MAP Pharmaceuticals, Inc.
Form 10-Q
November 08, 2011
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# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-Q

(MARK ONE)

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

**FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2011**

**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 001-33719**

# MAP PHARMACEUTICALS, INC.

**(Exact name of registrant as specified in its charter)**

| **Delaware** | **20-0507047** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification No.)** |

**2400 Bayshore Parkway, Suite 200**

| **Mountain View, California** | **94043** |
|---|---|
| **(Address of principal executive offices)** | **(Zip code)** |

**(650) 386-3100**

**(Registrant s telephone number, including area code)**

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

Indicate by check mark whether the registrant 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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x 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. (Check one):

| | | | |
|---|---|---|---|
| Large accelerated filer | ¨ | Accelerated filer | x |
| Non-accelerated filer | ¨ (Do not check if a smaller reporting company) | Smaller reporting company | ¨ |

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

As of October 31, 2011, the registrant had outstanding 30,497,188 shares of Common Stock.

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**PART I FINANCIAL INFORMATION**

**Item 1 Financial Statements**

**MAP PHARMACEUTICALS, INC.**

**(a development stage enterprise)**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

**(In thousands)**

**(Unaudited)**

| | September 30, 2011 | December 31, 2010 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 111,844 | $ 76,007 |
| Accounts receivable | 240 | |
| Prepaid expenses and other current assets | 675 | 644 |
| Total current assets | 112,759 | 76,651 |
| Property and equipment, net | 5,785 | 5,803 |
| Other assets | 27 | 30 |
| Restricted investment | 310 | 310 |
| Total assets | $ 118,881 | $ 82,794 |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,444 | $ 2,998 |
| Accrued liabilities | 6,171 | 9,442 |
| Debt | 1,690 | 7,581 |
| Current portion of deferred revenue | 11,748 | |
| Total current liabilities | 22,053 | 20,021 |
| Deferred revenue, less current portion | 6,715 | |
| Other liabilities | | 117 |
| Total liabilities | 28,768 | 20,138 |
| Commitments and contingencies (Note 6) | | |
| Stockholders equity: | | |
| Common stock | 299 | 296 |
| Additional paid-in capital | 309,193 | 301,924 |
| Deficit accumulated during the development stage | (219,379) | (239,564) |
| Total stockholders equity | 90,113 | 62,656 |
| Total liabilities and stockholders equity | $ 118,881 | $ 82,794 |

The accompanying notes are an integral part of these condensed consolidated financial statements.

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**MAP PHARMACEUTICALS, INC.**

**(a development stage enterprise)**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

**(In thousands, except per share amounts)**

**(Unaudited)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | | Period from July 3, 2003 (Inception) to September 30, 2011 |
|---|---|---|---|---|---|
| | 2011 | 2010 | 2011 | 2010 | |
| Collaboration revenue | $ 23,861 | $ | $ 61,536 | $ | $ 115,702 |
| Operating expenses: | | | | | |
| Research and development | 6,725 | 10,009 | 25,552 | 28,037 | 243,021 |
| Sales, general and administrative | 5,890 | 3,921 | 15,529 | 11,712 | 78,443 |
| Total operating expenses | 12,615 | 13,930 | 41,081 | 39,749 | 321,464 |
| Income (loss) from operations | 11,246 | (13,930) | 20,455 | (39,749) | (205,762) |
| Interest income | 6 | 5 | 58 | 11 | 6,463 |
| Interest expense | (43) | (284) | (316) | (1,016) | (7,309) |
| Other income (expense), net | (2) | 31 | (12) | 29 | (754) |
| Net income (loss) | 11,207 | (14,178) | 20,185 | (40,725) | (207,362) |
| Cumulative stock dividend attributed to preferred stockholders | | | | | (13,925) |
| Net income (loss) attributed to common stockholders | $ 11,207 | $ (14,178) | $ 20,185 | $ (40,725) | $ (221,287) |
| Net income (loss) per share attributed to common stockholders | | | | | |
| Basic | $ 0.37 | $ (0.53) | $ 0.67 | $ (1.55) | |
| Diluted | $ 0.35 | $ (0.53) | $ 0.64 | $ (1.55) | |
| Weighted average shares outstanding used in calculating net income (loss) per share attributed to common stockholders | | | | | |
| Basic | 30,440 | 26,629 | 30,329 | 26,323 | |
| Diluted | 31,611 | 26,629 | 31,605 | 26,323 | |

The accompanying notes are an integral part of these condensed consolidated financial statements.

