first half of 2010, the Company sold approximately \$3.7 million of auction rate securities, at par, to UBS AG (UBS). On July 1, 2010, the Company received \$9.1 million (par value) related to the remaining auction rate securities maintained at UBS.

The Company has one remaining auction rate security that is carried as a long-term investment on the Company's condensed consolidated balance sheet and continues to be treated as an available-for-sale investment. This auction rate security has a par value of \$3.1 million and is carried on the Company's condensed consolidated balance sheet at an estimated fair value of \$2.8 million at September 30, 2010. Approximately \$0.9 million of the original balance of this auction rate security has been redeemed thus far, at par, by the issuer. The fair value of this auction rate security is estimated utilizing a discounted cash flow analysis. The significant assumptions of this valuation model are a discount margin of 263 basis points which is based on industry recognized student loan sector indices, an additional liquidity discount of 150 basis points and an estimated term to liquidity of 6.25 years. Other items this analysis considers are the collateralization underlying the security investment, the creditworthiness of the counterparty, and the timing of expected future cash flows. This security was also compared, when possible, to other observable market data with similar characteristics as the securities held by the Company. Although this auction rate security continues to pay interest according to its stated term, based on a valuation model, the Company has reduced the par value for this auction rate security at September 30, 2010 by \$0.3 million to \$2.8 million.

Changes to estimates and assumptions used in estimating the fair value of this auction rate security may provide a materially different value. In addition, actual market exchanges, if any, may occur at materially different amounts. For example, a reduction of the expected term to redemption assumption by approximately two years for the auction rate security yielded a net increase in the valuation of this investment of \$0.1 million. Other factors that may impact the valuation of the Company's auction rate security include changes to credit ratings of the security as well as to the underlying assets supporting the security, rates of default of the underlying assets, underlying collateral value, discount rates, counterparty risk and ongoing strength and quality of market credit and liquidity.

At present, in the event the Company needs to access the funds that are in an illiquid state, it may not be able to do so without the possible loss of principal, until a future auction for this investment is successful, another secondary market evolves for this security, until it is redeemed by the issuer or it matures. If the Company is unable to sell this security in the market or it is not redeemed, it could be required to hold the security to maturity. The Company will continue to monitor and evaluate this investment on an ongoing basis for impairment.

**7. FAIR VALUE MEASUREMENTS**

The Company follows ASC 820-10, *Fair Value Measurements and Disclosures* (ASC 820-10) which, among other things, defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. ASC 820-10 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, ASC 820-10 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and



**Table of Contents****NEUROCRINE BIOSCIENCES, INC.****NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(unaudited)**

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The fair values of the Company's Level 1 financial assets are based on quoted market prices of the identical underlying security. The fair values of the Company's Level 2 financial assets are obtained from readily-available pricing sources for the identical underlying security that may not be actively traded. The Company utilizes a pricing service to assist in obtaining fair value pricing for the majority of this investment portfolio. The Company conducts reviews on a quarterly basis to verify pricing, assess liquidity, and determine if significant inputs have changed that would impact the fair value hierarchy disclosure.

Assets measured at fair value are classified below based on the three fair value hierarchy tiers described above (in millions):

|                                     |                   | Fair Value Measurements Using                                                 |                                                     |                                                 |
|-------------------------------------|-------------------|-------------------------------------------------------------------------------|-----------------------------------------------------|-------------------------------------------------|
|                                     |                   | Quoted Prices in<br>Active Markets for<br>Identical<br>Assets<br>(Level<br>1) | Significant Other<br>Observable Inputs<br>(Level 2) | Significant<br>Unobservable Inputs<br>(Level 3) |
|                                     | Carrying<br>Value |                                                                               |                                                     |                                                 |
| <b>September 30, 2010:</b>          |                   |                                                                               |                                                     |                                                 |
| Money market funds                  | \$ 83.6           | \$ 83.6                                                                       | \$                                                  | \$                                              |
| Certificates of deposit (1)         | 0.9               |                                                                               | 0.9                                                 |                                                 |
| Commercial paper (1)                | 26.1              |                                                                               | 26.1                                                |                                                 |
| U.S. Federal agency notes/bonds (1) | 2.5               |                                                                               | 2.5                                                 |                                                 |
| Corporate bonds (1)                 | 25.5              |                                                                               | 25.5                                                |                                                 |
| Auction rate securities (Note 6)    | 2.8               |                                                                               |                                                     | 2.8                                             |
| Total                               | \$ 141.4          | \$ 83.6                                                                       | \$ 55.0                                             | \$ 2.8                                          |
| <b>December 31, 2009:</b>           |                   |                                                                               |                                                     |                                                 |
| Money market funds                  | \$ 43.4           | \$ 43.4                                                                       | \$                                                  | \$                                              |
| Certificates of deposit (1)         | 3.3               |                                                                               | 3.3                                                 |                                                 |
| Auction rate securities (Note 6)    | 18.0              |                                                                               |                                                     | 18.0                                            |
| ARS Rights (Note 6)                 | 1.2               |                                                                               |                                                     | 1.2                                             |
| Total                               | \$ 65.9           | \$ 43.4                                                                       | \$ 3.3                                              | \$ 19.2                                         |

(1) Securities are classified as available-for-sale.

Activity for assets measured at fair value during the nine month period ended September 30, 2010 using significant unobservable inputs (Level 3) is presented in the table below (in millions):

|                                                                     | Fair Value<br>Measurements<br>Using Significant<br>Unobservable<br>Inputs (Level<br>3) |
|---------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| Beginning balance as of December 31, 2009                           | \$ 19.2                                                                                |
| Transfers into Level 3                                              |                                                                                        |
| Sales, settlements and redemptions                                  | (16.4)                                                                                 |
| Total unrealized gains reclassified from other comprehensive income | (0.6)                                                                                  |
| Total realized gains included in investment income                  | 0.6                                                                                    |
| Ending balance                                                      | \$ 2.8                                                                                 |

## 8. IMPAIRMENT OF LONG-LIVED ASSETS

In accordance with ASC 360-10-15, *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 the carrying amount is not recoverable, the Company measures the amount of any impairment by comparing the carrying value of the asset to the present value of the expected future cash flows associated with the use of the asset. The Company has determined that no impairment exists on its long-lived assets.

