MAP Pharmaceuticals, Inc.
Form 10-Q
November 06, 2012
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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, 2012

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, 2012, the registrant had outstanding 35,287,096 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, 2012	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 114,218	$ 98,816
Accounts receivable	448	636
Prepaid expenses and other current assets	579	763
Total current assets	115,245	100,215
Property and equipment, net	6,488	6,786
Other assets	27	27
Restricted investment	310	310
Total assets	$ 122,070	$ 107,338
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,461	$ 3,860
Accrued liabilities	7,447	6,933
Current portion of deferred revenue	3,512	3,349
Total current liabilities	12,420	14,142
Deferred revenue, less current portion	50,634	53,581
Other liabilities		63
Total liabilities	63,054	67,786
Commitments and contingencies (Note 6)		
Stockholders equity:		
Common stock	347	300
Additional paid-in capital	374,929	311,755
Deficit accumulated during the development stage	(316,260)	(272,503)
Total stockholders equity	59,016	39,552
Total liabilities and stockholders equity	$ 122,070	$ 107,338

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 COMPREHENSIVE INCOME (LOSS)

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from July 3, 2003 (Inception) to
	2012	2011	2012	2011	September 30, 2012
Collaboration revenue	$ 878	$ 20,837	$ 2,784	$ 22,232	$ 80,019
Operating expenses:					
Research and development	7,855	6,725	26,590	25,552	277,722
Sales, general and administrative	5,642	5,890	19,950	15,529	104,924
Total operating expenses	13,497	12,615	46,540	41,081	382,646
Income (loss) from operations	(12,619)	8,222	(43,756)	(18,849)	(302,627)
Interest income	6	1	58	6,469	
Interest expense	(43)		(316)	(7,309)	
Other expense, net	(3)	(2)	(2)	(12)	(776)
Net income (loss)	(12,622)	8,183	(43,757)	(19,119)	(304,243)
Cumulative stock dividend attributed to preferred stockholders					(13,925)
Net income (loss) attributed to common stockholders	$ (12,622)	$ 8,183	$ (43,757)	$ (19,119)	$ (318,168)
Net income (loss) per share attributed to common stockholders					
Basic	$ (0.38)	$ 0.27	$ (1.39)	$ (0.63)	
Diluted	$ (0.38)	$ 0.26	$ (1.39)	$ (0.63)	
Weighted average shares outstanding used in calculating net income (loss) per share attributed to common stockholders					
Basic	33,369	30,440	31,569	30,329	
Diluted	33,369	31,611	31,569	30,329	
Total comprehensive income (loss)	$ (12,622)	$ 8,183	$ (43,757)	$ (19,119)	$ (304,243)

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, 2012	2011	Cumulative Period from July 3, 2003 (Date of Inception) to September 30, 2012
Cash flows from operating activities:			
Net loss	$ (43,757)	$ (19,119)	$ (304,243)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	1,378	1,030	8,706
Accretion of investment discounts, net			(1,595)
Accretion of debt payment premium		64	999
Stock-based compensation	6,286	5,484	31,471
Loss on disposal of equipment and other non-cash items	177	11	2,461
Changes in operating assets and liabilities:			
Accounts receivable	188	(240)	(448)
Prepaid expenses and other current assets	184	(31)	(804)
Other assets		3	113
Accounts payable	(1,879)	424	1,247
Accrued liabilities	233	(3,355)	7,086
Deferred revenue	(2,784)	57,767	54,146
Other liabilities	(55)	(33)	8
Net cash provided by (used in) operating activities	(40,029)	42,005	(200,853)
Cash flows from investing activities:			
Purchase of intangible assets and in-process research and development			(412)
Purchase of property and equipment	(1,827)	(2,001)	(16,192)
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	(1,827)	(2,001)	(15,000)
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	1,128	1,786	7,839
Repayment of debt		(5,955)	(32,105)
Proceeds from issuance of common stock resulting from drawdown of equity line of credit, net of issuance costs			19,653
Proceeds from issuance of common stock in equity offering, net of issuance costs	56,130	2	196,950

Proceeds from issuance of convertible preferred stock, net of issuance costs			102,428
Net cash provided by (used in) financing activities	57,258	(4,167)	330,071
Net increase in cash and cash equivalents	15,402	35,837	114,218
Cash and cash equivalents at beginning of period	98,816	76,007	
Cash and cash equivalents at end of period	$ 114,218	$ 111,844	$ 114,218
Supplemental disclosures of non-cash investing activities			
Purchase of property and equipment through accounts payable	$ 135	$ 112	$ 135
Deferred offering cost in accrued liability	$ 273	$	$ 273
Deferred offering cost in accounts payable	$ 50	$	$ 50

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 enhance the therapeutic benefits and commercial attractiveness of proven drugs in the field of neurology, while minimizing risk by capitalizing on their known safety, efficacy and commercialization history, by applying our proprietary formulation and inhalation technologies. 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 programs and other expenses.

In May 2011 we submitted our New Drug Application, or NDA, for LEVADEX to the U.S. Food and Drug Administration, or FDA. The FDA reviewed our NDA and on March 26, 2012, we received a Complete Response letter, in which the FDA described the reasons it was unable to approve our NDA and identified issues that we need to address in order to obtain approval of LEVADEX. Specifically, the FDA requested that we address issues relating to the chemistry, manufacturing and controls, or CMC, of LEVADEX. The FDA also stated that manufacturing deficiencies identified during a recent facility inspection of one of our third party manufacturers needed to be resolved to the FDA s satisfaction. The FDA also indicated that it had not been able to complete its review of inhaler usability information requested late in the review cycle by the FDA. We have worked to address the issues identified in the Complete Response letter. We resubmitted the NDA for LEVADEX in October 2012.

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 consolidated balance sheet at December 31, 2011 was derived from audited financial statements, and does 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, 2011.

Reclassifications

Certain prior period amounts in the condensed consolidated statements of cash flows have been reclassified to conform to current period presentation. Such reclassification did not impact our net income (loss) or financial position.

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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. 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;
- 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 has not had 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 standalone basis.

When we are unable to establish the selling price of an element using VSOE or TPE, we use the ESP in our allocation of the upfront payment. The objective of the ESP is to determine the price at which we would transact a sale if the element of the license arrangement were sold on a standalone 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 estimated obligation period of one or more deliverables should change, the future amortization of the revenue would also change. We regularly review ESP and maintain internal controls over the establishment and updates of the estimates.

We entered into a Collaboration Agreement with Allergan, Inc. in January 2011 which requires us to provide multiple deliverables, including: a license to commercialize LEVADEX, clinical and regulatory work necessary for FDA approval of the first indication for LEVADEX (acute treatment of migraine in adults), manufacturing process development for LEVADEX, an option to include Canada in the territory in which

Allergan can promote LEVADEX, and participation in various committees jointly with Allergan throughout the term of the Collaboration Agreement. These deliverables are non-contingent in nature. We received an upfront cash payment of $60.0 million from Allergan upon execution of the Collaboration Agreement. In accordance with ASU 2009-13, we evaluated whether there is standalone value for each of the various non-contingent deliverables. We have determined that the license delivered by us and other non-contingent deliverables do not have standalone value separate from each other, based on contractual limitations in the Collaboration Agreement that restrict Allergan from using the license for its intended purpose without other non-contingent deliverables from us.

We believe that since the license does not have standalone value, it must be combined with all the remaining non-contingent deliverables because the license would not be fully delivered for its intended purpose unless we continue to perform our obligation to participate in the various committees jointly with Allergan. Accordingly, all of the non-contingent deliverables are treated as a single unit of accounting, and we have combined the delivered license with the remaining non-contingent deliverables for accounting purposes. As a result, revenue relating to the $60.0 million upfront cash payment was deferred and will be recognized on a straight-line basis over the term of the Collaboration Agreement through 2028, which represents the estimated obligation period of the participation in the various joint committees, the non-contingent deliverable with the longest term.

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The Collaboration Agreement also contains contingent deliverables that do not relate to the non-contingent deliverables identified above. For example, we will collaborate and share expenses with Allergan to develop LEVADEX for additional indications separate from and in addition to the first indication. Any reimbursements from Allergan to us for shared expenses relating to contingent deliverables are recorded in our financial statements in the quarters in which the cost sharing occurs.

Milestone payments relating to contingent deliverables, such as the acceptance for filing by the FDA of our NDA for LEVADEX, are recognized as revenue in their entirety upon our achievement of a substantive milestone and when the respective revenue recognition criteria are met. A milestone is substantive if the consideration earned from the achievement of the milestone (i) is consistent with performance required to achieve the milestone or the increase in value to the delivered item, (ii) relates solely to past performance and (iii) is reasonable relative to all of the other deliverables and payments within the arrangement.

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. ASC 718 requires companies to estimate the fair value of the stock-based payment awards on the date of grant using an option-pricing model. 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 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, after considering the estimated forfeitures.

For RSUs with performance-based vesting, the fair value is based on the closing price of our common stock on the date of 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.

Concentration of Credit Risk and Other Risks and Uncertainties

We invest cash that is not currently being used for operational purposes in accordance with our investment policy. The policy allows for the purchase of debt securities such as those issued by the U.S. government and its agencies and subject to certain concentration limits by corporations. We also strive to limit risk by specifying a minimum credit quality for corporate debt securities of A1/P1 for commercial paper and AAA for other securities. The maximum maturity for these securities does not exceed 12 months. We believe our established guidelines for investment of our excess cash maintains safety and liquidity through our policies on diversification and investment maturity. Our cash and cash equivalent balances can be in excess of federally insured amounts.

At September 30, 2012, our collaboration with Allergan accounted for 100% of our accounts receivable. For the three and nine months ended September 30, 2012 and 2011, our collaboration with Allergan accounted for 100% of our collaboration revenue.

We do not own or operate manufacturing facilities for clinical or commercial manufacture of our product candidates. We rely on our contract manufacturers for items such as drug substance and drug packaging, including the components of the TEMPO inhaler, the device used to administer certain of our drug candidates, including LEVADEX. If our contract manufacturers fail to deliver the required commercial quantities of finished product on a timely basis and at commercially reasonable prices and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality and on a timely basis, we would likely be unable to meet demand for our products and we would lose potential revenue. It may take a significant period of time to establish an alternative source of supply for our product candidates.

Our product candidates require approval from the FDA or other international regulatory agencies prior to commencing commercial sales. There can be no assurance that our product candidates will receive any of these required approvals. If we are denied such approvals or such approvals are delayed, our results of operations, financial position and future cash flows may be materially adversely affected.

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.

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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 per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net income (loss) attributed to common stockholders	$ (12,622)	$ 8,183	$ (43,757)	$ (19,119)
Basic:				
Weighted average common shares used in computing basic net income (loss) per common share	33,369	30,440	31,569	30,329
Basic income (loss) per common share	$ (0.38)	$ 0.27	$ (1.39)	$ (0.63)
Diluted:				
Weighted average common shares used in computing basic net income (loss) per common share	33,369	30,440	31,569	30,329
Add: Weighted average stock options		1,158		
Add: Weighted average warrants		13		
Add: Weighted average ESPP				
Add: Weighted average RSUs with time-based vesting				
Weighted average common shares used in computing diluted net income (loss) per common share	33,369	31,611	31,569	30,329
Diluted income (loss) per common share	$ (0.38)	$ 0.26	$ (1.39)	$ (0.63)

The following outstanding common stock options, RSUs with time-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. The RSUs with performance-based vesting were also excluded from the computation of diluted net loss per share because they were contingently issuable shares (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Options to purchase common stock	4,980	1,570	4,980	4,386
RSUs with time-based vesting	293	142	293	156
Common stock issuable pursuant to the ESPP	54		54	35
Warrants to purchase common stock	27		27	27
RSUs with performance-based vesting	35	39	35	39

New Accounting Standard Adopted

Effective January 1, 2012, we adopted revised guidance related to the presentation of comprehensive income that increases comparability between U.S. GAAP and International Financial Reporting Standards. This guidance eliminates the current option to report other comprehensive income, or OCI, and its components in the statement of changes in stockholders equity. We adopted this guidance during the first quarter of 2012 and elected to disclose OCI in a single continuous statement during interim reporting periods.

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

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Agreements, we have granted Allergan a co-exclusive license (the Allergan License) to market and co-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 commercialization to neurologists and pain specialists in Canada. 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.

Under the Allergan Agreements, 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 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.

Contingent upon FDA approval of LEVADEX for the initial indication (the acute treatment of migraine), the parties will collaborate in the development of LEVADEX for the treatment of pediatric migraine and for at least one other indication. The parties generally share equally all other costs of developing LEVADEX in such additional indications 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. 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 distributing LEVADEX, if approved by the FDA, and anticipate booking product revenues from sales of LEVADEX resulting from the parties collaboration. The parties will each provide sales representatives and other sales support for 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. Shared commercialization costs are those costs and expenses directly related to the commercialization of LEVADEX and are agreed upon periodically by both parties. The parties share profits and losses resulting from the collaboration equally.

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 we have recognized $0.9 million and $2.8 million, respectively, for the three and nine months ended September 30, 2012, compared to $0.8 million and $2.2 million, respectively, for the same periods in 2011. We have recognized $5.9 million of the $60.0 million for the cumulative period from July 3, 2003 (date of inception) to September 30, 2012. As of September 30, 2012, $54.1 million of the initial $60.0 million remained unrecognized and will be amortized as collaboration revenue through the end date of the non-contingent deliverable in the Collaboration Agreement with the longest term. Our participation in joint committees with Allergan has the longest obligation period, requiring our participation throughout the term of the Collaboration Agreement. The term of the Collaboration Agreement is the later of (a) December 31, 2025, and (b) the date that our last patent right covering LEVADEX in the United States expires. The date that our last patent right covering LEVADEX in the United States expires is 2028. As a result, we will amortize the remaining $54.1 million of the initial $60.0 million through 2028.

During the third quarter ended September 30, 2011, the FDA accepted for filing our LEVADEX NDA. As a result, pursuant to the terms of the Allergan Agreements, Allergan paid us a milestone payment of $20.0 million. We have determined that the achievement of this contingent milestone was substantive and we recorded the $20.0 million as collaboration revenue on our consolidated statements of operations for the year ended December 31, 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 $50.0 million for the first commercial sale of LEVADEX associated with the initial indication (the acute treatment of migraine), up to $25.0 million for the achievement of certain FDA-approved product labeling in the United States and $2.0 million for regulatory approval of the initial indication for LEVADEX in Canada.