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**MAP PHARMACEUTICALS, INC.**

**(a development stage enterprise)**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(In thousands)**

**(Unaudited)**

| | Nine Months Ended September 30, | | Cumulative Period from July 3, 2003 (Date of Inception) to September 30, 2011 |
|---|---|---|---|
| | 2011 | 2010 | |
| **Cash flows from operating activities:** | | | |
| Net income (loss) | $ 20,185 | $ (40,725) | $ (207,362) |
| Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities: | | | |
| Depreciation and amortization | 1,030 | 931 | 6,908 |
| Accretion of investment discounts, net | | | (1,595) |
| Accretion of debt payment premium | 64 | 199 | 999 |
| Stock-based compensation | 5,484 | 4,804 | 23,325 |
| Loss on disposal of equipment and other non-cash items | 11 | 306 | 2,269 |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | (240) | | (240) |
| Prepaid expenses and other current assets | (31) | 156 | (900) |
| Other assets | 3 | 83 | 113 |
| Accounts payable | (666) | (640) | 1,213 |
| Accrued liabilities | (3,355) | (3,072) | 6,007 |
| Deferred revenue | 18,463 | | 18,463 |
| Other liabilities | (33) | 33 | 84 |
| Net cash provided by (used in) operating activities | 40,915 | (37,925) | (150,716) |
| **Cash flows from investing activities:** | | | |
| Purchase of intangible assets and in-process research and development | | | (412) |
| Purchase of property and equipment | (911) | (1,976) | (12,432) |
| Purchase of short-term investments | | | (169,497) |
| Sales and maturities of short-term investments | | | 171,411 |
| Purchase of restricted investment | | | (310) |
| Net cash used in investing activities | (911) | (1,976) | (11,240) |
| **Cash flows from financing activities:** | | | |
| Proceeds from issuance of convertible notes payable | | | 4,300 |
| Proceeds from issuance of debt | | | 31,006 |
| Net Proceeds from issuance of common stock through equity plans | 1,786 | 1,681 | 6,008 |
| Repayment of debt | (5,955) | (5,394) | (30,415) |
| Proceeds from issuance of common stock resulting from drawdown of equity line of credit, net of issuance costs | | 19,654 | 19,653 |
| Proceeds from issuance of common stock in equity offerings, net of issuance costs | 2 | | 140,820 |
| Proceeds from issuance of convertible preferred stock, net of issuance costs | | | 102,428 |

| | | | |
|---|---|---|---|
| Net cash provided by (used in) financing activities | (4,167) | 15,941 | 273,800 |
| Net increase (decrease) in cash and cash equivalents | 35,837 | (23,960) | 111,844 |
| Cash and cash equivalents at beginning of period | 76,007 | 65,776 | |
| Cash and cash equivalents at end of period | $ 111,844 | $ 41,816 | $ 111,844 |
| **Supplemental disclosures of non-cash investing activities** | | | |
| Purchase of property and equipment through accounts payable | $ 112 | $ | $ 112 |

The accompanying notes are an integral part of these condensed consolidated financial statements.

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**MAP PHARMACEUTICALS, INC.**

**(a development stage enterprise)**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(Unaudited)**

**NOTE 1. THE COMPANY**

MAP Pharmaceuticals, Inc., incorporated in the state of Delaware, originally was formed as a limited liability company on July 3, 2003 and converted to a corporation on December 11, 2003. Our goal is to use proprietary inhalation technologies to enhance the therapeutic benefits and commercial attractiveness of proven drugs while minimizing risk by capitalizing on their known safety, efficacy and commercialization history. Our current focus is to advance the development of our product candidate, LEVADEX®, formerly known as MAP0004, a proprietary orally inhaled version of dihydroergotamine for the potential treatment of migraine. We are in the development stage and since inception have devoted substantially all of our efforts to research and development, raising capital and recruiting personnel.

We have incurred losses and negative cash flow since our inception in July 2003. We will continue to incur losses until we generate sufficient revenue to offset our expenses, and we anticipate that we may continue to incur net losses for the next several years. We will need substantial additional capital in the future in connection with the development and potential commercialization of LEVADEX and to fund the development and potential commercialization of any future product candidates. Prior to achieving profitable operations, we intend to continue to fund operations through public or private financings, strategic partnerships or other arrangements. Such funding, if needed, may not be available on favorable terms, if at all. In the event we are unable to obtain additional capital, we may delay or reduce the scope of our current research and development programs and other expenses.

**NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

***Basis of Presentation***

We have prepared the accompanying interim condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, these financial statements and accompanying notes do not include all of the information and disclosures required by generally accepted accounting principles for complete financial statements. The financial statements include all adjustments (consisting of normal recurring adjustments) that management believes are necessary for the fair statement of the balances and results for the periods presented. These interim financial statement results are not necessarily indicative of the results to be expected for the full fiscal year or any future interim period.

The year-end condensed balance sheet at December 31, 2010 was derived from audited financial statements, but do not include all the disclosures required by accounting principles generally accepted in the United States. The financial statements and related disclosures have been prepared with the presumption that users of the interim financial statements have read or have access to the audited financial statements for the preceding fiscal year. Accordingly, these financial statements should be read in conjunction with the audited financial statements and notes thereto contained in our Form 10-K for the year ended December 31, 2010.

***Revenue Recognition***

We recognize revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or determinable; and collectability is reasonably assured. Determination of whether persuasive evidence of an arrangement exists and whether delivery has occurred or services have been rendered are based on management s judgments regarding the fixed nature of the fee charged for deliverables and milestones met, and the collectability of those fees. Should changes in conditions cause management to determine these criteria are not met for certain future transactions, revenue recognized for any reporting period could be adversely affected.

Collaboration revenue, which is earned under license agreements with third parties, may include nonrefundable license fees, cost reimbursements and contingent milestones.

Before January 1, 2011, we evaluated license arrangements with multiple elements in accordance with Accounting Standards Codification, or ASC, 605-25 *Revenue Recognition Multiple-Element Arrangements*. In October 2009, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2009-13 *Revenue Arrangements with Multiple Deliverables*, or ASU 2009-13, which amended the accounting standards for certain multiple element revenue arrangements to:

provide updated guidance on whether multiple elements exist, how the elements in an arrangement should be separated, and how the arrangement consideration should be allocated to the separate elements;

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require an entity to allocate arrangement consideration to each element based on a selling price hierarchy, also called the relative selling price method, where the selling price for an element is based on vendor-specific objective evidence ( VSOE ), if available; third-party evidence ( TPE ), if available and VSOE is not available; or the best estimate of selling price ( ESP ), if neither VSOE nor TPE is available; and

eliminate the use of the residual method and require an entity to allocate arrangement consideration using the selling price hierarchy.

The revenue allocated to each element is then recognized when the basic revenue recognition criteria are met for that element.

On January 1, 2011, we adopted ASU 2009-13 on a prospective basis. The new accounting standard for revenue recognition, if applied in the same manner to the year ended December 31, 2010, would not have any impact to total revenue and deferred revenue for that fiscal year as we did not have any collaboration revenue in fiscal 2010 or any deferred revenue as of December 31, 2010. The new accounting guidance for revenue recognition is not expected to have a significant effect on total net revenue in periods after initial adoption, although the impact on the timing of revenue will vary depending on the evaluation of the elements of any new arrangements.

VSOE is based on the price charged when the element is sold separately and is the price actually charged for that deliverable. We typically are not able to establish VSOE for the elements of a license arrangement because each arrangement is unique, an arrangement typically consists of multiple elements and we have limited history of entering into license arrangements.

When VSOE cannot be established, we attempt to establish the selling price of the elements of a license arrangement based on TPE. TPE is determined based on a competitor s price for similar deliverables when sold separately. We typically are not able to determine TPE for license arrangements, as they contain a significant level of differentiation such that the comparable pricing of a competitor s license arrangement with similar functionality cannot be obtained, and we are therefore unable to reliably determine what a similar competitor s license arrangement s selling price would be on a stand-alone basis.

When we are unable to establish the selling price of an element using VSOE or TPE, we use the best ESP in our allocation of the upfront payment. The objective of the best ESP is to determine the price at which we would transact a sale if the element of the license arrangement were sold on a stand-alone basis.

Our process for determining ESPs involves management s judgment. Our process considers multiple factors such as discounted cash flows, estimated direct expenses and other costs and available data, which may vary over time, depending upon the circumstances, and relate to each deliverable. If the circumstances underlying the factors considered change or should future circumstances lead us to consider additional factors, our ESP could change. If the estimated obligation period of one or more deliverables should change, the future amortization of the revenue would also change. We regularly review best ESP and maintain internal controls over the establishment and updates of the estimates.