## 9. SHARE-BASED COMPENSATION

The Company's net income (loss) for the three months ended September 30, 2010 and 2009 included \$0.9 million and \$1.7 million, respectively, of compensation expense related to the Company's share-based compensation awards. The Company's net loss for the nine months ended September 30, 2010 and 2009 included \$2.3 million and \$4.6 million, respectively, of compensation expense related to the Company's share-based compensation awards. As of September 30, 2010,

**Table of Contents****NEUROCRINE BIOSCIENCES, INC.****NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(unaudited)**

total unrecognized estimated compensation cost related to non-vested stock options and non-vested restricted stock units (RSUs) granted prior to that date was \$3.0 million and \$0.6 million, respectively, which is expected to be recognized over a weighted average period of approximately 2.1 and 0.4 years, respectively. The compensation expense related to the Company's share-based compensation arrangements is recorded as components of general and administrative expense and research and development expense. The following is a summary of the components of the Company's compensation expense related to share-based compensation (in millions):

|                            | <b>Three Months Ended<br/>September 30,</b> |             | <b>Nine Months Ended<br/>September 30,</b> |             |
|----------------------------|---------------------------------------------|-------------|--------------------------------------------|-------------|
|                            | <b>2010</b>                                 | <b>2009</b> | <b>2010</b>                                | <b>2009</b> |
| General and administrative | \$ 0.5                                      | \$ 1.0      | \$ 1.2                                     | \$ 2.5      |
| Research and development   | \$ 0.4                                      | \$ 0.7      | \$ 1.1                                     | \$ 2.1      |

During the nine months ended September 30, 2010, stock options for approximately 10,000 shares of the Company's common stock were exercised. The cash received by the Company from stock option exercises during the nine months ended September 30, 2010 was approximately \$25,000. There were no stock option exercises for the nine months ended September 30, 2009. The Company issued approximately 0.4 million and 0.6 million shares of common stock pursuant to the vesting of RSUs during the nine months ended September 30, 2010 and September 30, 2009, respectively.

***Stock Option Assumptions***

The exercise price of all options granted during the nine month periods ended September 30, 2010 and 2009 was equal to the closing price of the Company's common stock on the date of grant. The estimated fair value of each option award granted was determined on the date of grant using the Black-Scholes option valuation model. There were no equity awards granted during the three months ended September 30, 2009. The following weighted-average assumptions were used for the option grants during the three and nine months ended September 30, 2010 and 2009:

|                                     | <b>Three Months Ended<br/>September 30,</b> |             | <b>Nine Months Ended<br/>September 30,</b> |             |
|-------------------------------------|---------------------------------------------|-------------|--------------------------------------------|-------------|
|                                     | <b>2010</b>                                 | <b>2009</b> | <b>2010</b>                                | <b>2009</b> |
| Risk-free interest rate             | 1.41%                                       |             | 2.24%                                      | 2.34%       |
| Expected volatility of common stock | 93.07%                                      |             | 90.05%                                     | 83.26%      |
| Dividend yield                      | 0.0%                                        |             | 0.0%                                       | 0.0%        |
| Expected option term                | 4.5 years                                   |             | 4.6 years                                  | 5.35 years  |

The Company estimates forfeiture rates for stock options and RSUs based on past behavior for similar equity awards with further consideration given to the class of employees to whom the equity awards were granted.

**10. STOCKHOLDERS' EQUITY*****Common Stock Issuances***

In March 2010, the Company completed a public offering of common stock in which the Company sold approximately 10.5 million shares of its common stock at an offering price of \$2.20 per share. The net proceeds generated from this transaction, after underwriting discounts and commissions and offering costs, were approximately \$21.4 million.

***Committed Equity Financing Facility***

## Edgar Filing: NEUROCRINE BIOSCIENCES INC - Form 10-Q

In September 2009, the Company entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge) pursuant to which Kingsbridge committed to purchase, subject to certain conditions, up to the lesser of 7.8 million newly issued shares of the Company's common stock or an aggregate of \$75.0 million newly issued shares over the three-year term of the CEFF. The Company may access capital under the CEFF by making draw downs up to a maximum of the lesser of (i) \$15 million and (ii) the greater of (x) 1.75% of its market capitalization as of the date of delivery of the draw down notice once per calendar quarter and up to 1.25% of its market capitalization as of the date of delivery of the draw down notice for any additional draw downs during such calendar quarter and (y) the lesser of (a) 2.75% of its market capitalization as of the date of delivery of the draw down notice and (b) a number of shares determined by a formula based in part on the average trading volume and trading price of the Company's common stock prior to the delivery of the draw down notice issued by the Company with respect to that draw down pricing period, subject to certain conditions, including a minimum share price threshold of \$1.00. Kingsbridge may purchase shares of common stock pursuant to the CEFF at discounts ranging from 5 to 10 percent, depending on the average market price of the Company's common stock during the applicable pricing period for a draw down. As of September 30, 2010, the Company had not issued any shares under the CEFF.

**Table of Contents**

**NEUROCRINE BIOSCIENCES, INC.**

**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(unaudited)**

**11. SIGNIFICANT COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENTS**

In June 2010, the Company announced an exclusive worldwide collaboration with Abbott International Luxembourg S.à r.l. (Abbott) to develop and commercialize elagolix and all next-generation gonadotropin-releasing hormone (GnRH) antagonists (collectively, GnRH Compounds) for women's and men's health. Abbott made an upfront payment of \$75 million and agreed to make additional development, regulatory and commercial milestone payments of up to approximately \$530 million. Under the terms of the agreement, Abbott is responsible for all third-party development, marketing and commercialization costs. The Company received funding for certain internal collaboration expenses which includes reimbursement from Abbott for internal and external expenses related to the GnRH Compounds, and reimbursement of up to approximately \$24 million in personnel funding through the end of 2012. The Company will be entitled to a percentage of worldwide sales of GnRH Compounds for the longer of 10 years or the life of the related patent rights. Abbott may terminate the collaboration at its discretion upon 180-days written notice to the Company. In such event, the Company would be entitled to specified payments for ongoing clinical development and related activities and all GnRH Compound product rights would revert to the Company. As of September 30, 2010, the Company had recorded revenues of \$9.7 million in amortization of up-front license fees and \$6.0 million in sponsored development. In addition, at September 30, 2010 the Company had \$65.3 million of deferred revenue related to the Abbott agreement, which is being amortized over the collaborative development period.

Also in June 2010, the Company announced a worldwide collaboration with Boehringer Ingelheim International GmbH (Boehringer Ingelheim) to research, develop and commercialize small molecule GPR119 agonists for the treatment of Type II diabetes and other indications. Under the terms of the agreement, the Company and Boehringer Ingelheim will work jointly to identify and advance GPR119 agonist candidates into pre-clinical development. Boehringer Ingelheim will then be responsible for the global development and commercialization of potential GPR119 agonist products. The Company received a \$10 million upfront payment, is currently receiving research funding to support discovery efforts and is eligible to receive up to approximately \$225 million in development, regulatory and commercial milestone payments. The Company will be entitled to a percentage of any future worldwide sales of GPR119 agonists. Boehringer Ingelheim may terminate the agreement at its discretion upon prior written notice to the Company. In such event, the Company may be entitled to specified payments and all product rights would revert to the Company. As of September 30, 2010, the Company had recorded revenues of \$1.5 million in amortization of up-front license fees and \$0.4 million in sponsored research. At September 30, 2010, the Company had \$8.5 million of deferred license fees that will be amortized over the collaborative research period of the agreement.