We agreed with Allergan, subsequent to the effective date of the Collaboration Agreement, to begin commercialization activities relating to the initial indication prior to initial approval of LEVADEX, and that those costs would be shared equally between the parties. Any reimbursements from Allergan for shared expenses relating to contingent deliverables are recorded in our financial

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statements in the quarters in which the cost sharing occurs. Sales, general and administrative expenses for the three and nine months ended September 30, 2012 were net of $0.5 million and $1.1 million, respectively, compared to $0.2 million and $0.7 million, respectively, for the same periods of 2011, of costs reimbursed or reimbursable by Allergan under cost-sharing provisions in the Allergan Agreements. Sales, general and administrative expenses for the cumulative period from July 3, 2003 (date of inception) to September 30, 2012 were net of $2.4 million of costs reimbursed or reimbursable by Allergan under cost-sharing provisions in the Allergan Agreements.

Agreement with Nektar

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 for both the three and nine months ended September 30, 2012, compared to $0 and $1.0 million, respectively, for the same periods in 2011. We paid $3.6 million for the cumulative period from July 3, 2003 (date of inception) to September 30, 2012. 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.

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The following is a summary of our cash, cash equivalents and restricted investment as of September 30, 2012 and December 31, 2011, respectively (in thousands):

	As of September 30, 2012		
	Amortized Cost	Unrealized Gain (Loss)	Estimated Fair Value
Cash	$ 2,967	$	$ 2,967
Certificates of deposit	310		310
Money market funds	111,251		111,251
	$ 114,528	$	$ 114,528
Reported as:			
Cash and cash equivalents			$ 114,218
Restricted investment			310
			$ 114,528

	As of December 31, 2011		
	Amortized Cost	Unrealized Gain (Loss)	Estimated Fair Value
Cash	$ 3,569	$	$ 3,569
Certificates of deposit	310		310
Money market funds	95,247		95,247
	$ 99,126	$	$ 99,126
Reported as:			
Cash and cash equivalents			$ 98,816
Restricted investment			310
			$ 99,126

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, 2012 and December 31, 2011, 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, 2012	Level 1	Level 2	Level 3	Total
Certificates of deposit	$	$ 310	$	$ 310

Money market funds	111,251			111,251
Total	$ 111,251	$ 310	$	$ 111,561

As of December 31, 2011	Level 1	Level 2	Level 3	Total
Certificates of deposit	$	$ 310	$	$ 310
Money market funds	95,247			95,247
Total	$ 95,247	$ 310	$	$ 95,557

Our investments in money market funds are measured at fair value on a recurring basis. Our money market funds comply with Rule 2a-7 of the Investment Company Act of 1940 and are required to be priced and have a fair value of $1.00 net asset value per share. These money market funds are actively traded and reported daily through a variety of sources. Due to the structure and valuation required by the Investment Company Act of 1940 regarding Rule 2a-7 funds, the fair value of the money market fund investments is classified as Level 1.

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The fair value of the certificates of deposit is classified as Level 2 due to the nature of a contractual restriction in our lease agreement which limits our ability to liquidate the investment.

NOTE 5. BALANCE SHEET COMPONENTS

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2012	December 31, 2011
Research and development	$ 2,267	$ 1,367
Payroll and related expenses	4,473	4,888
Professional services	647	596
Other	60	82
	$ 7,447	$ 6,933

NOTE 6. COMMITMENTS AND CONTINGENCIES

Operating Leases

In June 2004, we entered into a lease agreement for laboratory and office facilities in Mountain View, California, or the Lease. The Lease was subsequently amended in August 2006, March 2008 and September 2008. In November 2011, we further amended the Lease, providing for additional square footage in a separate building. The amended lease will expire in June 2013 and contains certain renewal options. Under the Lease, we pay operating costs, including property taxes, insurance and maintenance, in addition to monthly rent. Rent is subject to an annual increase for the duration of the Lease, which we recognize on a straight-line basis.

Rent expense was approximately $0.4 million and $1.2 million, respectively, for the three and nine months ended September 30, 2012, compared to $0.3 million and $0.9 million, respectively, for the same periods in 2011. Rent expense was approximately $8.3 million for the cumulative period from July 3, 2003 (date of inception) to September 30, 2012.

As of September 30, 2012, future minimum lease payments are as follows (in thousands):

Year ending December 31,	Amount
2012 (remaining three months)	$ 419
2013	863
Total future minimum lease payments	$ 1,282

In accordance with the terms of the Lease, we are obligated to maintain an irrevocable letter of credit from a bank as a security deposit. As collateral for the letter of credit, we are required to maintain a bank deposit account of $0.3 million, which is shown as a restricted investment on our condensed consolidated balance sheets at September 30, 2012 and December 31, 2011, respectively.

Contingencies

We are subject to claims and assessments from time to time in the ordinary course of business. We do not believe that any such matters, individually or in the aggregate, will have a material adverse effect on our financial condition or results of operation.

Indemnification

In the normal course of business, we enter into contracts and agreements that contain a variety of representations and warranties and provide for indemnification. Our exposure under these agreements is unknown because it involves claims that may be made against us in the future, but have not yet been made. To date, we have not paid any claims or been required to defend any action related to our indemnification obligations. However, we may record charges in the future as a result of these indemnification obligations.

In accordance with our certificate of incorporation and bylaws, we have indemnification obligations to our officers and directors for certain events or occurrences, subject to certain limits, while they are serving at our request in their respective capacities. There have been no claims to date and we have a director and officer insurance policy that enables us to recover a portion of any amounts paid for future potential claims.

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NOTE 7. STOCKHOLDERS EQUITY

Equity Offering

In August 2012, we completed an equity offering in which we sold and issued 4,462,686 shares of our common stock at an offering price of $13.40 per share. We raised a total of $59.8 million in gross proceeds, or approximately $55.8 million in net proceeds after deducting underwriting discounts and commissions and offering expenses.

Restricted Stock Units

In February 2010, the Compensation Committee of our Board of Directors approved awards of RSUs with performance-based vesting from our 2007 Equity Award Plan, or our 2007 Plan, to certain of our employees. Each RSU represents one equivalent share of our common stock to be awarded upon vesting at the end of the performance periods, if specific performance goals set by the Compensation Committee are achieved. No RSUs with performance-based vesting will vest if the performance goals are not met. The fair value of these RSUs is based on the closing price of our common stock on the date of grant. We measure compensation expense for these RSUs over the expected vesting period and we adjust it periodically for any changes to our probability assessment of the number of RSUs expected to vest as a result of our achievement of the performance goals. We make a quarterly probability assessment as to whether the performance goals will be achieved. The RSUs do not entitle participants to the rights of holders of common stock, such as voting rights, until the shares are issued.

Beginning in 2011, the Compensation Committee of our Board of Directors has approved awards of RSUs with time-based vesting from our 2007 Plan to certain of our employees. Each RSU represents one equivalent share of our common stock to be awarded after the vesting period. These RSUs vest over four years at a rate of 25% annually. The fair value for these 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 on a straight-line basis. The RSUs do not entitle participants to the rights of holders of common stock, such as voting rights, until the shares are issued.

For RSUs that vest, we withhold a number of shares of common stock equal in value to the amount of the minimum statutory tax withholding obligations that arise due to such vesting, and issue shares of common stock for the remainder of the vested amount. The settlement of vested RSUs on a net share basis results in fewer shares issued by us.

For the nine months ended September 30, 2012, activity for RSUs under our 2007 Plan was as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
RSUs outstanding at December 31, 2011	202,143	$ 15.88
RSUs granted	192,911	$ 14.09
RSUs vested	(37,680)	$ 15.87
RSUs forfeited	(29,558)	$ 15.22
Unvested RSUs outstanding at September 30, 2012	327,816	$ 14.89

Stock Options

For the nine months ended September 30, 2012, stock option activity under our 2007 Plan, was as follows:

	Number of Shares	Weighted Average Exercise Price
Balances, at December 31, 2011	4,378,053	$ 10.86

Options granted	914,750	$ 14.21
Options exercised	(122,622)	$ 6.91
Options forfeited	(150,332)	$ 14.11
Options expired	(39,653)	$ 15.21
Balances, at September 30, 2012	4,980,196	$ 11.44

As of September 30, 2012, we had 2,221,071 shares of common stock available for grant under our 2007 Plan.

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Warrants

We issued warrants to purchase 73,989 shares of common stock to selected lenders in connection with an earlier working capital loan which was fully paid in May 2008 and an equipment loan which was fully paid in September 2009. The warrants are exercisable at a price of $7.43 per share and expire in September 2013. In October 2009 and March 2010, warrants to purchase 22,418 shares and 24,668 shares were exercised, respectively, resulting in a net issuance of 5,817 shares and 12,295 shares, respectively. As of September 30, 2012, warrants to purchase the remaining 26,903 shares of common stock were outstanding.

In October 2012, the warrant to purchase the remaining 26,903 shares was exercised on a cashless basis, resulting in a net issuance of 14,312 shares of common stock. We did not receive any proceeds from the exercise of this warrant.

Stock-Based Compensation for Employees

The stock-based compensation expense recognized in the condensed consolidated statements of operations, including stock options granted, RSUs and shares purchased under the ESPP, was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Research and development	$ 796	$ 805	$ 2,707	$ 2,502
Sales, general and administrative	1,169	907	3,579	2,982
	$ 1,965	$ 1,712	$ 6,286	$ 5,484

We used the following assumptions to estimate the fair value of options granted under our stock option plan for the three and nine months ended September 30, 2012 and 2011, respectively:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Risk-free interest rate	0.7%	0.9% - 1.6%	0.7% - 0.9%	0.9% - 2.2%
Expected volatility	99%	70%	94% - 99%	69% - 70%
Expected term (in years)	5	5	5	5
Expected dividend yield	0%	0%	0%	0%

We used the following assumptions to estimate the fair value of shares purchased under the ESPP for the three and nine months ended September 30, 2012 and 2011, respectively:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Risk-free interest rate	0.1%	0.1%	0.05% - 0.1%	0.1% - 0.2%
Expected volatility	49%	30%	49% - 52%	30% - 38%
Expected term (in years)	0.5	0.5	0.5	0.5
Expected dividend yield	0%	0%	0%	0%

We selected the Black-Scholes valuation model as the most appropriate valuation method for stock option grants and shares from the ESPP. The fair value of the stock option grants and shares from the ESPP is estimated as of the date of grant using the Black-Scholes valuation model.

Risk-Free Interest Rate: The risk-free interest rate assumption was based on U.S. Treasury instruments with a term that is consistent with the expected term of our stock options or shares from the ESPP.

Expected Volatility: Historically, the expected stock price volatility of stock options was determined by examining the historical volatilities for industry peers and using an average of the historical volatilities of our industry peers as we did not have sufficient trading history for our

common stock. Industry peers consist of several public companies in the biopharmaceutical industry similar to us in size, stage of life-cycle and financial leverage. Beginning in the first quarter of 2012, the expected stock price volatility was calculated based on the historical volatility of industry peers and the historical volatility of our common stock. We will continue to analyze the expected stock price volatility of stock options as more historical data for our common stock becomes available. The expected stock price volatility for shares from the ESPP is determined based on our own historical volatilities.

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Expected Term: The expected term of stock options represents the weighted average period the stock options are expected to remain outstanding. It was calculated based on the historical experience that we have had with stock option grants as well as the expected term of industry peers, as we did not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for the full term of our stock options. We will continue to analyze the expected term of stock options as more historical data for our common stock becomes available. The expected term for shares from the ESPP is determined based on the length of offering periods for the ESPP.

Expected Dividend Yield: The expected dividend yield of 0% is based on our history and expectation of dividend payouts. We do not anticipate paying any dividends in the near future. We have not paid any dividends, other than a cumulative dividend on our preferred stock paid in connection with our Initial Public Offering, or IPO, in 2007, pursuant to the terms of our certificate of incorporation.

Forfeitures: Forfeitures are determined based on when awards are ultimately expected to vest. ASC 718 *Compensation Stock Compensation,* requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on our historical experience.

As of September 30, 2012, there were unrecognized compensation costs of approximately $7.3 million related to non-vested stock option awards granted after January 1, 2006 that will be recognized on a straight-line basis over the weighted average remaining period of 2.2 years.

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ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This quarterly report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the safe harbor created by those sections. Forward-looking statements are based on our management s beliefs and assumptions and on information currently available to them. In some cases you can identify forward-looking statements by words such as may, will, should, could, would, expects, plans, anticipates, believes, estimates, projects, predicts, potential and similar expressions intended to identify forward-looking statements. Examples of these statements include, but are not limited to, statements regarding: our belief that we addressed in our resubmission all issues and observations raised by the FDA, including those cited during an inspection of our third party manufacturer, the implications of interim or final results of our clinical trials, the progress of our research programs, including clinical testing, the extent to which our issued and pending patents may protect our products and technology, our ability to identify new product candidates, the potential of such product candidates to lead to the development of commercial products, our anticipated timing for initiation or completion of our clinical trials for any of our product candidates, our future operating expenses, our future losses, our future expenditures for research and development, and the sufficiency of our cash resources. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks faced by us and described in Part II, Item 1A of this quarterly report on Form 10-Q and our other filings with the SEC. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this quarterly report on Form 10-Q. You should read this quarterly report on Form 10-Q completely and with the understanding that our actual future results may be materially different from those we expect. Except as required by law, we assume no obligation to update these forward-looking statements, whether as a result of new information, future events or otherwise.

The following discussion and analysis should be read in conjunction with the unaudited financial statements and notes thereto included in Part I, Item 1 of this quarterly report on Form 10-Q and with the audited consolidated financial statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2011.

Overview

Our goal is to enhance the therapeutic benefits and commercial attractiveness of proven drugs in the field of neurology, while minimizing risk by capitalizing on their known safety, efficacy and commercialization history, by applying our proprietary formulation and inhalation technologies. We are developing proprietary product candidates that address large market opportunities in the field of neurology.

Our strategy is to commercialize and develop differentiated neurology product candidates that can address significant unmet medical needs and overcome limitations of existing products. Key elements of our strategy include:

- Obtain regulatory approval for our most advanced product candidate, LEVADEX® orally inhaled migraine drug, for the potential acute treatment of migraine in adults;
- Build a specialized sales force to commercialize LEVADEX to neurologists and pain specialists in the United States (U.S.);
- Expand the market opportunity for LEVADEX; and
- Advance and expand our neurology product pipeline by leveraging our technologies and our extensive scientific expertise in aerosol science and pharmaceutical technology to develop additional potential product candidates offering unique features and benefits.

Our current focus is to advance our lead product candidate, LEVADEX, formerly known as MAP0004, a proprietary orally inhaled version of dihydroergotamine mesylate, or DHE, for the potential acute treatment of migraine. We are in the development stage and since our inception we have devoted substantially all of our efforts to research and development, raising capital and recruiting personnel. We completed clinical development for LEVADEX in 2010 and in May 2011 we submitted our New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA. The FDA reviewed our NDA and on March 26, 2012, we received a Complete Response letter in which the FDA requested that we address issues relating to the chemistry, manufacturing and controls, or CMC, of LEVADEX. The FDA also stated that manufacturing deficiencies identified during a recent facility inspection of one of our third party manufacturers need to be resolved to the FDA s satisfaction. The FDA indicated in the Complete Response letter that it has not been able to complete its review of inhaler usability information

requested late in the review cycle by the FDA. We have had an End-of-Review meeting with the FDA to discuss our proposed plan for responding to the Complete Response letter and we have worked to address the issues identified in the Complete Response letter. We resubmitted the NDA for LEVADEX in October 2012. The FDA will determine the type of resubmission (Class 1 or Class 2) and the resulting review timeline only after the resubmission has been accepted for filing.