The Allergan Agreements entered into in February 2011 contain multiple elements. An upfront payment was received upon execution of the Allergan Agreements. In accordance with ASU 2009-13, we evaluated whether there is stand-alone value for the deliverables and then allocated the upfront payment to each deliverable based upon the relative selling price of such deliverable. Significant deliverables are discussed below.

For the LEVADEX License deliverable, we determined the best estimate of selling price by using a discounted cash flow analysis. We conducted a cash flow analysis over the contractual period using forecasts for revenues and operating expenses, considering key factors such as overall market size, market share, growth rate, the competitive landscape, the regulatory environment and a discount rate. The cash flows are estimated over a significant future period of time for the contractual terms of the Allergan Agreements, which make our estimates subject to a high degree of uncertainty.

For the NDA Approval deliverable, we determined the best estimate of selling price by considering key factors such as the estimated costs in headcount, expenses related to the NDA and process validation required to perform the activities, based on our annual budget and estimated future forecasts. Obtaining approval of an NDA is a lengthy, expensive and uncertain process subject to regulation by the FDA. If there is a delay in the regulatory approval for LEVADEX, the future amortization of the deferred revenue could change on a prospective basis.

For the Manufacturing Process deliverable, we determined the best estimate of selling price by considering key factors such as estimated costs in headcount, manufacturing and process development operation required to perform the activities, based on our annual budget and estimated future forecasts, together with a market-based margin. We are dependent on numerous third parties for the manufacture of our product candidates and our supply chain and, if we experience problems with any of these suppliers, the manufacturing of our products could be delayed and the future amortization of the deferred revenue could change on a prospective basis.

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Revenue allocated to the LEVADEX License deliverable was recognized in the first quarter of 2011, and revenue allocated to the other deliverables was deferred and is being recognized on a straight-line basis over the estimated obligation periods.

We recognize a contingent milestone payment as revenue in its entirety upon our achievement of the milestone. A milestone is substantive if the consideration earned from the achievement of the milestone is consistent with performance required to achieve the milestone or the increase in value to the delivered item, relates solely to past performance and is reasonable relative to all of the other deliverables and payments within the arrangement.

***Pre-clinical Study and Clinical Trial Accruals***

We estimate our pre-clinical study and clinical trial expenses based on the services received pursuant to contracts with several research institutions and contract research organizations that conduct and manage pre-clinical studies and clinical trials on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven expenses and payment flows. Pre-clinical study and clinical trial expenses include the following:

- fees paid to contract research organizations, or CROs, in connection with pre-clinical studies;
- fees paid to CROs and investigative sites in connection with clinical trials; and
- fees paid to contract manufacturers and service providers in connection with the production and testing of active pharmaceutical ingredients and drug materials for use in pre-clinical studies and clinical trials.

Payments under some of these contracts depend on factors such as the milestones accomplished, successful enrollment of certain number of patients, site initiation and completion of clinical trial milestones. In accruing services fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, correspondence and status meetings with CROs and review of contractual terms. Our estimates are dependent on the timeliness and accuracy of data provided by our CROs and other vendors.

***Stock-Based Compensation***

Effective January 1, 2006, we adopted ASC 718 *Compensation Stock Compensation,* or ASC 718, using the prospective transition method, which requires the measurement and recognition of compensation expense for all stock-based payment awards granted, modified and settled to our employees and directors after January 1, 2006. Our financial statements reflect the impact of ASC 718. We chose the straight-line attribution method for allocating compensation costs and recognized the fair value of each stock option on a straight-line basis over the requisite service period.

For restricted stock units, or RSUs, with time-based vesting, the fair value for the RSUs is based on the closing price of our common stock on the date of grant. We measure compensation expense for these RSUs at fair value on the date of grant and recognize the expense over the expected vesting period.

For RSUs with performance-based vesting, the fair value was determined using the stock price of our common stock on the date of the grant. A probability assessment that performance goals will be achieved is made quarterly. The compensation expense is recognized over the vesting period, and is adjusted periodically for forfeiture rate and any changes to our probability assessment of the number of performance-based RSUs expected to vest as a result of our achievement of the performance goals.