Revenues under collaborative research agreements are recognized as research 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, 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. Upfront, nonrefundable payments for license fees, grants, 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.

**12. REAL ESTATE**

In December 2007, the Company closed the sale of its facility and associated real property for a purchase price of \$109.0 million. Concurrent with the sale, the Company retired the entire \$47.7 million in mortgage debt previously outstanding with respect to the facility and associated real property, and received cash of \$61.0 million net of transaction costs and debt retirement. Upon the closing of the sale of the facility and associated real property, the Company entered into a lease agreement (Lease) with DMH Campus Investors, LLC (DMH) whereby it leased back, for an initial term of 12 years, its corporate headquarters comprised of two buildings located at 12790 El Camino Real (Front Building) and 12780 El Camino Real (Rear Building) in San Diego, California. The Company entered into a first lease amendment (First Lease Amendment) in December 2008 and a second lease amendment (Second Lease Amendment) in September 2009 (collectively, Amendments).

## Edgar Filing: NEUROCRINE BIOSCIENCES INC - Form 10-Q

The Lease has been characterized as an operating lease for financial reporting purposes.

In accordance with ASC 840-40, *Sale-Leaseback Transactions*, and ASC 360-20, *Real Estate Sales*, the Company initially deferred the gain on the sale of its facility and associated real property due to a repurchase right. The Company initially established a long-term liability of \$108.7 million upon the close of the transaction, which represented the gross proceeds from the real estate sale. The First Lease Amendment terminated the repurchase right and the Company removed from its balance sheet the long-term liability of \$108.7 million and the previously conveyed real estate related assets of \$69.6 million during the fourth quarter of 2008. Additionally, the Company began to recognize the deferred gain of \$39.1 million on the sale of the real estate over the remaining term of the Lease. The Company has recognized approximately \$0.7 million per

**Table of Contents**

**NEUROCRINE BIOSCIENCES, INC.**

**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(unaudited)**

quarter of deferred gain in 2009 and 2010, and has recognized \$2.1 million of the deferred gain in both of the nine-month periods ended September 30, 2010 and 2009. The Company will continue to recognize the balance of the deferred gain over the remaining term of the Lease.

Under the terms of the Lease and the Amendments, the Company pays base annual rent (subject to an annual fixed percentage increase), plus a 3.5% annual management fee, property taxes and other normal and necessary expenses associated with the Lease such as utilities, repairs and maintenance, etc. In lieu of a cash security deposit under the Lease, Wells Fargo Bank, N.A. issued on the Company's behalf a letter of credit in the amount of \$5.7 million. The letter of credit is secured by a deposit of \$6.3 million with the same bank. The Company has the right to extend the Lease for two consecutive ten-year terms and will have the first right of refusal to lease, at market rates, any facilities built on the vacant lot included in the real property sold by the Company. The terms of the Lease also require that the Company maintains \$50.0 million in cash and investments at all times, or increase the security deposit by \$5.0 million.

In December 2008, the Company entered into the First Lease Amendment which provided for the renovation of the Front Building in a manner that facilitates multiple tenant usage and establishes a mechanism for the Company to terminate its use of the Front Building. The Company continues to occupy the Rear Building.

Pursuant to the terms of the First Lease Amendment, the Company is obligated to reimburse the landlord for the total cost of renovating a portion of the Front Building such that the Front Building becomes suitable for multiple tenant usage. The Company made a one-time payment of \$1.0 million toward renovation costs in January 2009 and is reimbursing the landlord for the balance of the renovation costs over a four-year period through an increase in monthly rental payments (currently estimated at \$108,000 per month) which began in October 2008.

As a result of signing the First Lease Amendment and physically vacating the Front Building, the Company triggered a cease-use date for the Front Building and has estimated lease termination costs in accordance with ASC 420-10, *Exit or Disposal Cost Obligations*. Estimated lease termination costs for the Front Building under the First Lease Amendment included the net present value of future minimum lease payments, taxes, insurance, construction, and maintenance costs from the cease-use date to the end of the Lease net of estimated sublease rental income. During the fourth quarter of 2008, the Company recorded an expense of \$15.7 million for the net present value of these estimated lease termination costs, of which \$0.3 million was paid in 2008. During 2009, the Company increased the liability by \$6.0 million in response to the declining economic conditions in San Diego by extending the expected period to lease the Front Building.

In September 2009, the Company and DMH entered into the Second Lease Amendment. The Second Lease Amendment obligated the Company to vacate the Front Building and make an immediate payment of \$4.0 million to DMH as an initial release fee, which was paid in October 2009. The Company continues to occupy the entire Rear Building. Upon payment of the initial release fee, the Company was released from its obligations with respect to the Front Building, except with respect to 1) certain indemnity obligations for events prior to the payment of the initial release fee, 2) certain operating expenses for the Front Building in accordance with the terms of the Lease through July 2011, and 3) 50% of tenant improvement costs between \$65 and \$100 per square foot in connection with initial leases between DMH and other third parties for space in the Front Building. As of December 31, 2009, the Company had completely satisfied its obligation with respect to payment of tenant improvement costs. Pursuant to the Second Lease Amendment, the Company is also obligated to pay DMH an amount equivalent to the rent on the Front Building through July 2011 and then approximately \$44,000 per month beginning in August 2011 through December 2019 as a rent differential payment for the Front Building, which such rent differential amounts may be prepaid by the Company in its sole discretion. Should the Company be in monetary default under the Lease beyond the normal cure periods and prior to repaying the entire rent differential balance, the rent differential payment will double.

The changes to the accrued liability for lease termination costs since initial recognition are as follows (in millions):

|                                                                 |         |
|-----------------------------------------------------------------|---------|
| Initial cease-use expense recognized for lease termination cost | \$ 15.7 |
| Cash payments for lease termination costs during the period     | (0.3)   |

# Edgar Filing: NEUROCRINE BIOSCIENCES INC - Form 10-Q

|                                                                   |         |
|-------------------------------------------------------------------|---------|
| Accrued lease termination costs at December 31, 2008              | \$ 15.4 |
| Lease termination costs incurred during the period                | 6.0     |
| Cash payments for lease termination costs during the period       | (9.9)   |
| Accrued lease termination costs at December 31, 2009              | \$ 11.5 |
| Lease termination costs net present value accretion during period | 0.4     |
| Cash payments for lease termination costs during the period       | (3.4)   |
| Accrued lease termination costs at September 30, 2010             | \$ 8.5  |



**Table of Contents**

**NEUROCRINE BIOSCIENCES, INC.**

**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(unaudited)**

**13. EARNINGS (LOSS) PER COMMON SHARE**

The Company computes net income (loss) per share in accordance with ASC 260-20, *Earnings Per Share* (ASC 260-20). Under the provisions of ASC 260-20, basic net 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 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 exercise of stock options and warrants and the vesting of RSUs, are excluded from historical diluted loss per share because of their anti-dilutive effect. Potentially dilutive securities were less than 0.1 million for the three months ended September 30, 2009 and for the nine month periods ended September 30, 2010 and 2009. For the third quarter of 2010, the Company realized net income of \$3.3 million. This resulted in the addition of 804,000 of potentially dilutive securities, consisting of employee equity awards, to the total diluted shares outstanding used in the calculation of net income per common share for the three months ended September 30, 2010.