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If LEVADEX is approved by the FDA for the first indication (acute treatment of migraine in adults), we plan to commercialize LEVADEX in collaboration with Allergan, Inc. directly to neurologists and pain specialists in the U.S. and Canada. We are also evaluating options to commercialize LEVADEX to additional physicians in the U.S. and Canada and to physicians in markets outside the U.S. and Canada.

Our Lead Product Candidate - LEVADEX

Migraine is a chronic and debilitating neurological disorder characterized by episodic attacks. Migraine attacks typically manifest themselves as moderate to severe headache pain, with associated symptoms that often include nausea and vomiting, photophobia, phonophobia, and visual disturbances or aura. Migraines usually involve pounding or throbbing pain on one side of the head, although pain may occur on both sides. Migraines limit the normal functioning of patients, who often seek dark, quiet surroundings until the episode has passed. Most migraines last between four and 24 hours, but some last as long as three days. According to published studies, the median frequency of attack is 1.5 times per month, although approximately 25% of migraine sufferers experience one or more attacks every week.

Migraine is a major public health problem that affects approximately 12% of the population in the U.S. and approximately 15% in Europe. According to the National Headache Foundation, approximately 30 million people in the U.S. suffer from migraine. Migraine is more common in women, with about 18% of women affected and 6% of men. Migraine prevalence is highest during the peak productive ages of 25 to 55, which results in high costs to employers and managed care organizations.

Migraine is listed in the top 20 causes of disabling conditions and in the top four neurologic disabling conditions by the World Health Organization, or WHO. Related disability from migraine is substantial, with over 90% of sufferers experiencing functional impairment with their migraine that can disrupt every aspect of day to day life, including work, school, family and social relationships. More than half of the sufferers report severe impairment or the need for bed rest as a result of their migraines, according to published surveys. The economic burden of migraine remains substantial despite existing treatments with patients losing four to six work days each year due to migraine. The combination of direct and indirect costs of migraine in the U.S. is estimated at over $20 billion annually.

In 2011, there were approximately 13 million migraine-specific prescriptions written for the acute treatment of migraine, generating approximately $1.7 billion in revenues in the U.S. The majority of the prescriptions written were in the triptan class, and the leading branded agent, Maxalt, generated approximately $450 million in revenues in the U.S. However, in 2008 when the leading migraine-specific agent, Imitrex, became generic, the total market for migraine-specific prescriptions generated approximately $2.5 billion in revenues in the U.S.

LEVADEX is an easy to use, at-home therapy in development that patients self-administer using our proprietary hand-held TEMPO inhaler. We have designed LEVADEX to provide faster onset and longer-lasting migraine relief than triptans, the class of drugs most often prescribed for treating migraine. DHE currently is available as an intravenous, or IV, therapy which has been used in clinical settings for over 50 years for the safe and effective treatment of migraine, particularly forms of migraine that are severe or do not respond to triptans or other therapies. We believe LEVADEX has the potential to be suitable as a first-line therapy for some migraine patients.

The LEVADEX clinical development program was a comprehensive program under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FFDCA, that evaluated the efficacy, safety, pharmacokinetics and pharmacodynamics of LEVADEX in approximately 1,000 patients across nine trials. In our clinical trials conducted for LEVADEX, no drug-related serious adverse events have been reported.

In the efficacy portion of our pivotal Phase 3 FREEDOM-301 clinical trial, LEVADEX met all four primary endpoints, showing statistically significant improvement in pain relief ($p<0.0001$), freedom from phonophobia (sensitivity to sound) ($p<0.0001$), freedom from photophobia (sensitivity to light) ($p<0.0001$) and freedom from nausea ($p=0.02$) as reported two hours after dosing. Additional endpoints showed that LEVADEX provided rapid pain relief in 30 minutes and sustained pain relief for up to 48 hours after dosing. LEVADEX was well tolerated, with the most common adverse event reported being medication aftertaste at 6%, with 2% of patients receiving placebo also reporting medication aftertaste. The next most common adverse event was nausea at 5%, compared with 2% for placebo. We completed a 12 month open-label safety extension of our FREEDOM-301 trial, which evaluated lung function and cardiovascular parameters, during which approximately 9,500 headaches were treated and over 250 subjects completed 12 months of exposure. There were no mean decreases in lung function, as measured by spirometry, between the LEVADEX and placebo groups. There were no drug-related serious adverse events reported in the trial.

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We also have completed additional clinical pharmacology trials that include a pharmacokinetic (PK) trial in smokers, a pharmacodynamics (PD) trial evaluating pulmonary artery pressure using echocardiogram, a thorough QT trial, a PK trial in asthmatics and a drug-drug interaction trial.

Neurology Pipeline

We are exploring options to advance and expand our neurology product pipeline by leveraging our technologies and our extensive scientific expertise in aerosol science and pharmaceutical technology to develop additional neurological product candidates offering unique features and benefits.

Our goal is to enhance the therapeutic benefits and commercial attractiveness of proven drugs in the field of neurology, while minimizing risk by capitalizing on their known safety, efficacy and commercialization history, by applying our proprietary formulation and inhalation technologies. Our strategy is to develop differentiated neurology products that address large market opportunities with significant unmet medical needs. We intend to commercialize potential future products through the sales force we intend to build upon the potential commercialization of LEVADEX. We are currently developing two early stage, pre-clinical product candidates, including one in Parkinson s disease and another in epilepsy.

Allergan Collaboration

In January 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 (the Allergan License) to market and co-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 commercialization to neurologists and pain specialists in Canada. 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.

Under the Allergan Agreements, 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 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.

Contingent upon FDA approval of LEVADEX for the initial indication (the acute treatment of migraine), the parties will collaborate in the development of LEVADEX for the treatment of pediatric migraine and for at least one other indication. The parties generally share equally all other costs of developing LEVADEX in such additional indications 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. 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 distributing LEVADEX, if approved by the FDA, and anticipate booking product revenues from sales of LEVADEX resulting from the parties collaboration. The parties will each provide sales representatives and other sales support for 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. Shared commercialization costs are those costs and expenses directly related to the commercialization of LEVADEX and are agreed upon periodically by both parties. The parties share profits and losses resulting from the collaboration equally.

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 we have recognized $0.9 million and $2.8 million, respectively, for the three and nine months ended September 30, 2012, compared to $0.8 million and $2.2 million, respectively, for the same periods in 2011. We have recognized $5.9 million of the $60.0 million for the cumulative period from

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July 3, 2003 (date of inception) to September 30, 2012. As of September 30, 2012, $54.1 million of the initial $60.0 million remained unrecognized and will be amortized as collaboration revenue through the end date of the non-contingent deliverable in the Collaboration Agreement with the longest term. Our participation in joint committees with Allergan has the longest obligation period, requiring our participation throughout the term of the Collaboration Agreement. The term of the Collaboration Agreement is the later of (a) December 31, 2025, and (b) the date that our last patent right covering LEVADEX in the United States expires. The date that our last patent right covering LEVADEX in the United States expires is 2028. As a result, we will amortize the remaining $54.1 million of the initial $60.0 million through 2028.

During the third quarter ended September 30, 2011, the FDA accepted for filing our LEVADEX NDA. As a result, pursuant to the terms of the Allergan Agreements, Allergan paid us a milestone payment of $20.0 million. We have determined that the achievement of this contingent milestone was substantive and we recorded the $20.0 million as collaboration revenue on our consolidated statements of operations for the year ended December 31, 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 $50.0 million for the first commercial sale of LEVADEX associated with the initial indication (the acute treatment of migraine), up to $25.0 million for the achievement of certain FDA-approved product labeling in the United States and $2.0 million for regulatory approval of the initial indication for LEVADEX in Canada.

We agreed with Allergan, subsequent to the effective date of the Collaboration Agreement, to begin commercialization activities relating to the initial indication prior to initial approval of LEVADEX, and that those costs would be shared equally between the parties. Any reimbursements from Allergan for shared expenses relating to contingent deliverables are recorded in our financial statements in the quarters in which the cost sharing occurs. Sales, general and administrative expenses for the three and nine months ended September 30, 2012 were net of $0.5 million and $1.1 million, respectively, compared to $0.2 million and $0.7 million, respectively, for the same periods of 2011, of costs reimbursed or reimbursable by Allergan under cost-sharing provisions in the Allergan Agreements. Sales, general and administrative expenses for the cumulative period from July 3, 2003 (date of inception) to September 30, 2012 were net of $2.4 million of costs reimbursed or reimbursable by Allergan under cost-sharing provisions in the Allergan Agreements.

Critical Accounting Policies and Significant Judgments and Estimates

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. 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;
- 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 has not had 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.

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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 standalone basis.

When we are unable to establish the selling price of an element using VSOE or TPE, we use the ESP in our allocation of the upfront payment. The objective of the ESP is to determine the price at which we would transact a sale if the element of the license arrangement were sold on a standalone 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 estimated obligation period of one or more deliverables should change, the future amortization of the revenue would also change. We regularly review ESP and maintain internal controls over the establishment and updates of the estimates.

We entered into a Collaboration Agreement with Allergan, Inc. in January 2011 which requires us to provide multiple deliverables, including: a license to commercialize LEVADEX, clinical and regulatory work necessary for FDA approval of the first indication for LEVADEX (acute treatment of migraine in adults), manufacturing process development for LEVADEX, an option to include Canada in the territory in which Allergan can promote LEVADEX and participation in various committees jointly with Allergan throughout the term of the Collaboration Agreement. These deliverables are non-contingent in nature. We received an upfront cash payment of $60.0 million from Allergan upon execution of the Collaboration Agreement. In accordance with ASU 2009-13, we evaluated whether there is standalone value for each of the various non-contingent deliverables. We have determined that the license delivered by us and other non-contingent deliverables do not have standalone value separate from each other, based on contractual limitations in the Collaboration Agreement that restrict Allergan from using the license for its intended purpose without other non-contingent deliverables from us.

We believe that since the license does not have standalone value, it must be combined with all the remaining non-contingent deliverables because the license would not be fully delivered for its intended purpose unless we continue to perform our obligation to participate in the various committees jointly with Allergan. Accordingly, all of the non-contingent deliverables are treated as a single unit of accounting, and we have combined the delivered license with the remaining non-contingent deliverables for accounting purposes. As a result, revenue relating to the $60.0 million upfront cash payment was deferred and will be recognized on a straight-line basis over the term of the Collaboration Agreement through 2028, which represents the estimated obligation period of the participation in the various joint committees, the non-contingent deliverable with the longest term.

The Collaboration Agreement also contains contingent deliverables that do not relate to the non-contingent deliverables identified above. For example, we will collaborate and share expenses with Allergan to develop LEVADEX for additional indications separate from and in addition to the first indication. Any reimbursements from Allergan to us for shared expenses relating to contingent deliverables are recorded in our financial statements in the quarters in which the cost sharing occurs.

Milestone payments relating to contingent deliverables, such as the acceptance for filing by the FDA of our NDA for LEVADEX, are recognized as revenue in their entirety upon our achievement of a substantive milestone and when the respective revenue recognition criteria are met. A milestone is substantive if the consideration earned from the achievement of the milestone (i) is consistent with performance required to achieve the milestone or the increase in value to the delivered item, (ii) relates solely to past performance and (iii) is reasonable relative to all of the other deliverables and payments within the arrangement.

There have been no other significant changes in critical accounting policies during the nine months ended September 30, 2012, as compared to the critical accounting policies described in *Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Significant Judgments and Estimates* in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011.

Financial Overview

Collaboration Revenue

Collaboration revenue, which is earned under agreements with third parties for various activities, may include nonrefundable license fees, cost reimbursements and contingent milestone payments.

Through September 30, 2012, we had recorded approximately $80.0 million in collaboration revenue since our inception in 2003.

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Research and Development Expenses

Research and development expenses include, but are not limited to: (i) expenses incurred under agreements with contract research organizations and investigative sites, which conduct our clinical trials and a substantial portion of our pre-clinical studies; (ii) milestone payments paid to our collaborative partners who work on our processing and supply of clinical trial material; (iii) the cost of manufacturing and supplying clinical trial materials; (iv) payments to contract service organizations, as well as consultants; (v) employee-related expenses, which include salaries and benefits; (vi) facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, depreciation of leasehold improvements and equipment and laboratory and other supplies; and (vii) stock-based compensation expense. All research and development expenses are expensed as incurred.

Conducting a significant amount of research and development is central to our business model. Through September 30, 2012, we had incurred approximately $277.7 million in research and development expenses since our inception in 2003. Product candidates in later-stage clinical development generally have higher development costs than those in earlier stages of development, primarily due to the significantly increased size and duration of later-stage clinical trials. We plan to incur substantial research and development expenses for the foreseeable future in order to complete development of and pursue additional indications for our most advanced product candidate, LEVADEX, and to conduct earlier-stage research and development projects.

The following table summarizes the percentages of our research and development expenses related to our LEVADEX program, our Unit Dose Budesonide, or UDB, program, which has been suspended, and other earlier stage projects for the three and nine months ended September 30, 2012 and 2011, respectively, and for the cumulative period from July 3, 2003 (date of inception) to September 30, 2012. The percentages summarized in the following table reflect costs directly attributable to each development candidate, which are tracked on a project basis. A portion of our internal costs, including indirect costs relating to our product candidates, is not tracked on a project basis and has been allocated based on management estimates.

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from July 3, 2003 (Inception) through September 30, 2012
	2012	2011	2012	2011	
Our product candidates:					
LEVADEX	73%	90%	78%	91%	63%
UDB (suspended)					27%
Other projects	27%	10%	22%	9%	10%
Total	100%	100%	100%	100%	100%

The process of conducting pre-clinical studies and clinical trials necessary to obtain FDA approval is costly and time consuming. The probability of success for each product candidate and clinical trial may be affected by a variety of factors, including, among other things, the quality of the product candidate s early clinical data, investment in the program, competition, manufacturing capabilities and commercial viability. As a result of the uncertainties discussed above, uncertainty associated with clinical trial enrollment and risks inherent in the development process, we are unable to determine the duration and completion costs of current or future clinical stages of our product candidates or when, or to what extent, we will generate revenues from the commercialization and sale of any of our product candidates. Development timelines, probability of success and development costs vary widely. We are currently focused on developing our most advanced product candidate, LEVADEX. We will need substantial additional capital in the future in order to commercialize LEVADEX and to fund the development and commercialization of future product candidates. We may receive additional payments pursuant to the Allergan Agreements.