***Comprehensive Income (loss)***

We report comprehensive income (loss) in accordance with ASC 220 *Reporting Comprehensive Income.* Components of other comprehensive income (loss), including unrealized gains (losses) on our available-for-sale securities, are included in total comprehensive loss.

For both of the three and nine months ended September 30, 2011 and 2010, there was no difference between net income (loss) and comprehensive income (loss).

***Net Income (loss) per Share***

Basic net income (loss) per common share and diluted net income (loss) per common share are presented in conformity with ASC 260 *Earnings per Share*, for all periods presented. Basic net income (loss) per share is computed by dividing net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Diluted net income (loss) per share is computed using the weighted average number of shares of common stock outstanding and potential shares assuming the dilutive effect of outstanding stock options, warrants, common stock issuable pursuant to our employee stock purchase plan, or ESPP, and RSUs with time-based vesting using the treasury stock method.

The following table presents the calculation of weighted average shares of common stock used in the computations of basic and diluted income (loss) per share amounts presented in the accompanying condensed consolidated statements of operations (in thousands, except share and per share amounts):

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| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2011 | 2010 | 2011 | 2010 |
| Net income (loss) attributed to common stockholders | $ 11,207 | $ (14,178) | $ 20,185 | $ (40,725) |
| Basic: | | | | |
| Weighted average common shares used in computing basic net income (loss) per common share | 30,439,769 | 26,629,481 | 30,328,717 | 26,323,425 |
| Basic income (loss) per common share | $ 0.37 | $ (0.53) | $ 0.67 | $ (1.55) |
| Diluted: | | | | |
| Weighted average common shares used in computing basic net income (loss) per common share | 30,439,769 | 26,629,481 | 30,328,717 | 26,323,425 |
| Add: Weighted average stock options | 1,157,647 | | 1,259,833 | |
| Add: Weighted average warrants | 12,956 | | 13,780 | |
| Add: Weighted average ESPP | 372 | | 1,393 | |
| Add: Weighted average RSUs with time-based vesting | 411 | | 998 | |
| Weighted average common shares used in computing diluted net income (loss) per common share | 31,611,155 | 26,629,481 | 31,604,721 | 26,323,425 |
| Diluted income (loss) per common share | $ 0.35 | $ (0.53) | $ 0.64 | $ (1.55) |

The following outstanding common stock options, RSUs with time-based vesting, RSUs with performance-based vesting, common stock issuable pursuant to our ESPP and warrants to purchase common stock were excluded from the computation of diluted net loss per share for the periods presented because including them would have had an anti-dilutive effect:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2011 | 2010 | 2011 | 2010 |
| Options to purchase common stock | 1,570,300 | 4,006,986 | 1,494,570 | 4,006,986 |
| RSUs with time-based vesting | 142,413 | | 9,406 | |
| RSUs with performance-based vesting | 39,250 | 98,000 | 39,250 | 98,000 |
| Common stock issuable pursuant to the ESPP | | 24,563 | | 24,563 |
| Warrants to purchase common stock | | 26,903 | | 26,903 |

***Recent Accounting Pronouncements***

In May 2011 the FASB and International Accounting Standards Board, or IASB, issued ASU No. 2011-04, *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs,* or ASU 2011-04. ASU 2011-04 created a uniform framework for applying fair value measurement principles for companies around the world and clarified existing guidance in US GAAP. ASU 2011-04 is effective for the first reporting annual period beginning after December 15, 2011 and shall be applied prospectively. We will adopt ASU 2011-04 in the first quarter of fiscal year 2012. We do not believe that the adoption of ASU 2011-04 will have a material impact on our condensed consolidated financial statements.

In June 2011 the FASB issued ASU No. 2011-05*, Comprehensive Income (ASC Topic 220): Presentation of Comprehensive Income,* or ASU 2011-05, which amends current comprehensive income guidance. This accounting update eliminates the option to present the components of other comprehensive income as part of the statement of shareholders equity. Instead, we must report comprehensive income in either a single continuous statement of comprehensive income which contains two sections, net income and other comprehensive income, or in two separate but consecutive statements. ASU 2011-05 will be effective for public companies during the interim and annual periods beginning after December 15, 2011 with early adoption permitted. We will adopt ASU 2011-05 in the first quarter of fiscal year 2012. We do not believe that the adoption of ASU 2011-05 will have a material impact on our condensed consolidated financial statements.