**14. COMPREHENSIVE INCOME (LOSS)**

Comprehensive income (loss) is calculated in accordance with ASC 220-10, *Comprehensive Income* (ASC 220-10). ASC 220-10 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 available-for-sale investments. For the three months ended September 30, 2010 and 2009, comprehensive income (loss) was \$3.3 million and \$(8.0) million, respectively. For the nine months ended September 30, 2010 and 2009, comprehensive loss was \$11.0 million and \$40.3 million, respectively.

**15. RESEARCH AND DEVELOPMENT**

Research and development (R&D) expenses are recognized as incurred and include related salaries, contractor fees, clinical trial costs, facilities costs, administrative expenses and allocations of certain other costs. 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 at other companies and research institutions under agreements, which are generally cancelable. The Company reviews and accrues clinical trial expenses based on work performed, a method that relies on estimates of total costs incurred based on patient enrollment, completion of patient studies and other events. The Company follows this method since 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.

---

**Table of Contents**

**NEUROCRINE BIOSCIENCES, INC.**

**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(unaudited)**

**16. INCOME TAXES**

The Company adopted the provisions of ASC 740-10, *Income Taxes* (ASC 740-10) on January 1, 2007. There were no unrecognized tax benefits as of the date of adoption. As a result of the implementation of ASC 740-10, the Company did not recognize an increase in the liability for unrecognized tax benefits. There are no unrecognized tax benefits included in the Company's balance sheet as of September 30, 2010 that would, if recognized, affect the effective tax rate.

The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties on the Company's balance sheets at December 31, 2009 and at September 30, 2010, and has not recognized interest and/or penalties in the statement of operations for the first nine months of 2010.

The Company is subject to taxation in the United States and various state jurisdictions. The Company's tax years for 1993 and forward are subject to examination by the United States and California tax authorities due to the carryforward of unutilized net operating losses and R&D credits.

At January 1, 2010, the Company had net deferred tax assets of \$61.4 million. Due to uncertainties surrounding the Company's ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset the net deferred tax assets. Additionally, the future utilization of the Company's net operating loss and research and development credit carryforwards to offset future taxable income may be subject to a substantial annual limitation, pursuant to Internal Revenue Code Sections 382 and 383, as a result of ownership changes that may have occurred previously or that could occur in the future. Although the Company determined that an ownership change had not occurred through January 31, 2007, it is possible that an ownership change occurred subsequent to that date. The Company is in the process of completing an update of its Section 382 analysis subsequent to January 31, 2007. Until this analysis has been completed, the Company has removed the deferred tax assets for net operating losses of \$253.7 million and research and development credits of \$42.0 million generated through 2009 from its deferred tax asset schedule and has recorded a corresponding decrease to its valuation allowance. Due to the existence of the full valuation allowance, future changes in the Company's unrecognized tax benefits will not impact the Company's effective tax rate.

**17. SUBSEQUENT EVENTS**

The Company evaluated all subsequent events that have occurred after the date of the accompanying financial statements and determined that there were no events or transactions occurring during this subsequent event reporting period which require recognition or disclosure in the Company's financial statements.

## **Table of Contents**

### **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, 2009 and the three and six months ended March 31 and June 30, 2010, respectively, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, which are contained in our Annual Report on Form 10-K for the year ended December 31, 2009 and our Quarterly Reports on Form 10-Q for the three and six months ended March 31 and June 30, 2010, respectively.*

### **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 endometriosis, anxiety, depression, pain, diabetes, irritable bowel syndrome, insomnia and other neurological and endocrine related diseases and disorders. To date, we have not generated any revenues from the sale of products. We have funded our operations primarily through private and public offerings of our common stock and payments received under research and development agreements. We are developing certain products with corporate collaborators and intend to rely on existing and future collaborators to meet funding requirements. We expect to generate future net losses due to increases in operating expenses as product candidates are advanced through the various stages of clinical development. As of September 30, 2010, we had an accumulated deficit of \$764.8 million and expect to incur operating losses in the near future, which may be greater than losses in prior years. 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 collaborations for four of our programs.

In June 2010, we announced an exclusive worldwide collaboration with Abbott International Luxembourg S.à r.l. (Abbott) to develop and commercialize elagolix and all next-generation GnRH antagonists (collectively, GnRH Compounds) for women's and men's health. Abbott made an upfront payment of \$75 million and agreed to make additional development, regulatory and commercial milestone payments of up to approximately \$530 million. Under the terms of the agreement, Abbott is responsible for all third-party development, marketing and commercialization costs. We receive funding for certain internal collaboration expenses which includes reimbursement from Abbott for internal and external expenses related to the GnRH Compounds, and reimbursement of up to approximately \$24 million in personnel funding through the end of 2012. We will be entitled to a percentage of worldwide sales of GnRH Compounds for the longer of 10 years or the life of the related patent rights. Abbott may terminate the collaboration at its discretion upon 180-days written notice to us. In such event, we would be entitled to specified payments for ongoing clinical development and related activities and all GnRH Compound product rights would revert to us. As of September 30, 2010, we had recorded revenues of \$9.7 million in amortization of up-front license fees and \$6.0 million in sponsored development. In addition, at September 30, 2010 we had \$65.3 million of deferred revenue related to the Abbott agreement, which is being amortized over the collaborative development period.

Also in June 2010, we announced a worldwide collaboration with Boehringer Ingelheim International GmbH (Boehringer Ingelheim) to research, develop and commercialize small molecule GPR119 agonists for the treatment of Type II diabetes and other indications. Under the terms of the agreement, we will work jointly with Boehringer Ingelheim to identify and advance GPR119 agonist candidates into pre-clinical development. Boehringer Ingelheim will then be responsible for the global development and commercialization of potential GPR119 agonist products. We received a \$10 million upfront payment, are receiving research funding to support discovery efforts and are eligible to receive up to approximately \$225 million in development, regulatory and commercial milestone payments. We will be entitled to a percentage of any future worldwide sales of GPR 119 agonists. Boehringer Ingelheim may terminate the agreement at its discretion upon prior written notice to us. In such event, we may be entitled to specified payments and all product rights would revert to us. As of September 30, 2010, we had recorded revenues of \$1.5 million in license fees and \$0.4 million in sponsored research. At September 30, 2010 we had \$8.5 million of deferred license fees that will be amortized over the collaborative research period.