Sales, General and Administrative Expenses

Sales, general and administrative expenses consist primarily of compensation for executive, finance, marketing, legal and administrative personnel, including stock-based compensation. Other sales, general and administrative expenses include facility costs not otherwise included in research and development expenses, legal and accounting services, other professional services, the cost of market research activities and consulting fees. Included in sales, general and administrative expenses are costs reimbursed or reimbursable by Allergan under cost-sharing provisions in the Allergan Agreements.

Through September 30, 2012, we incurred approximately $104.9 million in sales, general and administrative expenses since our inception in 2003.

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Results of Operations

Collaboration Revenue

The change in collaboration revenue as compared to the prior year is as follows (dollar amounts are presented in thousands):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2012	2011	Increase/ (Decrease)	% Increase/ (Decrease)	2012	2011	Increase/ (Decrease)	% Increase/ (Decrease)
Collaboration revenue	$ 878	$ 20,837	$ (19,959)	*	$ 2,784	$ 22,232	$ (19,448)	*

* Percentage is not meaningful.

The collaboration revenue was due to the Allergan Agreements which were effective in January 2011. In February 2011, Allergan paid us an upfront payment of $60.0 million, out of which we recognized $0.9 million and $2.8 million, respectively, as collaboration revenue for the three and nine months ended September 30, 2012, compared to $0.8 million and $2.2 million, respectively, for the same periods in 2011. As of September 30, 2012, $54.1 million of the initial $60.0 million remained unrecognized and will be amortized as collaboration revenue over the estimated obligation period.

During the third quarter ended September 30, 2011, the FDA accepted for filing our LEVADEX NDA. As a result, pursuant to the terms of the Allergan Agreements, Allergan paid us a milestone payment of $20.0 million. We recorded the $20.0 million as collaboration revenue on our consolidated statements of operations for the three and nine 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 $50.0 million for the first commercial sale of LEVADEX associated with the initial indication (the acute treatment of migraine), up to $25.0 million for the achievement of certain FDA-approved product labeling in the United States and $2.0 million for regulatory approval of the initial indication for LEVADEX in Canada.

Research and Development Expenses

Research and development expenses and percentage changes as compared to the prior year are as follows (dollar amounts are presented in thousands):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2012	2011	Increase/ (Decrease)	% Increase/ (Decrease)	2012	2011	Increase/ (Decrease)	% Increase/ (Decrease)
Research and development expenses	$ 7,855	$ 6,725	$ 1,130	17%	$ 26,590	$ 25,552	$ 1,038	4%

For the three months ended September 30, 2012 compared to the same period in 2011, the increase in research and development expenses was due primarily to an increase of $1.1 million in expenses related to early stage research projects.

For the nine months ended September 30, 2012 compared to the same period in 2011, the increase in research and development expenses was due primarily to an increase of $2.4 million in expenses related to early stage research projects, an increase of $0.5 million in personnel related expenses including stock-based compensation, partially offset by a decrease of $1.6 million in expenses related to the LEVADEX program and a decrease of $0.2 million in other administrative expenses.

Sales, General and Administrative Expenses

Sales, general and administrative expenses and percentage changes as compared to the prior year are as follows (dollar amounts are presented in thousands):

	Three Months Ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)	Nine Months Ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2012	2011			2012	2011		
Sales, general and administrative expenses	$ 5,642	$ 5,890	$ (248)	(4)%	$ 19,950	$ 15,529	$ 4,421	28%

For the three months ended September 30, 2012 compared to the same period in 2011, the decrease in sales, general and administrative expenses was due primarily to a decrease of $1.4 million in professional services, partially offset by an increase of $0.6 million in personnel related expenses primarily within sales and marketing, including stock-based compensation, and an increase of $0.6 million in other administrative expenses.

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For the nine months ended September 30, 2012 compared to the same period in 2011, the increase in sales, general and administrative expenses was due primarily to an increase of $3.3 million in personnel related expenses primarily within sales and marketing, including stock-based compensation, an increase of $1.6 million in other administrative expenses, partially offset by a decrease of $0.5 million in professional services.

Interest Income

Interest income and percentage changes as compared to the prior year are as follows (dollar amounts are presented in thousands):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2012	2011	Increase/ (Decrease)	% Increase/ (Decrease)	2012	2011	Increase/ (Decrease)	% Increase/ (Decrease)
Interest income	$	$ 6	$ (6)	*	$ 1	$ 58	$ (57)	*

* Percentage is not meaningful.

For the three and nine months ended September 30, 2012 compared to the same periods in 2011, our interest income was nominal due to the low interest rate environment that currently exists.

Interest Expense

Interest expense and percentage changes as compared to the prior year are as follows (dollar amounts are presented in thousands):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2012	2011	Increase/ (Decrease)	% Increase/ (Decrease)	2012	2011	Increase/ (Decrease)	% Increase/ (Decrease)
Interest expense	$	$ 43	$ (43)	*	$	$ 316	$ (316)	*

* Percentage is not meaningful.

In May 2008, we entered into an agreement to borrow $20.0 million, or the 2008 Working Capital Loan. We repaid the 2008 Working Capital Loan in full in October 2011.

Liquidity and Capital Resources

We have incurred losses since our inception in July 2003 and as of September 30, 2012 we had an accumulated deficit of $316.3 million. 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 at least the next several years. We expect to incur increased research and development and sales, general and administrative expenses related to our development and potential commercialization of LEVADEX and, as a result, we will need to generate significant net product sales, royalty and other revenues to achieve profitability.

We have financed our operations through equity financing, debt financing, the issuance of convertible notes and collaboration payments, as follows:

Equity

Prior to our IPO in October 2007, we received net proceeds of $106.7 million from the issuance of convertible notes and convertible preferred stock;

With the completion of our IPO, we received net proceeds of $62.1 million after deducting expenses and underwriters discounts and commissions;

In August 2009, we completed a follow-on public offering in which we sold and issued 3,500,000 shares of our common stock at a price of $9.70 per share. We raised a total of $34.0 million in gross proceeds, or approximately $31.6 million in net proceeds after deducting expenses and underwriters discounts and commissions;

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In January 2010, we accessed our equity line of credit with Azimuth Opportunity Ltd., or Azimuth, and sold 1,527,695 shares of common stock at a price of approximately $13.70 per share, less a discount of approximately 4.5% per share, for a net price of approximately $13.09 per share. The total purchase price for these shares was $20.0 million or approximately $19.7 million after deducting the offering expenses;

In October 2010, we completed an equity offering in which we sold and issued a total of 3,450,000 shares of common stock at an offering price of $14.50 per share. We raised a total of $50.0 million in gross proceeds, or approximately $47.0 million in net proceeds after deducting underwriting discounts and commissions and offering expenses;

In August 2012, we completed an equity offering in which we sold and issued 4,462,686 shares of our common stock at an offering price of $13.40 per share. We raised a total of $59.8 million in gross proceeds, or approximately $55.8 million in net proceeds after deducting underwriting discounts and commissions and offering expenses.

Debt

In September 2006, we entered into a loan facility agreement and borrowed $10.0 million to finance working capital and a $1.0 million loan facility to finance equipment purchases. We repaid in full the $10.0 million working capital loan and the $1.0 million equipment loan in May 2008 and September 2009, respectively;

In May 2008, we entered into the 2008 Working Capital Loan to borrow $20.0 million, in order to repay an earlier working capital loan and to support general corporate purposes. We repaid in full the 2008 Working Capital Loan in October 2011;

Collaboration

In 2009, we received $54.2 million in an upfront payment and reimbursement of qualified development expenses pursuant to our now terminated collaboration agreement with AstraZeneca AB;

In February 2011, we received a $60.0 million upfront payment pursuant to the Allergan Agreements;

In August 2011, we received a $20.0 million milestone payment from Allergan upon the FDA s acceptance for filing of our LEVADEX NDA; and

As of September 30, 2012, we have received $2.0 million in cash from Allergan as cost reimbursements under cost-sharing provisions in the Allergan Agreements.

As of September 30, 2012, we had approximately $114.2 million in cash and cash equivalents. Our cash and cash equivalents are held primarily in money market funds. Cash in excess of immediate requirements is invested in accordance with our investment policy with a view toward capital preservation and liquidity.

Cash Flows

The following table shows a summary of our cash flows for the periods indicated (in thousands):

	Nine Months Ended September 30,	
	2012	2011
Cash provided by (used in):		
Operating activities	$ (40,029)	$ 42,005
Investing activities	(1,827)	(2,001)
Financing activities	57,258	(4,167)

Net cash provided by (used in) operating activities. We used $40.0 million of cash for operating activities for the nine months ended September 30, 2012 compared to receiving cash of $42.0 million from the corresponding period in 2011. The cash used for operating activities for the nine months ended September 30, 2012 was due primarily to a net loss of $43.8 million, a decrease in deferred revenue of $2.8 million and a decrease in accounts payable of $1.9 million resulting from payments to certain vendors, partially offset by stock-based compensation of $6.3 million. The cash provided by operating activities for the nine months ended September 30, 2011 was due primarily to a $60.0 million nonrefundable upfront payment we received from Allergan in February 2011, which resulted in an increase in deferred revenue of $57.8 million, a $20.0 million milestone payment we received from Allergan in August 2011, and stock-based compensation of $5.5 million, partially offset by a net loss of $19.1 million and a decrease in accrued liabilities of $3.4 million as a result of the payment of expenses related to the LEVADEX Phase 3 clinical program.

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Net cash used in investing activities. We used $1.8 million and $2.0 million of cash for investing activities for the nine months ended September 30, 2012 and 2011, respectively. The usage of cash for both the nine months ended September 30, 2012 and 2011 were due primarily to purchase of property and equipment.

Net cash provided by (used in) financing activities. We received $57.3 million of cash from financing activities for the nine months ended September 30, 2012, compared to cash usage of $4.2 million for the corresponding period in 2011. The receipt of cash of $57.3 million from financing activities for the nine months ended September 30, 2012 was due primarily to the net proceeds of approximately $56.1 million from the issuance of common stock from the August 2012 equity offering and $1.1 million from the issuance of common stock through equity plans. The usage of cash of $4.2 million for the nine months ended September 30, 2011 was due primarily to the repayment of $6.0 million of outstanding debt in the nine months ended September 30, 2011, partially offset by the net proceeds from issuance of shares through equity plans of $1.8 million.

Equity Line of Credit

On November 11, 2009, we entered into a Common Stock Purchase Agreement, or the Purchase Agreement, with Azimuth, which provides us with what is sometimes termed an equity line of credit arrangement. Upon the terms and subject to the conditions set forth in the Purchase Agreement, Azimuth is committed to purchase up to $60.0 million worth of shares of our common stock over the 24-month term of the Purchase Agreement; provided, however, in no event may we sell under the Purchase Agreement more than such number of shares of common stock which is equal to one share less than 20% of our outstanding shares of common stock on the effective date of the Purchase Agreement. From time to time over the term of the Purchase Agreement, and at our sole discretion, pursuant to an effective registration statement covering the shares, we may present Azimuth with draw down notices requiring Azimuth to purchase a specified dollar amount of shares of our common stock, based on the price per share over ten consecutive trading days or such other period mutually agreed upon by Azimuth and us, with each draw down subject to limitations based on the price of our common stock and a maximum limit of 2.5% of our market capitalization at the time of such draw down, or such other limit of our market capitalization as mutually agreed upon by Azimuth and us.

In January 2010 we accessed our equity line of credit and sold 1,527,695 shares of common stock at a price of approximately $13.70 per share less a discount of approximately 4.5% per share for a net price of approximately $13.09 per share. The total purchase price for all these shares was $20.0 million or approximately $19.7 million after deducting offering expenses.

On November 29, 2011, we amended the Purchase Agreement to extend the term by up to 24 months past the original expiration date of December 1, 2011. As of September 30, 2012, the remaining aggregate dollar value of shares available for sale under the Purchase Agreement was $40.0 million.

Agreement with Allergan

Under the Allergan Agreements, 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 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.

Contingent upon FDA approval of LEVADEX for the initial indication (the acute treatment of migraine), the parties will collaborate in the development of LEVADEX for the treatment of pediatric migraine and for at least one other indication. The parties generally share equally all other costs of developing LEVADEX in such additional indications 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. 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 distributing LEVADEX, if approved by the FDA, and anticipate booking product revenues from sales of LEVADEX resulting from the parties collaboration. The parties will each provide sales representatives and other sales support for 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. Shared commercialization costs are those costs and expenses directly related to the commercialization of LEVADEX and are agreed upon periodically by both parties. The parties share profits and losses resulting from the collaboration equally.

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

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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.

We agreed with Allergan, subsequent to the effective date of the Collaboration Agreement, to begin commercialization activities relating to the initial indication prior to initial approval of LEVADEX, and that those costs would be shared equally between the parties. Any reimbursements from Allergan for shared expenses relating to contingent deliverables are recorded in our financial statements in the quarters in which the cost sharing occurs.

Operating Capital and Capital Expenditure Requirements

Our future capital requirements will depend on many forward looking factors and are not limited to the following:

- the initiation, progress, timing and completion of clinical trials for our product candidates and potential product candidates;
- the length of time it takes us to address any items in the FDA s Complete Response letter of March 26, 2012 if the FDA determines that such items were not completely addressed in the NDA for LEVADEX that we resubmitted to the FDA in October 2012, including if we have to make changes to our manufacturing processes or controls, conduct additional studies or provide additional information with respect to LEVADEX;
- the outcome, timing and cost of regulatory approvals and the regulatory approval process;
- the cost and timing of establishing commercial infrastructure including sales, marketing, manufacturing and distribution capabilities;
- the cost of procuring clinical and commercial supplies of our product candidates;
- the rate of market adoption of our product candidates for which we receive regulatory approval;
- delays that may be caused by changing regulatory requirements;
- the number of product candidates that we pursue;
- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;
- the timing and terms of in-licensing and out-licensing transactions;
- the cost of maintaining adequate working capital;
- the extent to which we acquire or invest in businesses, products or technologies; and

the possible costs of litigation.

We believe that our existing cash and cash equivalents will be sufficient to fund our projected operating requirements for at least 12 months. We will need substantial additional capital in the future in order to complete the development and commercialization of LEVADEX and to fund the development and commercialization of any future product candidates. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing 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.

If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates or grant licenses on terms that may not be favorable to us. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

New Accounting Standard Adopted

Effective January 1, 2012, we adopted revised guidance related to the presentation of comprehensive income that increases comparability between U.S. GAAP and International Financial Reporting Standards. This guidance eliminates the current option to report other comprehensive income, or OCI, and its components in the statement of changes in stockholders equity. We adopted this guidance during the first quarter of 2012 and elected to disclose OCI in a single continuous statement during interim reporting periods.