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**NOTE 3. LICENSE AND SUPPLY AGREEMENTS**

***Agreement with Allergan***

On January 28, 2011, we entered into a Collaboration Agreement (the Collaboration Agreement ) and a Co-Promotion Agreement (the Co-Promotion Agreement, and together with the Collaboration Agreement, the Allergan Agreements ) with Allergan, Inc., Allergan USA, Inc. and Allergan Sales, LLC (collectively, Allergan ). Pursuant to the terms of the Allergan Agreements, we have granted Allergan a co-exclusive license to market and promote LEVADEX®, our proprietary novel migraine therapy for delivery by inhalation, to neurologists and pain specialists in the United States in collaboration with us.

In July 2011, Allergan exercised its option to expand the Collaboration Agreement to include Canada for neurologists and pain specialists. Under the Allergan Agreements, we retain the right to market and promote LEVADEX to other physicians within the United States and Canada and also retain all rights to LEVADEX in all other countries. We and Allergan will each provide sales representatives and other sales support for such marketing and promotional efforts. The Allergan Agreements specify minimum annual sales detail requirements to be provided by each party, and establish maximum annual amounts of detailing costs that each party will be obligated to incur pursuant to a commercialization plan.

The parties will collaborate in the development of LEVADEX for the treatment of migraine in adolescents 12 to 18 years of age, and for at least one other indication. We may develop LEVADEX for certain other indications independently of the collaboration if Allergan does not agree to develop LEVADEX for such indications pursuant to the Allergan Agreements. We are responsible for manufacturing and supplying LEVADEX, and for distributing the product and recording product revenues from sales of LEVADEX resulting from the parties collaboration.

The parties share profits and losses resulting from the collaboration equally. We are solely responsible for payment of all remaining costs of obtaining regulatory approval of LEVADEX for the acute treatment of migraine in adults, except that if the U.S. Food and Drug Administration, or FDA, notifies us that additional development or manufacturing activities costing in excess of a certain threshold amount will be required for such regulatory approval, the parties will share any such excess costs. The parties generally share equally all other costs of developing LEVADEX under the Allergan Agreements, except that neither party shall be obligated for more than a certain threshold amount in a given year, or for more than a certain threshold amount in the aggregate, for development or manufacturing costs or expenses incurred by us for such activities.

The Collaboration Agreement may be terminated (i) by Allergan, at will, after first commercial sale of LEVADEX in the United States, upon 180 days prior written notice, (ii) by Allergan, upon written notice to us, if we receive a complete response letter or equivalent communication from the FDA, that Allergan determines will extend potential approval beyond a certain date or requires a certain minimum level of additional investment, (iii) by us, upon written notice to Allergan, if Allergan commercializes a competing product in the United States or Canada and (iv) by us, upon written notice to Allergan, if Allergan challenges or opposes patent rights licensed to Allergan pursuant to the Collaboration Agreement. Additionally, either party may terminate the Collaboration Agreement in the event of an uncured material breach. The Co-Promotion Agreement will terminate upon termination of the Collaboration Agreement.

In February 2011, Allergan paid us an upfront payment of $60.0 million, out of which $3.9 million and $41.5 million were recognized as collaboration revenue for the three and nine months ended September 30, 2011, respectively. The remaining $18.5 million is deferred and will be amortized as collaboration revenue over the estimated obligation periods.

During the third quarter ended September 30, 2011, the FDA accepted for filing our LEVADEX NDA. As a result, pursuant to the terms of our Collaboration Agreement with Allergan, we received a milestone payment of $20.0 million from Allergan. We have determined that the achievement of this milestone was substantive and we recorded the $20.0 million milestone payment as collaboration revenue on our condensed consolidated statements of operations for the three months ended September 30, 2011.

In addition to the $20.0 million milestone described above, under the terms of the Collaboration Agreement, we may also receive up to an additional $77.0 million in milestone payments, including a $50.0 million milestone for the first commercial sale associated with the initial indication (the acute treatment of migraine), $25.0 million in milestones for the achievement of certain FDA-approved product labeling in the United States and a $2.0 million milestone for regulatory approval of the initial indication for LEVADEX in Canada.

Sales, general and administrative expenses for the three and nine months ended September 30, 2011 were net of $0.2 million and $0.7 million, respectively, of costs reimbursed or reimbursable by Allergan under cost-sharing provisions in our Collaboration Agreement. Sales, general and administrative expenses for the cumulative period from July 3, 2003 (date of inception) to September 30, 2011 were net of $0.7 million of costs reimbursed or reimbursable by Allergan under cost-sharing provisions in our Collaboration Agreement.