## **Table of Contents**

### **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 and grants, clinical trial accruals (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, 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. Upfront, nonrefundable payments for license fees, grants, 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 requires 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, grants and in-licensing arrangements. In addition, we fund R&D and clinical trials at other companies and research institutions under agreements, which are generally cancelable. We review and accrue clinical trials expense based on work performed, a method that relies on estimates of total costs incurred based on patient enrollment, completion of studies and other events. We follow this method since 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. Historically, revisions have not resulted in material changes to R&D costs; however a modification in the protocol of a clinical trial or cancellation of a trial could result in a charge to our results of operations.

In accordance with Accounting Standards Codification (ASC) 360-10-15, *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 asset, which is generally determined based on the present value of the expected future cash flows. We have determined that no impairment exists on our long-lived assets.

We grant stock options to purchase our common stock to our employees and directors under our 2003 Incentive Stock Plan, as amended (the 2003 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 (RSUs) under the 2003 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 ASC 718-10, *Compensation-Stock Compensation* (ASC 718-10). Share-based compensation expense recognized under ASC 718-10 for each of the three months ended September 30, 2010 and 2009 was \$0.9 million and \$1.7 million, respectively. Share-based compensation expense recognized under ASC 718-10 for each of the nine months ended September 30, 2010 and 2009 was \$2.3 million and \$4.6 million, respectively.

Stock option awards and RSUs generally vest over a three 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 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 ASC 718-10, and therefore individual share-based compensation awards may impact earnings disproportionately in any individual fiscal quarter.



## **Table of Contents**

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.

ASC 718-10 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.

### **THREE MONTHS ENDED SEPTEMBER 30, 2010 AND 2009**

Revenues for the third quarter of 2010 were \$14.4 million, compared to \$0.7 million for the same period in 2009. The increase in revenue is due to our recently executed collaboration agreements with Abbott and Boehringer Ingelheim, for our GnRH and GPR119 programs, respectively. During the third quarter of 2010 we recognized revenue of \$8.5 million from amortization of up-front license fees and \$5.2 million resulting from sponsored development reimbursement under these two agreements. During the third quarters of both 2010 and 2009, we recognized \$0.7 million in revenue under our collaboration agreement with Dainippon Sumitomo Pharma Co. Ltd (DSP) from amortization of up-front licensing fees.

Research and development expenses increased to \$8.2 million for the third quarter of 2010 compared with \$7.4 million for the respective period in 2009. Research and development personnel expenses increased by \$1.4 million in the third quarter of 2010 compared with the third quarter of 2009, primarily as a result of a one time company-wide bonus which resulted in approximately \$0.7 million in expense during the third quarter of 2010. Development costs decreased by \$0.2 million in the third quarter of 2010 compared to the same period in 2009 due to the timing of preclinical and clinical trials and depreciation expense decreased by \$0.4 million in the third quarter of 2010 compared to the same period in 2009.

General and administrative expenses were \$3.6 million for the third quarter of 2010 compared with \$3.0 million during the same period in 2009. This increase in general and administrative expenses is primarily due to a one time company-wide bonus which resulted in approximately \$0.5 million in expense during the third quarter of 2010.

Net income (loss) for the third quarter of 2010 was \$3.3 million, or \$0.06 per share, compared to \$(8.2) million, or \$(0.21) per share, for the same period in 2009. This increase in net earnings was primarily a result of the revenue recognized under our recently executed collaboration agreements with Abbott and Boehringer Ingelheim.

### **NINE MONTHS ENDED SEPTEMBER 30, 2010 AND 2009**

Revenues for the nine months ended September 30, 2010 were \$19.8 million, compared with \$2.2 million for the same period in 2009. The increase in revenue is due to our recently executed collaboration agreements with Abbott and Boehringer Ingelheim, for our GnRH and GPR119 programs, respectively. During the first nine months of 2010 we recognized revenue of \$11.1 million from amortization of up-front license fees and \$6.5 million resulting from sponsored development reimbursement under these two collaboration agreements. During both nine month periods ended September 30, 2010 and 2009, we recognized \$2.2 million in revenue under our collaboration agreement with DSP from amortization of up-front licensing fees.

Research and development expenses decreased to \$23.1 million for the first nine months of 2010 compared with \$29.1 million for the same period in 2009. Research and development personnel expenses decreased by \$4.0 million in the first nine months of 2010 compared to the first nine months of 2009, primarily as a result of our restructuring program in the second quarter of 2009. Additionally, laboratory costs decreased by \$0.7 million in the first nine months of 2010 compared to the same period in 2009 due to expense management efforts. Depreciation expense decreased by \$1.3 million in the first nine months of 2010 compared to the same period in 2009.

General and administrative expenses were \$10.0 million for the nine months ended September 30, 2010 compared with \$12.0 million during the same period in 2009. This decrease in general and administrative expenses is primarily due to our restructuring program implemented during the second quarter of 2009 and ongoing expense management efforts.



## **Table of Contents**

During the nine months ended September 30, 2009, we recognized additional cease-use expense under ASC 420-10, *Exit or Disposal Cost Obligations*, of \$5.9 million due to an estimated increase in construction costs, and a change in assumptions on the timing of tenant occupancy and rental rates for our corporate headquarters located at 12780 El Camino Real. See Note 12, Real Estate to the accompanying financial statements.

Other income was \$1.6 million during the first nine months of 2009 compared to \$3.1 million for the first nine months of 2010. This increase in income resulted primarily from a \$1.5 million loss from an other-than-temporary impairment recognized on auction rate securities in the first quarter of 2009.

Net loss for the first nine months of 2010 was \$10.5 million, or \$0.20 per share, compared to \$43.1 million, or \$1.11 per share, for the same period in 2009. This decrease in net loss was a result of the revenue recognized under the above mentioned collaboration agreements, our restructuring program implemented during the second quarter of 2009 and expense management efforts during the first nine months of 2010.

To date, our revenues have been derived primarily from funded research and development, achievements of milestones under corporate collaborations, and licensing of product candidates. The nature and amount of these revenues from period to period may lead to substantial fluctuations in our quarterly revenues and earnings. Accordingly, results and earnings for one period are not predictive of future periods. Collaborations accounted for 100% of our revenue for the three and nine months ended September 30, 2010 and 2009.

We expect to incur operating losses for the foreseeable future because of the expenses we expect to incur related to progressing programs through our pipeline.

## **LIQUIDITY AND CAPITAL RESOURCES**

At September 30, 2010, our cash, cash equivalents, and investments totaled \$135.2 million compared with \$59.9 million at December 31, 2009. The increase in cash and investment balances at September 30, 2010 resulted primarily from our recently executed collaboration agreements with Abbott for our GnRH program and Boehringer Ingelheim for our GPR119 program which included upfront payments of \$75.0 million and \$10.0 million, respectively. In addition, our public offering of common stock in March 2010 resulted in net proceeds of approximately \$21.4 million. These influxes of capital have been offset by operating losses of \$10.5 million in the first nine months of 2010.