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Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is confined to our cash and cash equivalents. We consider all highly liquid investments purchased with an original maturity of less than or equal to ninety days to be cash equivalents. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and capturing a market rate of return based on our investment policy parameters and market conditions. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we maintain a portfolio of investments in securities of high credit quality.

Our primary exposure to market risk is interest rate related, which is affected by changes in the general level of U.S. interest rates. We currently do not hedge interest rate exposure. Because of the very short term maturity nature of our investments, we do not believe that an increase in market rates would have any material negative impact on the value of our investment portfolio. We do not have any foreign currency or other derivative financial instruments.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures: As required by paragraph (b) of Rules 13a-15 and 15d-15 promulgated under the Securities Exchange Act of 1934, as amended, for the Exchange Act, our management, including our Chief Executive Officer and Chief Financial Officer, conducted an evaluation as of the end of the period covered by this report, of the effectiveness of our disclosure controls and procedures as defined in Exchange Act Rule 13a-15(e) and 15d-15(e). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of September 30, 2012, the period covered by this report.

Changes in Internal Control over Financial Reporting: There were no significant changes in our internal control over financial reporting during our most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not a party to any material legal proceeding.

ITEM 1A. RISK FACTORS

We describe our business risk factors below. This description includes any material changes to and supersedes the description of the risk factors disclosed in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2011, as filed with the Securities and Exchange Commission on March 30, 2012 (the 2011 Annual Report). You should carefully consider the risks described below together with the other information set forth in this Quarterly Report on Form 10-Q, which could materially affect our business, financial condition or future results. The risks described below are not the only risks facing our company. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

Risks Relating to Our Financial Position and Need for Additional Capital

We have a history of net losses. Currently, we have no products approved for commercial sale, and to date we have not generated any product revenue. As a result, we may continue to incur substantial and increasing net losses for the foreseeable future, and we may never achieve or maintain profitability.

We are not profitable and do not expect to be profitable on a sustained basis in the foreseeable future. We have incurred significant net losses in each year since our inception, including net losses of approximately $32.9 million, $54.7 million and $9.0 million for the years ended December 31, 2011, 2010 and 2009, respectively. We have also incurred a net loss of $43.8 million for the nine months ended September 30, 2012. As of September 30, 2012, we had a deficit accumulated during the development stage of approximately $316.3 million. We have devoted most of our financial resources to research and development, including our pre-clinical development activities, clinical trials and manufacturing-related activities. We have not obtained regulatory approval for, or commercialized any product candidate and have therefore not generated any product revenues. In that regard, we expect to incur additional expenses as we continue to pursue our new drug application, or NDA, for LEVADEX, our most advanced product candidate, with the U.S. Food and Drug Administration, or the FDA. On March 26, 2012, we received a Complete Response letter in which the FDA described the reasons it was unable to approve our NDA and identified issues that we need to address in order to obtain FDA approval of LEVADEX. Following receipt of the Complete Response letter, we worked to address the issues identified in the Complete Response letter and had an End-of-Review meeting with the FDA to discuss our proposed plan for responding to the Complete Response letter. We resubmitted the NDA for LEVADEX in October 2012. Even though we submitted what we believe is a complete response to the items in the Complete Response letter, the FDA may not agree that we have completely addressed their concerns or approve our NDA. If the FDA determines that our resubmission does not provide a complete response or identifies additional concerns or issues with our NDA, the FDA may request that we conduct additional studies or provide additional data or analysis. If we are ultimately required by the FDA to perform studies in addition to those we have conducted, our expenses will increase beyond expectations and the timing of any potential product approval may be delayed. We expect an increase in our expenses associated with our manufacturing work and with preparing for commercialization. In addition, we expect to continue to incur costs to support operations as a public company. As a result, we may continue to incur substantial net losses and negative cash flow for the foreseeable future. These losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders equity and working capital.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of substantial expenses or when, or if, we will be able to achieve or maintain profitability. We have financed our operations primarily through the sale of equity securities, collaboration payments and debt financings. The size of our future net losses will depend, in part, on the rate of growth of our expenses and the rate of growth, if any, of our revenues. Revenues from potential strategic partnerships are uncertain because we may not enter into any additional strategic partnerships, including with respect to promotion of LEVADEX to additional physicians including primary care physicians. On January 28, 2011, we entered into a collaboration agreement with Allergan pursuant to which Allergan will co-promote LEVADEX with us in the United States to neurologists and pain specialists. In addition to the $80.0 million in upfront and milestone payments already received

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from Allergan, we are eligible to receive additional payments upon achievement of regulatory milestones and first commercial sale. If we do not meet these milestones, we will not receive additional payments and, under certain circumstances, Allergan may terminate our collaboration. If we are unable to develop and commercialize our other product candidates, including pursuant to strategic partnerships, or if sales revenue from any product candidate that receives marketing approval is insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability.

We have a limited operating history, and we expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.

Our operations to date have been primarily limited to organizing and staffing our company, developing our technology, undertaking pre-clinical studies, clinical trials and manufacturing-related activities of our product candidates and preparing for the potential commercialization of our initial product candidate, LEVADEX, if approved. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history. Specifically, our financial condition and operating results have varied significantly in the past and will continue to fluctuate from quarter-to-quarter and year-to-year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following factors, among others:

- our ability to obtain additional funding to develop our product candidates;
- the need to obtain regulatory approval of our most advanced product candidate, LEVADEX for the potential acute treatment of migraine;
- potential risks related to any collaborations we may enter into for our product candidates, including our current collaboration with Allergan for LEVADEX;
- our ability to receive regulatory approval for or commercialize our LEVADEX product candidate, as well as future product candidates;
- any delays in regulatory review and approval of our LEVADEX product candidate or future product candidates, including any requirements to perform additional preclinical or clinical trials;
- our ability to rely on Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FFDCA, to seek FDA marketing approval of our product candidates;
- the success of clinical trials of our LEVADEX product candidate or future product candidates;
- delays in the commencement, enrollment and completion of clinical testing, as well as the analysis and reporting of results from such clinical testing;
- market acceptance and rate of market adoption of our product candidates for which we obtain regulatory approval;

our ability, and our partners ability, to commercialize our products including establishing an effective sales and marketing infrastructure;

the ability of patients to obtain coverage of or sufficient reimbursement for our products;

competition from existing products or new products that may emerge;

the impact of competition, including generics, in the migraine market on our ability to commercialize LEVADEX;

the ability to receive regulatory approval or commercialize our products outside of the United States;

potential side effects of our products that have received regulatory approval that could delay or prevent commercialization or cause an approved drug to be taken off the market;

regulatory difficulties and post-market requirements relating to products that have already received regulatory approval;

our ability to obtain FDA approval of the proposed product names for our product candidates without delay;

practice guidelines and recommendations of therapies published by various organizations;

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potential product liability claims;

potential liabilities associated with hazardous materials;

our ability to maintain adequate insurance policies;

our dependency on third-party manufacturers to supply or manufacture our products;

our ability to establish or maintain collaborations, licensing or other arrangements;

our ability, our partners abilities, and third parties abilities to protect and assert intellectual property rights;

costs related to and outcomes of potential intellectual property litigation;

compliance with obligations under intellectual property licenses with third parties;

our need to transform our company by adding commercial expertise;

our ability to manage future growth;

our ability to remediate a material weakness in our internal controls over financial reporting and risks related to that material weakness; and

our ability to attract and retain key personnel to manage our business effectively.

Due to the various factors mentioned above, and others, the results of any prior quarterly or annual periods should not be relied upon as indications of our future operating performance.

We will need substantial additional funding and if we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate our product development programs.

Developing biopharmaceutical products, including conducting pre-clinical studies and clinical trials, and establishing manufacturing capabilities and an effective sales and marketing infrastructure, is expensive. While we have completed our clinical development program for LEVADEX for the acute treatment of migraine in adults, we expect to have continued expenses in connection with our ongoing activities, particularly as we seek to obtain approval of our NDA for LEVADEX, our most advanced product candidate, for the acute treatment of migraine in adults. In the March 26, 2012 Complete Response letter received from the FDA, the FDA requested that we address issues relating to the chemistry, manufacturing and controls, or CMC, of LEVADEX. The FDA also stated that manufacturing deficiencies identified during a recent facility inspection of one of our third party manufacturers need to be resolved to the FDA s satisfaction. The FDA indicated in the Complete Response letter that it had not been able to complete its review of inhaler usability information requested late in the review cycle by the FDA. We resubmitted the NDA for LEVADEX in October 2012. The FDA will not determine the type of resubmission (Class 1 or Class 2) and the resulting review timeline until after the resubmission has been accepted for filing. Even though we submitted what we believe is a complete response to the items in the Complete Response letter, the FDA may not agree that we have completely addressed their concerns or approve our NDA. If the FDA determines that our resubmission does not provide a complete response or identifies additional concerns or issues with our

NDA, the FDA may request that we conduct additional studies or provide additional data or analysis. If any additional studies, analysis or data are required by the FDA after our resubmission, it would require additional time and resources and may further delay our ability to obtain regulatory approval for LEVADEX, and our expenses will increase beyond expectations.

We believe that our existing cash and cash equivalents will be sufficient to fund our projected operating requirements for at least 12 months. We will need substantial additional capital in the future in order to commercialize LEVADEX and to fund the development and commercialization of future product candidates. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, including our collaboration with Allergan. 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

If adequate funds are not available, we may be required to delay or reduce the scope of our commercialization efforts or delay, reduce the scope of or eliminate one or more of our research or development programs. To the extent that we raise additional

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funds by issuing equity securities, our stockholders may experience additional significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates or to grant licenses on terms that may not be favorable to us. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this Risk Factors section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

- the costs and timing of regulatory approval including any potential delays that may occur;
- the cost and timing of commercial-scale manufacturing and distribution activities;
- the costs of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval;
- rate of market adoption of our product candidates for which we obtain regulatory approval.
- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effect of competing technological and market developments; and.
- the terms and timing of any collaboration, licensing or other arrangements that we may establish, including our current collaboration agreement with Allergan.

Risks Relating to the Development, Regulatory Approval and

Commercialization of Our Product Candidates

We are largely dependent on the success of one product candidate, and we cannot be certain that this product candidate will receive regulatory approval.

We have invested a significant portion of our efforts and financial resources in the development of LEVADEX and our Unit Dose Budesonide, or UDB, product candidate. In February 2009, we announced top-line results from our first Phase 3 trial of UDB, indicating that the trial did not meet its co-primary endpoints in either dose evaluated when compared to placebo. On July 8, 2009, we received a notice of termination of our license agreement with AstraZeneca AB, or the AstraZeneca Agreement, related to our UDB product candidate. Following the termination of the AstraZeneca Agreement, we suspended development of UDB. We are now largely dependent on the success of one product candidate, LEVADEX, for which we have completed a Phase 3 clinical development program for the acute treatment of migraine in adults. Our ability to generate product revenue is dependent on the successful regulatory approval and commercialization of this product candidate. In the March 26, 2012 Complete Response letter received from the FDA, the FDA requested that we address issues relating to the chemistry, manufacturing and controls, or CMC, of LEVADEX. The FDA also stated that manufacturing deficiencies identified during a recent facility inspection of one of

our third party manufacturers need to be resolved to the FDA s satisfaction. The FDA indicated in the Complete Response letter that it had not been able to complete its review of inhaler usability information requested late in the review cycle by the FDA. We resubmitted the NDA for LEVADEX in October 2012. The FDA will not determine the type of resubmission (Class 1 or Class 2) and the resulting review timeline until after the resubmission has been accepted for filing. Even though we submitted what we believe is a complete response to the items in the Complete Response letter, the FDA may not agree that we have completely addressed their concerns or approve our NDA. If the FDA determines that our resubmission does not provide a complete response or identifies additional concerns or issues with our NDA, the FDA may request that we conduct additional studies or provide additional data or analysis. If any additional studies, analysis or data are required by the FDA after our resubmission, it would require additional time and resources and may further delay our ability to obtain regulatory approval for LEVADEX, and our expenses will increase beyond expectations.

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We may have inadequate financial or other resources to advance LEVADEX through the NDA process, depending on the requirements of the FDA. In May 2009, we announced top-line results from the efficacy portion of our first Phase 3 trial of LEVADEX, indicating that the trial met all its co-primary endpoints when LEVADEX was compared to placebo. A long-term safety extension of the trial has also been completed and no drug-related serious adverse events were reported in the trial. Although we had planned to initiate a second Phase 3 efficacy study in the first quarter of 2010, we have been informed by the FDA that a second pivotal efficacy study is not required for submission of our NDA if the top-line efficacy results we submitted in 2009 are confirmed during the NDA review. We have completed a pharmacokinetics trial in 23 adult smokers comparing them to 24 adult non-smokers. The trial was designed to measure whether the systemic absorption of LEVADEX is higher and exposure to dihydroergotamine mesylate, or DHE, is greater in smokers than in non-smokers. In the trial, the systemic absorption of LEVADEX was not higher and systemic exposure to DHE was not greater in smokers than in non-smokers. We have completed a pharmacodynamics trial evaluating pulmonary artery pressure in approximately 24 healthy volunteers using echocardiograms. The trial compared the acute effects on pulmonary artery pressure of LEVADEX, DHE administered intravenously and placebo. In the trial, there was no statistically significant difference between the LEVADEX and placebo groups in the primary endpoint of pulmonary artery pressure over two hours after administration. We have completed a thorough QT trial in which LEVADEX did not increase QTc intervals as measured by electrocardiograms. We also completed a drug-drug interaction trial in which co-administration of LEVADEX with a potent CYP3A4 inhibitor showed no effects on the plasma levels of DHE or its elimination. Our clinical development program for LEVADEX may not lead to regulatory approval from the FDA and similar foreign regulatory agencies if we fail to demonstrate that the product candidate is safe and effective, and we may therefore fail to commercialize LEVADEX. Any failure to obtain regulatory approval of LEVADEX would have a material and adverse impact on our business.

With the suspension of development for our UDB product candidate, LEVADEX is our only current late stage product candidate. Our drug development efforts may not produce any other proprietary product candidates. We cannot be certain that we will be able to acquire or in-license other product candidates or develop other product candidates. Our failure to develop product candidates will limit our ability to generate additional revenue.

We currently have no approved drug products for sale and we cannot guarantee that we will ever have marketable drug products. The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, with regulations differing from country to country. We are not permitted to market our product candidates in the United States until we receive approval of an NDA from the FDA for each product candidate. We have not received marketing approval for any of our product candidates in any country. Obtaining approval of an NDA is a lengthy, expensive and uncertain process. Markets outside of the United States also have requirements for approval of drug candidates which we must comply with prior to marketing.

We have entered into a collaboration arrangement with Allergan, pursuant to which Allergan will commercialize LEVADEX, with us, to neurologists and pain specialists in the United States, following regulatory approval of LEVADEX. We may not fully realize the potential benefits of our collaboration with Allergan which may lead to an inability to obtain significant sales within the neurology and pain specialist segment of the migraine market and we may not be able to commercialize LEVADEX to primary care physicians.