***Agreement with Nektar***

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Under our June 2004 agreement, as amended, with Nektar Therapeutics UK Limited, or the Nektar Agreement, we were granted a worldwide, exclusive license, with a right to sublicense, under Nektar patents and know-how, to develop and commercialize any formulation of a form of dihydroergotamine for administration by inhalation using a device. We also agreed to pay royalties at specified rates based on net sales.

We paid $0 and $1.0 million for the three and nine months ended September 30, 2011, respectively. For the nine months ended September 30, 2011, we paid Nektar a milestone payment of $1.0 million as a result of entering into the Allergan Agreements, and recorded it as research and development expenses on our condensed consolidated statements of operations for the nine months ended September 30, 2011. We paid $0 for both the three and nine months ended September 30, 2010. We have paid $3.6 million for the cumulative period from July 3, 2003 (date of inception) to September 30, 2011. Either party may terminate the Nektar Agreement upon a material, uncured default of the other party. We may terminate the Nektar Agreement, with or without cause, at any time upon six months prior written notice.

**NOTE 4. FAIR VALUE MEASUREMENTS**

We adopted ASC 820, *Fair Value Measurements,* or ASC 820, as it relates to financial assets and financial liabilities. ASC 820 defines fair value, establishes a framework for measuring fair value in GAAP and expands disclosures about fair value measurements.

ASC 820 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. This standard is now the single source in GAAP for the definition of fair value, except for the fair value of leased property as defined in ASC 840 *Accounting for Leases,* which establishes a fair value hierarchy that distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs) and (2) an entity s own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs). The fair value hierarchy consists of three broad levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy under ASC 820 are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Directly or indirectly observable inputs as of the reporting date through correlation with market data, including quoted prices for similar assets and liabilities in active markets and quoted prices in markets that are not active. Level 2 also includes assets and liabilities that are valued using models or other pricing methodologies that do not require significant judgment since the input assumptions used in the models, such as interest rates and volatility factors, are corroborated by readily observable data from actively quoted markets for substantially the full term of the financial instrument.

Level 3: Unobservable inputs that are supported by little or no market activity and reflect the use of significant management judgment. These values are generally determined using pricing models for which the assumptions utilize management s estimates of market participant assumptions.

In determining fair value, we utilize valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible, as well as consider counterparty credit risk in our assessment of fair value.

The following is a summary of our cash, cash equivalents and restricted investment as of September 30, 2011 and December 31, 2010, respectively (in thousands):

| | As of September 30, 2011 | | |
|---|---|---|---|
| | Amortized Cost | Unrealized Gain (Loss) | Estimated Fair Value |

| | | | |
|---|---|---|---|
| Cash | $ 4,598 | $ | $ 4,598 |
| Certificates of deposit | 310 | | 310 |
| Money market funds | 107,246 | | 107,246 |
| | $ 112,154 | $ | $ 112,154 |

| | |
|---|---|
| Reported as: | |
| Cash and cash equivalents | $ 111,844 |
| Restricted investment | 310 |
| | $ 112,154 |

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| | As of December 31, 2010 | | |
|---|---|---|---|
| | Amortized Cost | Unrealized Gain (Loss) | Estimated Fair Value |
| Cash | $ 2,327 | $ | $ 2,327 |
| Certificates of deposit | 310 | | 310 |
| Money market funds | 73,680 | | 73,680 |
| | $ 76,317 | $ | $ 76,317 |
| Reported as: | | | |
| Cash and cash equivalents | | | $ 76,007 |
| Restricted investment | | | 310 |
| | | | $ 76,317 |

Our investment instruments are classified within Level 1 or Level 2 of the fair value hierarchy because they are valued using quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. The types of instruments that are generally classified within Level 1 of the fair value hierarchy include money market securities. The types of investments that are generally classified within Level 2 of the fair value hierarchy include U.S. government and agency securities, corporate debt securities and certificates of deposit.

As of September 30, 2011 and December 31, 2010, financial assets measured and recognized at fair value on a recurring basis and classified under the appropriate level of the fair value hierarchy as described above were as follows, respectively (in thousands):

| As of September 30, 2011 | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| Certificates of deposit | $ | $ 310 | $ | $ 310 |
| Money market funds | 107,246 | | | 107,246 |
| Total | $ 107,246 | | | |