Net cash provided by (used in) operating activities during the first nine months of 2010 was \$67.2 million compared with \$(39.1) million during the same period in 2009. The \$106.3 million change in cash provided by operating activities is primarily due to upfront payments from Abbott and Boehringer Ingelheim related to our partnering of our GnRH and GPR119 programs of \$75.0 million and \$10.0 million, respectively. Net loss for the first nine months of 2010 was \$10.5 million compared to \$43.1 million for the same period in 2009. This decrease in net loss was primarily due to our restructuring program implemented during the second quarter of 2009 and ongoing expense management efforts during the first nine months of 2010.

Net cash (used in) provided by investing activities during the first nine months of 2010 was \$(48.6) million compared to \$6.0 million for the first nine months of 2009. 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.

Net cash provided by financing activities during the first nine months of 2010 was \$21.4 million due to the net proceeds received on our public offering of common stock. No cash was utilized in or provided by financing activities during the first nine months of 2009.

We and DMH Campus Investors, LLC (DMH) are parties to a lease agreement, dated December 4, 2007, pursuant to which we lease our corporate headquarters, located at 12790 El Camino Real (Front Building) and 12780 El Camino Real (Rear Building) in San Diego, California (Lease). We entered into a first lease amendment (First Lease Amendment) in December 2008 and a second lease amendment (Second Lease Amendment) in September 2009 (collectively, Amendments).

Under the terms of the Lease and the Amendments, we pay base annual rent (subject to an annual fixed percentage increase), plus a 3.5% annual management fee, property taxes and other normal and necessary expenses associated with the Lease such as utilities, repairs and maintenance, etc. In lieu of a cash security deposit under the Lease, Wells Fargo Bank, N.A. issued on our behalf a letter of credit in the amount of \$5.7 million. The letter of credit is secured by a deposit of \$6.3 million with the same bank. We have the right to extend the Lease for two consecutive ten-year terms and will have the first right of refusal to lease, at market rates, any facilities built on the vacant lot included in the real property sold by us. The terms of the Lease also require that we maintain \$50.0 million in cash and investments at all times, or increase our



security deposit by \$5.0 million.

## **Table of Contents**

In December 2008, we entered into the First Lease Amendment which provided for the renovation of the Front Building in a manner that facilitates multiple tenant usage and establishes a mechanism for us to terminate our use of the Front Building. We continue to occupy the Rear Building.

Pursuant to the terms of the First Lease Amendment, we are obligated to reimburse the landlord for the total cost of renovating a portion of the Front Building such that the Front Building becomes suitable for multiple tenant usage. We made a one-time payment of \$1.0 million toward renovation costs in January 2009 and are reimbursing the landlord for the balance of the renovation costs over a four-year period through an increase in monthly rental payments (currently estimated at \$108,000 per month) which began in October 2008.

In September 2009, we and DMH entered into the Second Lease Amendment. The Second Lease Amendment obligated us to vacate the Front Building and make an immediate payment of \$4.0 million to DMH as an initial release fee, which was paid in October 2009. We continue to occupy the entire Rear Building. Upon payment of the initial release fee, we were released from our obligations with respect to the Front Building, except with respect to 1) certain indemnity obligations for events prior to the payment of the initial release fee, 2) certain operating expenses for the Front Building in accordance with the terms of the Lease through July 2011, and 3) 50% of tenant improvement costs between \$65 and \$100 per square foot in connection with initial leases between DMH and other third parties for space in the Front Building. As of December 31, 2009, we had completely satisfied our obligation with respect to payment of tenant improvement costs. Pursuant to the Second Lease Amendment, we are also obligated to pay DMH an amount equivalent to the rent on the Front Building through July 2011 and then approximately \$44,000 per month beginning in August 2011 through December 2019 as a rent differential payment for the Front Building, which such rent differential amounts may be prepaid by us at our sole discretion. Should we be in monetary default under the Lease beyond the normal cure periods and prior to repaying the entire rent differential balance, the rent differential payment will double.

In September 2009, we entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge) pursuant to which Kingsbridge committed to purchase, subject to certain conditions, up to the lesser of 7.8 million newly issued shares of our common stock or an aggregate of \$75.0 million newly issued shares over the three-year term of the CEFF. We may access capital under the CEFF by making draw downs up to a maximum of the lesser of (i) \$15 million and (ii) the greater of (x) 1.75% of our market capitalization as of the date of delivery of the draw down notice once per calendar quarter and up to 1.25% of our market capitalization as of the date of delivery of the draw down notice for any additional draw downs during such calendar quarter and (y) the lesser of (a) 2.75% of our market capitalization as of the date of delivery of the draw down notice and (b) a number of shares determined by a formula based in part on the average trading volume and trading price of our common stock prior to the delivery of the draw down notice issued by us with respect to that draw down pricing period, subject to certain conditions, including a minimum share price threshold of \$1.00. Kingsbridge may purchase shares of common stock pursuant to the CEFF at discounts ranging from 5 to 10 percent, depending on the average market price of our common stock during the applicable pricing period for a draw down. As of September 30, 2010, we had not issued any shares under the CEFF.

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.

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, and any additional equity financings will be dilutive to our stockholders. Recently, the credit markets and the financial services industry have been experiencing a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the United States federal government. These events have generally made equity and debt financing more difficult to obtain. 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.

## **Table of Contents**

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.

### **INTEREST RATE RISK**

We are exposed to interest rate risk on our short and long 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 initial average maturity of our investments does not exceed 24 months. If a 10% change in interest rates had occurred on September 30, 2010, 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 and the nature of our investments, we have concluded that we do not have a material financial market interest rate risk exposure.

### **NEW ACCOUNTING PRONOUNCEMENTS**

In April 2010, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2010-17, *Revenue Recognition (Topic 605), Milestone Method of Revenue Recognition* (ASU 2010-17) and Accounting Standards Codification (ASC) Subtopic 605-28, *Revenue Recognition Milestone Method* (ASC 605-28), which covers research and development milestone recognition. This guidance is not required and does not represent the only acceptable method of revenue recognition. This guidance is effective for milestones achieved in fiscal years and interim periods beginning on or after June 15, 2010 and will not have a material impact on our results of operations as it is consistent with our historical practice of milestone revenue recognition.

In February 2010, the FASB issued amended guidance on subsequent events. Under this amended guidance, Securities and Exchange Commission (SEC) filers are no longer required to disclose the date through which subsequent events have been evaluated in originally issued and revised financial statements. This guidance was effective immediately and we adopted these new requirements upon issuance of this guidance.

In January 2010, the FASB issued ASU No. 2010-06, *Improving Disclosures about Fair Value Measurements* (ASU 2010-06). This guidance requires the disclosure of separate amounts of significant transfers in and out of Level 1 and Level 2 fair value measurements and the reason for such transfers. ASU 2010-06 also requires information related to purchases, sales, issuances, and settlements of Level 3 financial assets and liabilities to be presented separately in the reconciliation of fair value measurements for the period presented. In addition, ASU 2010-06 clarifies existing disclosure guidance with respect to the level of disaggregation for classes of financial assets and liabilities as well as valuation techniques and inputs used for both recurring and nonrecurring fair value measurements of Level 2 and Level 3 assets and liabilities. We have provided the additional required disclosures effective January 1, 2010.