We have entered into a collaboration agreement with Allergan targeting the neurology and pain specialist segment of the United States and Canada markets. We believe that adoption of LEVADEX by neurologists and pain specialists, who regularly treat migraine patients, will help to lead to broader adoption in the United States market. Our dependence on Allergan to help us to commercialize LEVADEX in this market segment and Allergan s performance under our collaboration agreement may not lead to physician uptake in this market and we may not be able to successfully commercialize LEVADEX in the neurology and pain specialist market. Our profits from the collaboration, if any, will be shared equally with Allergan and this arrangement may limit our overall profits and financial performance. While we believe that neurologists and pain specialists, because they treat migraine patients, may be early prescribers of LEVADEX and drive market adoption in the primary care physician segment of the market, our ability to enter into a partnership targeting primary care physicians may have an effect on the overall sales of LEVADEX. If we are unable to enter into a commercial partnership targeting primary care physicians, we may be unable to commercialize LEVADEX to primary care physicians on our own, and we may not realize significant revenues from product sales relating to that segment.

We may enter into additional collaborations with third parties to develop and commercialize our product candidates, including LEVADEX. These collaborations may place the development and commercialization of our product candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

We may enter into additional collaborations with third parties to develop and commercialize our product candidates, including LEVADEX. If LEVADEX is approved, we plan to jointly develop and fund research and development for two additional LEVADEX indications together with our partner Allergan. In addition, we may enter into a collaboration with a third party in the United States of America to commercialize LEVADEX to additional physicians including primary care physicians and/or to develop or commercialize LEVADEX outside the United States. Our dependence on current and future partners for development and commercialization of our product candidates will subject us to a

number of risks, including:

- we may not be able to control the amount and timing of resources that our partners may devote to the development or commercialization of product candidates or to their marketing and distribution;

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partners may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

disputes may arise between us and our partners that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management s attention and resources;

partners may experience financial difficulties;

partners may not properly maintain or defend our intellectual property rights, or may use our proprietary information, in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or proprietary information or expose us to potential litigation;

business combinations or significant changes in a partner s business strategy may adversely affect a partner s willingness or ability to meet its obligations under any arrangement;

a partner could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and

the collaborations with our partners may be terminated or allowed to expire, which would delay the development and may increase the cost of developing our product candidates.

All of our product candidates in development require regulatory review and approval prior to commercialization. Any delay in the regulatory review or approval of any of our product candidates in development will harm our business.

All of our product candidates in development require regulatory review and approval prior to commercialization, including review of pre-clinical data, clinical data and inspection of facilities and processes, including those relating to clinical and manufacturing activities. Any delays in the regulatory review or approval of our product candidates in development would delay market launch, increase our cash requirements and result in additional operating losses. In the March 26, 2012 Complete Response letter received from the FDA, the FDA requested that we address issues relating to the chemistry, manufacturing and controls, or CMC, of LEVADEX. The FDA also stated that manufacturing deficiencies identified during a recent facility inspection of one of our third party manufacturers need to be resolved to the FDA s satisfaction. The FDA indicated in the Complete Response letter that it had not been able to complete its review of inhaler usability information requested late in the review cycle by the FDA. We resubmitted the NDA for LEVADEX in October 2012. The FDA will not determine the type of resubmission (Class 1 or Class 2) and the resulting review timeline until after the resubmission has been accepted for filing. Even though we submitted what we believe is a complete response to the items in the Complete Response letter, the FDA may not agree that we have completely addressed their concerns or approve our NDA. If the FDA determines that our resubmission does not provide a complete response or identifies additional concerns or issues with our NDA, the FDA may request that we conduct additional studies or provide additional data or analysis. If any additional studies, analysis or data are required by the FDA after our resubmission, it would require additional time and resources and may further delay our ability to obtain regulatory approval for LEVADEX, and our expenses will increase beyond expectations.

The process of obtaining FDA and other required regulatory approvals, including foreign approvals, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. Furthermore, this approval process is extremely complex, expensive and uncertain. We or our partners may not be able to maintain our proposed schedules for the submission of any NDA in the United States or any marketing approval application or other foreign applications for any of our products. If we or our partners submit any NDA, including any amended NDA or supplemental NDA, to the FDA seeking marketing approval for any of our product candidates, the FDA must decide whether to either accept or reject the submission for filing. We cannot be certain that any of these submissions will be accepted for filing and reviewed by the FDA, or that our marketing approval application submissions to any other regulatory authorities will be accepted for filing and review by those authorities. We cannot be certain that we or our partners will be able to respond to any regulatory requests during the review period in a timely manner without delaying potential regulatory action. We also cannot be certain that any of our product candidates will receive

favorable recommendation from any FDA advisory committee or foreign regulatory bodies or be approved for marketing by the FDA or foreign regulatory authorities. In addition, delays in approvals or rejections of marketing applications may be based upon many factors, including regulatory requests for additional analyses, reports, data and/or studies, regulatory questions regarding data and results, changes in regulatory policy during the period of product development and/or the emergence of new information regarding our products or other products.

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Data obtained from pre-clinical studies and clinical trials are subject to different interpretations, which could delay, limit or prevent regulatory review or approval of any of our products. In addition, as a routine part of the evaluation of any potential drug, clinical studies are generally conducted to assess the potential for drug-drug interactions that could impact potential product safety. We conducted a drug-drug interaction trial in which co-administration of LEVADEX with a potent CYP3A4 inhibitor showed no effects on the plasma levels of DHE or its elimination. Furthermore, regulatory attitudes towards the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects.

In addition, the environment in which our regulatory submissions may be reviewed changes over time. For example, average review times at the FDA for marketing approval applications have fluctuated over the last ten years, and we cannot predict the review time for any of our submissions with any regulatory authorities. In addition, review times can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

We may not be able to rely on Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, which could result in additional costly trials and would delay obtaining marketing approval for LEVADEX.

We submitted our NDA for LEVADEX under Section 505(b)(2) of the FFDCA. Section 505(b)(2) allows the NDA we submitted to rely in part on data in the public domain or the FDA s prior conclusions regarding the safety and effectiveness of approved compounds. We may not be able to receive FDA marketing approval of this product candidate under Section 505(b)(2). If we are unable to rely on this Section, we would likely have to conduct additional clinical trials, and we would be delayed in obtaining, or may not be able to obtain, marketing approval for this product candidate.

If clinical trials of our LEVADEX product candidate or future product candidates do not produce results necessary to support regulatory approval in the United States or elsewhere or show undesirable side effects, we will be unable to commercialize these products.

To receive regulatory approval for the commercial sale of LEVADEX or any other product candidates, we must conduct adequate and well-controlled clinical trials to demonstrate efficacy and safety in humans. Clinical testing is expensive, takes many years and has an uncertain outcome. Clinical failure can occur at any stage of the testing. Our clinical trials may produce negative or inconclusive results. In such cases, we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing, or we may decide not to pursue further development of a product candidate, such as the case of our UDB product candidate, where top-line results of our Phase 3 clinical trial indicated that the trial failed to meet the primary endpoints. Subsequently we suspended development of UDB. In addition, the results of our clinical trials may show that our product candidates may cause undesirable side effects, which could interrupt, delay or halt clinical trials, resulting in our inability to obtain regulatory approval by the FDA and other regulatory authorities.

In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the Government Accounting Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials and regulatory approval. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion, or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

Our failure to adequately demonstrate the efficacy and safety of LEVADEX or any other product candidates would prevent regulatory approval and, ultimately, the commercialization of that product candidate.

Because the results of prior clinical trials are not necessarily predictive of future results, LEVADEX or any other product candidate advanced into clinical trials may not have favorable results in subsequent clinical trials or receive regulatory approval.

Success in pre-clinical studies and clinical trials does not ensure that subsequent clinical trials will generate adequate data to demonstrate the efficacy and safety of the investigational drug. A number of companies in the pharmaceutical industry, including those with greater resources and experience, have suffered significant setbacks in Phase 3 clinical trials, even after seeing promising results in prior clinical trials.

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The data collected from our clinical trials may not be adequate to support regulatory approval of LEVADEX or any of our other product candidates. In May 2009, we announced top-line results from the efficacy portion of our Phase 3 trial of LEVADEX, indicating that the trial met all four of its co-primary endpoints when LEVADEX was compared to placebo. We have completed a long-term safety extension of this Phase 3 trial, and no drug-related serious adverse events were reported in the trial. In July 2010, we announced that in a pharmacokinetics trial of LEVADEX, systemic absorption of LEVADEX was not higher and systemic exposure to DHE was not greater in smokers than in non-smokers. In September 2010, we reported results from a pharmacodynamics trial comparing the acute effects on pulmonary artery pressure of LEVADEX, DHE administered intravenously and placebo. In the trial, there was no statistically significant difference between the LEVADEX and placebo groups in the primary endpoint of pulmonary artery pressure over two hours after administration. In November 2010, we announced that in a thorough QT trial, a supra-therapeutic dose of LEVADEX did not increase QTc intervals. We also completed a drug-drug interaction trial in which co-administration of LEVADEX with a potent CYP3A4 inhibitor showed no effects on the plasma levels of DHE or its elimination. Even if we obtain regulatory approval of a product candidate, the FDA may require continuing evaluation and study of our product through clinical trials as a condition of any approval. Despite the results reported in prior clinical trials for our product candidates, we do not know whether subsequent clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates. For example, after receiving positive data from a previous Phase 2 trial, in February 2009 we announced top-line results from our Phase 3 trial of UDB, indicating that the trial did not meet its co-primary endpoints in either dose evaluated when compared to placebo. Subsequently, we suspended development of UDB.

Delays in the commencement, enrollment and completion of clinical testing could result in increased costs to us and delay or limit our ability to obtain regulatory approval for our product candidates.

Delays in the commencement, enrollment and completion of clinical testing could significantly affect our product development costs. While we have completed clinical development for our LEVADEX product candidate for the acute treatment of migraine in adults, we may be requested by the FDA to conduct additional clinical trials. In addition we will need to conduct clinical trials for future product candidates. The commencement and completion of clinical trials requires us to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs for the same indication as our product candidates or may be required to withdraw from our clinical trial as a result of changing standards of care or may become ineligible to participate in clinical studies. The commencement, enrollment and completion of clinical trials can be delayed for a variety of other reasons, including delays related to:

- reaching agreements on acceptable terms with prospective contract research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining regulatory approval to commence a clinical trial;
- obtaining institutional review board, or IRB, approval to conduct a clinical trial at numerous prospective sites;
- recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our study and competition from other clinical trial programs for the same indication as our product candidates;
- retaining patients who have initiated a clinical trial but may be prone to withdraw due to the treatment protocol, lack of efficacy, personal issues or side effects from the therapy or who are lost to further follow-up;
- maintaining and supplying clinical trial material on a timely basis; and
- collecting, analyzing and reporting final data from the clinical trials.

In addition, a clinical trial may be suspended or terminated by us, the FDA or other regulatory authorities due to a number of factors, including:

failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;

unforeseen safety issues or any determination that a trial presents unacceptable health risks; and

lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties.

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We have completed a Phase 3 clinical program to support our NDA for LEVADEX. In October 2009, we submitted our top-line efficacy results for the double-blind efficacy portion of our pivotal Phase 3 study. We also have completed the long-term safety extension of our pivotal Phase 3 trial, a pharmacokinetics trial in healthy adult smokers and non-smokers, a pharmacodynamics trial measuring pulmonary artery pressure in healthy adults, a thorough QT trial and a drug-drug interaction trial in support of our NDA for LEVADEX. FDA communicated its agreement with the design, execution, and analyses for our pivotal Phase 3 trial, which we submitted to the FDA under the Special Protocol Assessment, or SPA, process and modified as suggested by FDA. Under a SPA, the FDA agrees to not later alter its position with respect to adequacy of the design, execution, or analyses of the clinical trial intended to form the primary basis of an effectiveness claim in an NDA, without the sponsor s agreement unless the FDA identifies a substantial scientific issue essential to determining the safety or efficacy of the drug after testing begins. In March 2010, we held a pre-NDA meeting with the FDA to discuss the clinical portion of our anticipated NDA filing. The FDA s minutes of that meeting state that, while the FDA did not have a record of a formal SPA, the FDA concurred with the selection of our co-primary endpoints and confirmed that a second pivotal efficacy study was not necessary if top-line efficacy results were confirmed during the NDA review. We believe that our prior written correspondence and interactions with the FDA under the SPA process constitute an SPA with the agency. The FDA may take a different view and could request additional safety and efficacy studies without having to identify a substantial scientific issue with our Phase 3 trial that is essential to determining the safety and efficacy of LEVADEX. If we are required to conduct additional clinical trials or other testing of our LEVADEX product candidate beyond those that we currently contemplate, we may be delayed in obtaining, or may not be able to obtain, marketing approval for this product candidate. We may not be able to obtain approval for indications that are as broad as intended or we may obtain approval for indications different than those indications for which we seek approval. Furthermore we may not be able to obtain approval for any of our other product candidates.

Additionally, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in the completion of, or if we terminate, our clinical trials, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Even if we are able to ultimately commercialize our product candidates, other therapies for the same or similar indications may have been introduced to the market and established a competitive advantage.

If any of our product candidates for which we or our partners receive regulatory approval do not achieve broad market acceptance, the revenues that we generate from their sales will be limited.

The commercial success of our product candidates for which we or our partners obtain marketing approval from the FDA or other regulatory authorities will depend upon the acceptance of these products among physicians, the medical community, patients, and coverage and reimbursement of them by third-party payors, including government payors. The degree of market acceptance of any of our approved products will depend on a number of factors, including:

- a product s FDA-approved labeling as well as limitations or warnings contained in the labeling;
- changes in the standard of care for the targeted indications for any of our product candidates, which could reduce the marketing impact of any claims that we could make following FDA approval;
- limitations inherent in the approved indication and product labeling for any of our product candidates compared to more commonly understood or addressed medical conditions;
- lower demonstrated efficacy and a less favorable safety or tolerability profile compared to other products;
- device-related difficulties associated with our TEMPO inhaler;
- prevalence and severity of adverse effects;

our failure to establish an effective sales and marketing infrastructure;

ineffective marketing and distribution efforts by us or our collaborators;

lack of availability of reimbursement from managed care plans and other third-party payors;

our ability to manufacture sufficient inventory and supply wholesale distributors;

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lack of cost-effectiveness;

timing of market introduction and perceived effectiveness of competitive products;

availability of alternative therapies, including generics, at similar or lower costs;

extent of a Risk Evaluation and Mitigation Strategies, or REMS, program, if any;

patients potential preferences to take oral medications over inhaled medications; and

potential product liability claims.

Our and our partners ability to effectively promote and sell our product candidates in the marketplace will also depend on pricing and cost effectiveness, including our and our partners ability to manufacture a product at a competitive price. We will also need to demonstrate acceptable evidence of safety and efficacy and may need to demonstrate relative convenience and ease of administration. Inhaled versions of certain previously approved drugs have suffered commercial failure, including inhaled insulin. If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, our and our partners efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful. If our approved drugs fail to achieve market acceptance, we will not be able to generate significant revenue, if any.

We have never marketed a drug before, and if we are unable to establish, or access an effective and specialized sales force and marketing infrastructure, we will not be able to commercialize our product candidates successfully.

We plan to market or co-promote our products where appropriate and build our own specialized sales force in the United States. We have entered into a collaboration with Allergan pursuant to which we will co-promote LEVADEX to neurologists and pain specialists in the United States, following potential FDA approval of LEVADEX. We currently do not have significant internal sales, distribution and marketing capabilities. The development of a sales and marketing infrastructure for our domestic operations will require substantial resources and additional personnel with sales, distribution and marketing experience whom we do not currently employ, will be expensive and time consuming and could negatively impact our commercialization efforts, including delay of any product launch. Many of these costs are being incurred in advance of notice to us that any of our product candidates has been approved. For example, in order to commercialize LEVADEX, we will need to hire, train and deploy a specialized sales force and establish marketing capabilities in the United States directed at high prescribers, including specialists such as neurologists and pain specialists. We may not be able to hire a specialized sales force in the United States that is sufficient in size or has adequate expertise in the medical markets that we intend to target, including neurology. If we are unable to establish our specialized sales force and marketing capability for our most advanced product candidate, we may not be able to generate any product revenue, may generate increased expenses and may never become profitable.

We will also need to expend significant time and resources to train any sales force that we do hire to be credible and persuasive in discussing LEVADEX with these specialists. We will also need to train our sales force to ensure that a consistent and appropriate message about LEVADEX is being delivered to our potential customers. In addition, if we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits and risks of LEVADEX and its proper administration, our efforts to successfully commercialize LEVADEX could be put in jeopardy, which could have a material adverse effect on our financial condition, stock price and operations.

If our patients are unable to obtain coverage of or sufficient reimbursement for our products, it is unlikely that our products will be widely used.

Successful sales of our products depend on the availability of adequate coverage and reimbursement from third-party payors to cover the costs to our patients. Healthcare providers that purchase medicine or medical products for treatment of their patients generally rely on third-party payors to reimburse all or part of the costs and fees associated with the products. Adequate coverage and reimbursement from governmental payors, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Patients are unlikely to use our products if they do

not receive reimbursement adequate to cover the cost of our products.

In addition, the market for our future products will depend significantly on access to third-party payors drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. Industry competition to be included in such formularies results in downward pricing pressures on pharmaceutical companies. Third-party payors may refuse to include a particular branded drug in their formularies when a generic drug for the same or similar indication is available.

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All third-party payors, whether governmental or commercial, whether inside the United States or outside, are developing increasingly sophisticated methods for controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for medical technology exists among all these payors. Therefore, coverage of and reimbursement for medical products can differ significantly from payor to payor.

Further, we believe that future coverage and reimbursement may be subject to increased restrictions both in the United States of America and in international markets, pursuant to currently proposed healthcare reforms or otherwise. Third-party coverage and reimbursement for our products may not be available or adequate in either the United States or international markets, limiting our ability to sell our products on a profitable basis.

We expect intense competition with respect to our existing and future product candidates.

The pharmaceutical industry is highly competitive, with a number of established, large pharmaceutical companies, as well as many smaller companies. Many of these companies have greater financial resources, marketing capabilities and experience in obtaining regulatory approvals for product candidates. There are many pharmaceutical companies, biotechnology companies, public and private universities, government agencies and research organizations actively engaged in research and development of products which may target the same indications as our product candidates. We expect any future products we develop to compete on the basis of, among other things, product efficacy and safety, extent of adverse side effects, time to market, pricing and reimbursement, and convenience of treatment procedures. One or more of our competitors may develop alternative products or therapies that are safer, more effective and/or more cost effective than any products developed by us, obtain approvals for such products from the FDA more rapidly than us or develop products based upon the principles underlying our proprietary technologies earlier than us.

Competitors may seek to develop alternative formulations of our product candidates that address our targeted indications. The commercial opportunity for our product candidates could be significantly harmed if competitors are able to develop alternative formulations outside the scope of our products. Compared to us, many of our potential competitors have substantially greater:

- capital resources;
- research and development resources, including personnel and technology;
- clinical trial experience;
- regulatory experience;
- expertise in prosecution of intellectual property rights;
- manufacturing and distribution experience; and
- sales and marketing resources and experience.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, useful and less costly than ours and may also be more successful than us in manufacturing and marketing their products.

The migraine market is extremely competitive which may negatively impact our ability to commercialize LEVADEX.

If approved for the acute treatment of migraine, we anticipate that LEVADEX would compete against other marketed migraine therapies and may compete with products currently under development by both large and small companies. In 2011, there were approximately 13 million migraine-specific prescriptions written for the acute treatment of migraine, generating approximately $1.7 billion in revenues in the U.S. The majority of the prescriptions written were in the triptan class, and the leading branded agent, Maxalt, generated approximately $450 million in revenues in the U.S. However, in 2008 when the leading migraine-specific agent, Imitrex, became generic, the total market for migraine-specific prescriptions generated approximately $2.5 billion in revenues in the U.S. There are at least six other branded triptan therapies being sold by pharmaceutical companies. Alternative formulations of triptans are available that may have faster onset of action than solid oral dosage forms. In April 2008, GlaxoSmithKline s Treximet, a combination oral formulation of sumatriptan and naproxen sodium, was approved by the FDA for the acute treatment of migraine. In July 2009, Zogenix, Inc. s Sumavel DosePro needle-free sumatriptan was approved by the FDA for the acute treatment of migraine

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and cluster headache. Alternative formulations of dihydroergotamine, or DHE, include Migranal, which is nasally delivered, and which may become generically available prior to any commercial introduction of LEVADEX. In addition to the marketed migraine therapeutics, there may be product candidates under development by companies that could potentially be used for the acute treatment of migraine and compete with LEVADEX. In October 2010, Allergan, Inc. s BOTOX botulinum toxin was approved by the FDA for the treatment of chronic migraine, a different indication than the acute treatment of migraine.

We would also face competition from generic sumatriptan, the active ingredient in Imitrex. The FDA has approved generic versions of sumatriptan. Although we believe generic sumatriptan could not be substituted for LEVADEX, generic sumatriptan may be more quickly adopted by health insurers and patients than LEVADEX. Financial pressure to use generic products and uncertainty of reimbursement for single source alternatives, such as LEVADEX, may encourage the use of a generic product over LEVADEX.

Even if our product candidates receive regulatory approval in the United States, we or our partners may never receive approval or commercialize our products outside of the United States.

In order to market and commercialize any products outside of the United States, we and our partners must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures and requirements vary among countries and can involve additional pre-clinical studies and clinical trials and additional administrative review periods. For example, European regulatory authorities generally require clinical testing comparing the efficacy of the new drug to an existing drug prior to granting approval. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States, as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the United States. As described above, such effects include the risks that our product candidates may not be approved for all indications requested, which could limit the uses of our product candidates and have an adverse effect on product sales and potential royalties, and that such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

Our product candidates may have undesirable side effects and cause our approved drugs to be subject to more restricted use or to be taken off the market.

If our most advanced product candidate, LEVADEX, or any other product candidate, receives marketing approval and we or others later identify undesirable side effects caused by such products:

- regulatory authorities may require the addition of labeling statements, specific warnings, contraindications or field alerts to physicians and pharmacies;
- regulatory authorities may withdraw their approval of the product and require us to take our approved drug off the market;
- we may be required to change the way the product is administered, conduct additional clinical trials, change the labeling of the product or conduct a Risk Evaluation and Mitigation Strategies, or REMS, program;
- we may have limitations on how we promote our drugs;
- sales of products may decrease significantly;
- we may be subject to litigation or product liability claims; and

our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase our commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from its sale.

Even if our product candidates receive regulatory approval, we and our partners may still face future development and regulatory difficulties.

Even if we obtain U.S. regulatory approval for LEVADEX, the FDA may still impose significant restrictions on its indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. Given the number of recent high profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk management programs which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special

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packaging or labeling, expedited reporting of certain adverse events, pre-approval of promotional materials and restrictions on direct-to-consumer advertising. In addition, the FDA could condition any approval of LEVADEX on our implementation of a post-approval risk management plan. Furthermore, heightened Congressional scrutiny on the adequacy of the FDA s drug approval process and the agency s efforts to provide adequate oversight of the safety of marketed drugs has resulted in the proposal of new legislation addressing drug safety issues. Any new legislation could result in delays or increased costs during the period of product development, clinical trials and regulatory review and approval, as well as increased costs to assure compliance with any new post-approval regulatory requirements. Any of these restrictions or requirements could force us to conduct costly studies or increase the time for us to become profitable. For example, any labeling approved for LEVADEX or any other product candidates may include a restriction on the term of its use, such as a black box warning, or it may not include one or more of our intended indications. The FDA historically has required that labeling for products containing DHE include a contraindication for use in women who are, or who may become, pregnant. Although we believe that this contraindication is not applicable to our formulation of DHE, the FDA may disagree and require the LEVADEX labeling to carry this contraindication.

Our product candidates will also be subject to ongoing FDA requirements for the current Good Manufacturing Practices, or cGMP, labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. In addition, approved products, manufacturers and manufacturers facilities are subject to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or us, including requesting withdrawal of the product from the market. If our product candidates fail to comply with applicable regulatory requirements, or fail to be made in compliance with applicable regulatory requirements such as cGMP, a regulatory agency may:

- issue warning letters or untitled letters identifying violations;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- impose other civil or criminal penalties;
- suspend regulatory review of pending NDAs or approval of new products;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require a product recall.

We or our potential partners will need to obtain FDA approval of the proposed product names for our product candidates and any failure or delay associated with such approval may adversely impact our business.

Any trade name we or our potential partners intend to use for our product candidates will require approval from the FDA regardless of whether we or our partners have secured a formal trademark registration from the U.S. Patent and Trademark Office. The FDA typically conducts a rigorous review of proposed product names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims. If the FDA objects to our product names, we may be required to adopt an alternative name for our product candidates. If we or our partners adopt an alternative name, we or our partners would lose the benefit of our existing trademark applications and may be required to expend significant additional resources in an effort to identify a

suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We or our partners may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Guidelines and recommendations published by various organizations may affect the use of our products.

Government agencies issue regulations and guidelines directly applicable to us and to our products. In addition, professional societies, practice management groups, private health/science foundations and organizations involved in various diseases from time to time publish guidelines or recommendations to the medical and patient communities. These various sorts of recommendations may relate to such matters as product usage, dosage, route of administration and use of related or competing therapies. Changes to this recommendation or other guidelines advocating alternative therapies could result in decreased use of our products, which may adversely affect our results of operations.

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We face potential product liability exposure and, if successful claims are brought against us, we may incur substantial liability for a product candidate and may have to limit its commercialization.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval, if any, expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- loss of revenues;
- the inability to commercialize our product candidates;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- costs of related litigation;
- substantial monetary awards to patients or other claimants; and
- impairment of our business reputation.

We have obtained limited product liability insurance coverage for our clinical trials domestically and in selected foreign countries where we conduct clinical trials. However, our insurance coverage 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, in the future, 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 our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Our operations involve hazardous materials, which could subject us to significant liabilities.

Our research and development processes involve the controlled use of hazardous materials, including chemicals. Our operations produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge or injury from these materials. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these materials. We could be subject to civil damages in the event of an improper or unauthorized release of, or exposure of individuals, including employees, to hazardous materials. In addition, claimants may sue us for injury or contamination that results from our use of these materials and our liability may exceed our total assets. We maintain limited insurance for the use of hazardous materials which may not be adequate to cover any claims. Compliance with environmental and other laws and regulations may be expensive and current or future regulations may impair our research, development or production efforts.

Our insurance policies are expensive and protect us only from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. For example, we do not carry earthquake insurance. In the event of a major earthquake in our region, our business could suffer significant and uninsured damage and loss. Some of the policies we currently maintain include general liability, property, auto, workers compensation, products liability and directors and officers insurance policies. Our insurance is expensive and we do not know if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

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Risks Related to Our Dependence on Third Parties

If we are unable to establish additional marketing, sales and distribution collaborations with third parties, we may not be able to commercialize LEVADEX successfully.

We have a collaboration agreement with Allergan to commercialize LEVADEX to neurologists and pain specialists in the United States and Canada. We may establish additional marketing, sales and distribution collaborations with third parties where appropriate. For example, if we choose to expand the marketing and sales of LEVADEX to additional physicians including primary care physicians beyond neurologists and pain specialists, we may establish partnerships with other companies to maximize the potential of the commercialization opportunity. Outside the United States and Canada, we may establish commercial partnerships for LEVADEX in order to effectively reach target markets in order to maximize its commercial opportunities. We expect to face competition in our efforts to identify appropriate collaborators or partners to help commercialize LEVADEX to primary care physicians or outside the United States and Canada. If we are unable to establish adequate marketing, sales and distribution collaborations to target primary care physicians, specialists and other large groups of prescribing physicians within and outside the United States, then we may not be able to achieve the full commercial opportunity for LEVADEX.

We have no experience manufacturing large clinical-scale or commercial-scale pharmaceutical products and we do not own or operate a manufacturing facility. As a result, 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.

We do not own or operate manufacturing facilities for clinical or commercial manufacture of our product candidates, which includes drug substance and drug packaging, including the components of the TEMPO inhaler, the device used to administer certain of our drug candidates, including LEVADEX. We have limited personnel with experience in drug manufacturing and we lack the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We currently outsource all manufacturing and packaging of our pre-clinical and clinical product candidates to third parties. In addition, we do not currently have all necessary agreements with third-party manufacturers for the long-term commercial supply of our product candidates. We may be unable to enter into agreements for commercial supply with all third-party manufacturers, or may be unable to do so on acceptable terms. Even if we enter into these agreements or, for those agreements that we have already entered into, the various manufacturers of each product candidate will likely be single source suppliers to us for a significant period of time. We may not be able to establish additional sources of supply for our products prior to commercialization. Such suppliers are subject to regulatory requirements covering manufacturing, testing, quality control and record keeping relating to our product candidates, and are subject to pre-approval and ongoing inspections by the regulatory agencies. Failure by any of our suppliers to comply with applicable regulations may result in long delays and interruptions to our manufacturing capacity while we seek to secure another supplier that meets all regulatory requirements.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the product candidates ourselves, including:

- reliance on the third parties for regulatory compliance, quality assurance and hazardous materials handling;
- the possible breach of the manufacturing and quality agreements by the third parties because of factors beyond our control; and
- the possibility of termination or nonrenewal of the agreements by the third parties because of our breach of the manufacturing agreement or based on their own business priorities.