### **FORWARD-LOOKING STATEMENTS**

This Quarterly Report on Form 10-Q and the information incorporated herein by reference contain forward-looking statements that involve a number of risks and uncertainties. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, these forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements.

Forward-looking statements can be identified by the use of forward-looking words such as believes, expects, hopes, may, will, plan, intends, estimates, could, should, would, continue, seeks, proforma, or anticipates, or other similar words (including their use in the negative). Discussions of future matters such as the development or regulatory approval of new products, technology enhancements, possible changes in legislation and other statements that are not historical. These statements include but are not limited to statements under the captions Risk Factors, and Management's Discussion and Analysis of Financial Condition and Results of Operations as well as other sections in this report. You should be aware that the occurrence of any of the events discussed under the heading in Part II titled Item 1A. Risk Factors and elsewhere in this report could substantially harm our business, results of operations and financial condition and that if any of these events occurs, the trading price of our common stock could decline and you could lose all or a part of the value of your shares of our common stock.

The cautionary statements made in this report are intended to be applicable to all related forward-looking statements wherever they may appear in this report. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this report.

## Edgar Filing: NEUROCRINE BIOSCIENCES INC - Form 10-Q

Except as required by law, we assume no obligation to update our forward-looking statements, even if new information becomes available in the future.

---

**Table of Contents**

**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 SEC'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 decisions 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.

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 control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2009, other than the revisions to the risk factors set forth below with an asterisk (\*) next to the title. 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 clinical trials may fail to demonstrate the safety and efficacy of our product candidates, which could prevent or significantly delay their regulatory approval.***

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 our product candidates, we face the risks that:

the product candidate may not prove to be effective or as effective as other competing product candidates;

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

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

the U.S. Food and Drug Administration (FDA) may require use of new or experimental endpoints that may prove insensitive to treatment effects;

we or the FDA or similar foreign regulatory authorities may suspend the trials;

the results may not be statistically significant;

patient recruitment may be slower than expected;

patients may drop out of the trials; and

regulatory requirements may change.

## **Table of Contents**

These risks and uncertainties impact all of our clinical programs. Specifically, with respect to our GnRH program, if the modified wording of the non-menstrual pain and dysmenorrhea daily scales used in our *elagolix* Daisy PETAL Study (901 study) is not accepted by the FDA as the appropriate endpoint for *elagolix* Phase III clinical trials, additional Phase II trials will be necessary and the development of *elagolix* will be delayed or otherwise adversely affected. Similarly, while academic collaborative clinical trials are ongoing to evaluate the effects of our lead Corticotropin Releasing Factor (CRF1) receptor GSK561679 in Post Traumatic Stress Disorder, anxiety and alcoholism, the top-line efficacy and safety results from a Phase II clinical trial utilizing GSK561679 in patients experiencing a major depressive episode revealed no benefit of GSK561679 compared with placebo. Uncertainty regarding future development of indiplon is described below under the risk factor entitled *There is uncertainty regarding future development of our product candidate, indiplon, which may never receive regulatory approval or be commercialized.*

In addition, 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. Any failure or substantial delay in completing clinical trials for our product candidates may severely harm our business.

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

Our strategy for fully 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 active collaboration agreements with Abbott, Boehringer Ingelheim, GlaxoSmithKline and Dainippon Sumitomo Pharma Co. Ltd. and previously have had collaborations with Pfizer, Wyeth, Johnson & Johnson, Novartis, Taisho and Eli Lilly and Company. We historically have been dependent upon these corporate collaborators to provide adequate funding for a number of our programs, and our recently executed collaboration agreements with Abbott and Boehringer Ingelheim provide for, among other things, significant future payments should certain development, regulatory and commercial milestones be achieved. 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 our current corporate collaborators and to enter into new collaborations in the future, the development and commercialization of our programs would be substantially delayed, and our ability to receive future funding would be substantially impaired 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;

## Edgar Filing: NEUROCRINE BIOSCIENCES INC - Form 10-Q

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.

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.



## **Table of Contents**

*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 to commercialize or fail to achieve market acceptance.

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

*\*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, to conduct preclinical studies and clinical trials, for operating expenses and to pursue regulatory approvals for product candidates, for the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims, if any, product in-licensing and any possible acquisitions, and we may require additional funding to establish manufacturing and marketing capabilities in the future. We believe that our existing capital resources, together with investment 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 to the full extent currently 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, enforcing patent claims, or engaging in interference proceedings or other patent litigation;

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. For example, we have an effective shelf registration statement on file with the Securities and Exchange Commission (SEC) which allows us to issue shares of our common stock from time to time for an aggregate initial offering price of up to an additional \$117 million, and we have a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge) covering the potential sale of shares of our common stock for up to \$75 million in gross proceeds. In addition, we have previously financed capital purchases and may continue to pursue opportunities to obtain additional debt financing in the future. Recently, the credit markets and the financial services industry have been experiencing a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the United States federal government. These events have generally made equity and debt financing more difficult to obtain. Accordingly, additional equity or debt financing might not be available on reasonable terms, if at all. Any additional equity financings, including funds raised under the CEFF, will be dilutive to our stockholders and any additional debt financings may involve operating covenants that restrict our business.

## Table of Contents

***\*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 \$51.0 million and \$88.6 million for the years ended December 31, 2009 and 2008, respectively. As a result of ongoing operating losses, we had an accumulated deficit of \$754.3 million as of December 31, 2009. Despite having net income of \$3.3 million for the quarter ended September 30, 2010, we do not expect to be profitable for the year ending December 31, 2010 or for the foreseeable future.

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;

develop, formulate, manufacture and commercialize our product candidates;

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 on an annual basis. We may not be able to generate these revenues, and we may never achieve profitability on an annual basis in the future. Our failure to achieve or maintain profitability on an annual basis could negatively impact the market price of our common stock. Even if we become profitable on an annual basis, we cannot assure you that we would be able to sustain or increase profitability on an annual basis.

***The CEFF that we entered into with Kingsbridge may not be available to us if we elect to make a draw down, may require us to make additional blackout or other payments to Kingsbridge, could cause our stock price to decline and may result in dilution to our stockholders.***

The CEFF entitles us to sell and obligates Kingsbridge to purchase, from time to time over a period of three years, newly issued shares of our common stock up to the lesser of an aggregate of approximately 7.8 million shares or \$75 million, subject to certain conditions and restrictions. Kingsbridge will not be obligated to purchase shares under the CEFF unless certain conditions are met, which include a minimum price for our common stock; the accuracy of representations and warranties made to Kingsbridge; compliance with laws; effectiveness of the registration statement filed by us with the SEC with respect to the CEFF; and the continued listing of our stock on the NASDAQ Global Select Market or other specified markets. In addition, Kingsbridge is permitted to terminate the CEFF if it obtains actual knowledge that a material and adverse event has occurred affecting our business, operations, properties or financial condition. If we are unable to access funds through the CEFF, or if the CEFF is terminated by Kingsbridge, we may be unable to access capital on favorable terms or at all.

We are entitled, in certain circumstances, to deliver a blackout notice to Kingsbridge to suspend the registration statement filed by us with the SEC with respect to the CEFF and prohibit Kingsbridge from selling shares. If we deliver a blackout notice in the 15 calendar days following the settlement of a draw down, or if the registration statement is not effective in circumstances not permitted by the registration rights agreement, then we must make a payment to Kingsbridge, calculated on the basis of the number of shares held by Kingsbridge acquired by way of the most recent drawdown prior to the blackout notice and actually held by Kingsbridge multiplied by the change in the market price of our common stock during the period in which the use of the registration statement is suspended. If the trading price of our common stock declines during a

## Edgar Filing: NEUROCRINE BIOSCIENCES INC - Form 10-Q

suspension of the registration statement, the blackout or other payment could be significant.

Should we continue to sell shares to Kingsbridge under the CEFF, or issue shares in lieu of a blackout payment, it will have a dilutive effect on the holdings of our current stockholders, and may result in downward pressure on the price of our common stock. If we draw down under the CEFF, we will issue shares to Kingsbridge at a discount of up to 10 percent from the volume weighted average price of our common stock. If we draw down amounts under the CEFF when our share price is decreasing, we will need to issue more shares to raise the same amount than if our stock price was higher. Issuances in the face of a declining share price will have an even greater dilutive effect than if our share price were stable or increasing, and may further decrease our share price.

## **Table of Contents**

*There is uncertainty regarding future development of our product candidate, indiplon, which may never receive regulatory approval or be commercialized.*

On December 12, 2007 we received an action letter from the FDA stating that indiplon 5mg and 10mg capsules are approvable (2007 FDA Approvable Letter). The 2007 FDA Approvable Letter acknowledged that our resubmitted NDA for indiplon 5mg and 10mg capsules had addressed the issues raised in a previous approvable letter, but set forth new requirements. The new requirements set forth in the 2007 FDA Approvable Letter are the following: (i) an objective/subjective clinical trial in the elderly, (ii) a safety study assessing the rates of adverse events occurring with indiplon when compared to a marketed product and (iii) a preclinical study to evaluate indiplon administration during the third trimester of pregnancy. After receipt of the 2007 FDA Approvable Letter, we ceased all indiplon clinical development activities in the United States as well as all pre-commercialization activities. We met with the FDA in July 2008 to discuss the 2007 FDA Approvable Letter. We have not received the final minutes of this meeting. We are currently evaluating various alternatives for the indiplon program.

The process of preparing and resubmitting the NDA for indiplon would require significant resources and could be time consuming and subject to unanticipated delays and cost. As a result of the 2007 FDA Approvable Letter, there is a significant amount of uncertainty regarding the future development of indiplon. Should the NDA be refiled, the FDA could again refuse to approve the NDA, or could still require additional data analysis or clinical trials, which would require substantial expenditures by us and would further delay the approval process. Even if our indiplon NDA is 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 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. The FDA could also require a Risk Evaluation and Mitigation Strategy (REMS) program for indiplon that could limit the commercial success of the product. 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.

*\*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 \$2.00 per share to approximately \$9.00 per share. The market price of our common stock may fluctuate in response to many factors, including:

the results of our clinical trials;

developments concerning new and existing collaboration agreements;

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

general economic and market conditions;

developments in patent or other proprietary rights;

developments related to the FDA;

future sales of our common stock by existing stockholders (and Kingsbridge, if we elect to draw down under our CEFF with Kingsbridge);

comments by securities analysts;

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.

***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.

## **Table of Contents**

***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, Inc. In addition, we license some of the core technologies used in our research and development activities and collaborations from third parties, including the CRF receptor we license from The Salk Institute and use in our CRF<sub>1</sub> program, urocortin 2 which we license from Research Development Foundation, and the GnRH receptor we license from Mount Sinai School of Medicine and use in our *elagolix* program. If we were to default on our obligations under any of our licenses, we could lose some or all of our rights to develop, market and sell products covered by these licenses. 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.

***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.

***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 (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 may delay or prevent 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, and will continue to 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 develop or 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;

## Edgar Filing: NEUROCRINE BIOSCIENCES INC - Form 10-Q

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



## **Table of Contents**

drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the U.S. Drug Enforcement Administration, and other 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.

***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. Our consultants 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 sustained 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.

## Edgar Filing: NEUROCRINE BIOSCIENCES INC - Form 10-Q

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, effective, superior and/or cost-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 laws, regulations and standards are subject to varying interpretations in some 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

## **Table of Contents**

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 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 these 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.

### ***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 endometriosis, anxiety, depression, pain, diabetes, irritable bowel syndrome, insomnia, and other neurological and 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.

---

**Table of Contents**

*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.

***\*Health care reform measures could adversely affect our business.***

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payers to contain or reduce the costs of health care. In the United States, comprehensive health care reform legislation was enacted by the Federal government and we expect that there will continue to be a number of federal and state proposals to implement government control over the pricing of prescription pharmaceuticals. In addition, increasing emphasis on reducing the cost of health care in the United States will continue to put pressure on the rate of adoption and pricing of prescription pharmaceuticals. Moreover, in some foreign jurisdictions, pricing of prescription pharmaceuticals is already subject to government control. We are currently unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect the recently enacted Federal healthcare reform legislation or any such additional legislation or regulation would have on our business. The pendency or approval of such proposals or reforms could result in a decrease in our stock price or limit our ability to raise capital or to enter into

## Edgar Filing: NEUROCRINE BIOSCIENCES INC - Form 10-Q

collaboration agreements for the further development and commercialization of our programs and products.

***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 collaborators with respect to technologies used in potential products. If a patent infringement suit were brought against us or our collaborators, we or our collaborators 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

## **Table of Contents**

collaborators rights to use its intellectual property. In such cases, we could be required to obtain 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 collaborators 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.

## **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 (3)
  - 3.5 Certificate of Amendment of Bylaws (4)
  - 3.6 Certificate of Amendment of Bylaws (5)
  - 4.1 Form of Common Stock Certificate (1)
  - 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 Annual Report on Form 10-K for the fiscal year ended December 31, 1997 filed on April 10, 1998
  - (4) Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed on August 9, 2004

## Edgar Filing: NEUROCRINE BIOSCIENCES INC - Form 10-Q

(5) Incorporated by reference to the Company's Current Report on Form 8-K filed on February 9, 2010

\* 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. The Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Report on Form 8-K, listed above, have a Commission File number of 000-22705.



**Table of Contents**

**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: October 29, 2010

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