Any of these factors could cause the delay of required approvals or commercialization of our products, could prevent us from commercializing our product candidates successfully, could cause the suspension of initiation or completion of clinical trials and regulatory submissions, and could lead to higher product costs. Furthermore, if our contract manufacturers fail to deliver the required commercial quantities of finished product on a timely basis and at commercially reasonable prices and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality and on a timely basis, we would likely be unable to meet demand for our products and we would lose potential revenue. It may take a significant period of time to establish an alternative source of supply for our product candidates and to have any such new source approved by the FDA. In the March 26, 2012 Complete Response letter received from the FDA, the FDA requested that we address issues relating to the chemistry, manufacturing and controls, or CMC, of LEVADEX. The FDA also stated that manufacturing deficiencies identified during a recent facility inspection of one of our third party

manufacturers need to be resolved to the FDA s satisfaction. While we believe that we have addressed the issues in the Complete Response letter, we continue to work closely with our third party manufacturer to ensure that the third party manufacturer has and will continue to meet all FDA requirements; however, we are dependent on the third-party manufacturer to do so.

The FDA may not agree that we and our third-party manufacturer have completely addressed their concerns or approve our NDA. If the FDA determines that our resubmission does not provide a complete response or identifies additional concerns or issues with our NDA, the FDA may request that we conduct additional studies or provide additional data or analysis, or request that we make changes to our manufacturing processes or controls.

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We will rely on third parties to perform many essential services for LEVADEX and any other products that we commercialize, including services related to warehousing and inventory control, distribution, customer service, accounts receivable management, cash collection and adverse event reporting, and if such third parties fail to perform as expected or to comply with legal and regulatory requirements, our efforts to commercialize LEVADEX or any other products may be significantly impacted and we may be subject to regulatory sanctions.

We intend to rely on third-party service providers to perform a variety of functions related to the sale and distribution of LEVADEX, key aspects of which are out of our direct control. The services provided by these third parties include warehousing and inventory control, distribution, customer service, accounts receivable management and cash collection. As a result, most of our inventory will be stored at a single warehouse maintained by one such service provider. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or if our products encounter physical or natural damage at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired. In addition, we have engaged, or will engage, third parties to perform various other services for us relating to adverse event reporting, safety database management, fulfillment of requests for medical information regarding LEVADEX and related services. If the quality or accuracy of the data maintained or services performed by these third parties is insufficient, we could be subject to regulatory sanctions.

We may not be successful in maintaining or establishing collaborations, which could adversely affect our ability to develop and commercialize certain of our product candidates.

We may not be able to establish or maintain collaborations around our product candidates, which may adversely affect our ability to develop and commercialize our product candidates. We have entered into a collaboration agreement and co-promotion agreement with Allergan pursuant to which Allergan will co-promote LEVADEX to neurologists and pain specialists in the United States, following potential FDA product approval, and will share expenses relating to the commercialization of LEVADEX. Under certain circumstances, Allergan has the right to terminate these agreements. If Allergan terminates our agreement, we would not receive milestones due after the termination date, and we would be responsible for commercialization expenses previously shared with Allergan. Also in the event of a termination by Allergan, we may have difficulty commercializing LEVADEX to neurologists and pain specialists, as we have no experience marketing pharmaceutical products on our own. In July 2009, we received a notice of termination of our AstraZeneca Agreement related to our UDB product candidate. Our AstraZeneca Agreement provided that AstraZeneca could terminate the agreement in the event that the primary endpoints of our Phase 3 clinical trial of UDB were not met. Following the termination of the AstraZeneca Agreement, we suspended development of UDB. In addition, our earlier stage product portfolio includes next generation budesonide, MAP0005 for the potential treatment of asthma and COPD and MAP0001 for the potential treatment of diabetes. We have no current intention to further develop any of these earlier stage product candidates independently. Developing pharmaceutical products, conducting clinical trials, establishing manufacturing capabilities and marketing approved products is expensive. Consequently, we may establish partnerships for further development and commercialization of these product candidates. We expect to face competition in seeking appropriate partners. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement and they may require substantial resources to maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements, if any. The terms of any collaboration or other arrangement that we establish may not be favorable to us. In addition, any collaboration that we enter into may not be successful. If we seek partners to help develop next generation budesonide, MAP0005 and MAP0001, but are unable to reach agreements with suitable partners, we may fail to commercialize such products.

Risks Relating to Our Intellectual Property

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our product candidates and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our products is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

We license certain intellectual property from third parties that covers our product candidates. We rely on certain of these third parties to file, prosecute and maintain patent applications and otherwise protect the intellectual property to which we have a license, and we have not had and do not have primary control over these activities for certain of these patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. Our enforcement of certain of these licensed patents or defense of any claims asserting the invalidity of these patents would also be subject to the cooperation of the third parties.

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The patent positions of pharmaceutical and biopharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biopharmaceutical patents has emerged to date in the United States. The biopharmaceutical patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents we own or to which we have a license from a third-party. Further, if any of our patents are deemed invalid and unenforceable, it could impact our ability to commercialize or license our technology.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make compositions or formulations that are similar to our product candidates but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by our issued patents or pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;
- our issued patents may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use, our technology.

If we or our partners choose to go to court to stop someone else from using the inventions claimed in our patents, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop a third party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to prevent the other party s activities on the ground that such other party s activities do not infringe our rights to these patents. In addition, the U.S. Supreme Court has recently invalidated some tests used by the U.S. Patent and Trademark Office in granting patents over the past 20 years. As a consequence, several issued patents may be found to

contain invalid claims according to the newly revised standards. Some of our own or in-licensed patents may be subject to challenge and subsequent invalidation in a re-examination proceeding before the U.S. Patent and Trademark Office or during litigation under the revised criteria which make it more difficult to obtain patents.

Furthermore, a third party may claim that we or our manufacturing or commercialization partners are using inventions covered by the third party s patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. We are aware that claims in patents owned by others may relate to our business and technologies. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. If we are sued for patent infringement, there is a risk that a court would order us or our partners to

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stop the activities covered by the patents. In addition, there is a risk that a court will order us or our partners to pay the other party damages for having violated the other party s patent rights. We have agreed to indemnify certain of our commercial partners against certain patent infringement claims brought by third parties. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents by others covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are a party to a license agreement with Nektar Therapeutics UK Limited, pursuant to which we license the use of key intellectual property, including intellectual property relating to our most advanced product candidate, LEVADEX. These existing licenses impose various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the licensors may have the right to terminate the license, in which event we might not be able to develop or market any product that is covered by the licensed patents. If we lose such license rights that are important to our product candidate, our business may be materially adversely affected. We may enter into additional licenses in the future and if we fail to comply with obligations under those agreements, we could suffer similar consequences.

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

As is common in the biotechnology and pharmaceutical industries, 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.

Risks Related to Employee Matters, Managing Growth and Accounting Matters

We need to transform our company by adding commercial expertise.

From inception to date, we have focused on research and development, including our pre-clinical development activities, clinical trials, manufacturing-related activities and the preparation of our NDA for LEVADEX. In connection with the potential commercialization of LEVADEX, if approved, we will need to add personnel with expertise in new areas for our company, such as sales, marketing and distribution, and to have our existing employees learn additional skills to support our commercialization efforts. We may not be able to attract or retain qualified employees with sales, marketing and distribution experience, due to competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the Silicon Valley region of California. In addition, we will need to integrate employees with sales, marketing and distribution expertise into our company, which to date has focused predominantly on research and development activities. If we are not able to attract and retain necessary personnel, we may experience constraints that will significantly impede the achievement of our commercialization strategy.

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

As September 30, 2012, we had 121 full-time employees. If LEVADEX is approved, we will need to expand our managerial, operational, administrative and other resources in order to commercialize our product candidates, manage and fund our operations and

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continue our development activities. To support this growth, we intend to hire additional employees within the next 12 months. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we:

- manage our development program for LEVADEX, including manufacturing and regulatory activities in support of the NDA process with the FDA, and potential approval from the FDA;
- begin activities related to commercialization, and effectively hire, train and manage a sales force, who will have no prior experience with our company or LEVADEX, and establish appropriate systems, policies and infrastructure to support our commercial organization; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our development and commercialization goals.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel.

We may not be able to attract or retain qualified management, commercial, scientific and clinical personnel in the future due to competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the Silicon Valley region of California. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the development, regulatory, commercialization and product acquisition expertise of our senior management, particularly Timothy S. Nelson, our President and Chief Executive Officer, and Thomas A. Armer, our co-founder and Chief Scientific Officer. If we lose one or more of these key employees, our ability to implement our business strategy successfully could be seriously harmed. Replacing key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, obtain regulatory approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel.

In addition, we have scientific and clinical advisors who assist us in our product development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development of products that may compete with ours. Because our business depends on certain key personnel and advisors, the loss of such personnel and advisors could weaken our management team and we may experience difficulty in attracting and retaining qualified personnel and advisors.

Our management s determination that there was a material weakness in our internal control over financial reporting and our disclosure controls and procedures, or any determination in the future that there are other deficiencies or weaknesses in our controls, could have a material adverse impact on our reported financial results or the price of our security.

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to evaluate the effectiveness of our internal controls over financial reporting as of the end of each fiscal year, and to include a management report assessing the effectiveness of our internal controls over financial reporting in our annual report on Form 10-K for that fiscal year. Section 404 also requires our independent registered public accounting firm to attest to, and report on, management s assessment of our internal controls over financial reporting.

As discussed in item 9A of our Annual Report on Form 10-K for the year ended December 31, 2011, our management determined that there was a material weakness in our internal controls over financial reporting in that we had not maintained effective controls over complex multiple element revenue arrangements. Specifically, effective controls, as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended, were not designed and in place with regard to the evaluation of, and accounting for, a complex multiple element arrangement (in this case timing of recognition of revenue related to an upfront payment from Allergan, which timing had no impact on the company s cash position, total assets or operating expenses). Due to this material weakness, our principal executive officer and principal financial officer also concluded

that our disclosure controls and procedures were not effective as of December 31, 2011, or as of March 31, 2012. Subsequent to the identification of the material weakness we enhanced our accounting and financial reporting controls for complex multiple element revenue arrangements, and our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective as of June 30, 2012 and as of September 30, 2012 to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer

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and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. However, a controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. If we have not adequately remediated the matters that caused the control deficiencies underlying the material weaknesses, or if we have any additional material weaknesses in our controls in the future, our business and results of operations could be harmed, we may be unable to report properly or timely the results of our operations, and investors may lose faith in the reliability of our financial statements. Accordingly, the price of our securities may be adversely and materially impacted.

Risks Relating to Owning Our Common Stock

Our share price may be volatile which may cause the value of our common stock to decline and subject us to securities class action litigation.

The market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

actual or anticipated fluctuations in our financial conditions and operating results;

regulatory actions with respect to our products or our competitors products;

actions and decisions by our collaborators or partners;

status and/or results of our clinical trials;

results of clinical trials of our competitors products;

our growth rate and actual or anticipated changes in our growth rate relative to our competitors;

rate of prescription growth for LEVADEX, if approved, and how that growth compares to analyst expectations;

actual or anticipated fluctuations in our competitors operating results or changes in their growth rate;

competition from existing products, new products or generics that may emerge;

issuance of new or updated research or reports by securities analysts;

fluctuations in the valuation of companies perceived by investors to be comparable to us;

share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;

market conditions for biopharmaceutical stocks in general; and

general economic and market conditions.

If securities or industry analysts do not publish research or reports about our business, or publish negative reports about our business, our stock price and trading volume could decline.

The trading market for our common stock depends on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our stock or change their opinion of our stock, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline.

Future sales of our common stock may cause our stock price to decline.

Persons who were our stockholders prior to the sale of shares in our IPO continue to hold a large number of shares of our common stock that they are now able to sell in the public market. Significant portions of these shares are held by a small number of stockholders. Sales by our current stockholders of a large number of shares, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. Moreover, the holders of a large number of shares of common stock may have rights, subject to certain conditions, to require us to file registration statements to permit the resale of their shares in the public market or to include their shares in registration statements that we may file for ourselves or other stockholders.

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We have also registered or plan to register all common stock that we may issue under our employee benefits plans. As a result, these shares can be freely sold in the public market upon issuance, subject to restrictions under the securities laws. In addition, our directors and executive officers may establish programmed selling plans under Rule 10b5-1 of the Exchange Act for the purpose of effecting sales of our common stock. If any of these events cause a large number of our shares to be sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

We will continue to incur significant increased costs as a result of operating as a public company.

As a public company, we will continue to incur significant legal, accounting and other expenses to comply with the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted by the Securities and Exchange Commission and by the NASDAQ Global Market. In addition, any changes in such regulations will result in increased costs to us as we respond to these requirements. For example, we must use certain required internal controls and disclosure controls and procedures, as required by Section 404 of the Sarbanes-Oxley Act of 2002. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 will require that we continue to incur substantial accounting expense and expend significant management efforts. In addition, we will continue to bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002 and related regulations implemented by the Securities and Exchange Commission and The NASDAQ Global Market, are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. We are currently evaluating and monitoring developments with respect to new and proposed rules and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We will continue to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management s time and attention from potentially revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and our bylaws may delay or prevent an acquisition of us. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management team. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits, with some exceptions, stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. Finally, our charter documents establish advanced notice requirements for nominations for election to our board of directors and for proposing matters that can be acted upon at stockholder meetings. Although we believe these provisions together provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders.

We have never paid dividends on our common stock, and because we do not anticipate paying any cash dividends in the foreseeable future, capital appreciation, if any, of our common stock will be your sole source of gain on an investment in our stock.

We have never paid cash dividends on our common stock and we currently intend to retain our cash and future earnings, if any, to fund the development and growth of our business. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biotechnology and biopharmaceutical companies. These broad market fluctuations may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management s attention and resources, which could adversely affect our business.

ITEM 6. EXHIBITS

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant (filed as Exhibit 3.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2007 and incorporated herein by reference).
3.2	Amended and Restated Bylaws of the Registrant (filed as Exhibit 3.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2007 and incorporated herein by reference).
4.1	Specimen Stock Certificate (filed as Exhibit 4.1 to the Registrant s Registration Statement on Form S-1-A (File No. 333-143823), filed on September 20, 2007, and incorporated herein by reference).
31.1	Certification of Principal Executive Officer Required under Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer Required under Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of Principal Executive Officer and Principal Financial Officer Required under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.
101.INS^	XBRL Instance Document
101.SCH^	XBRL Taxonomy Extension Schema Document
101.CAL^	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB^	XBRL Taxonomy Extension Label Linkbase Document
101.PRE^	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF^	XBRL Taxonomy Extension Definition Linkbase Document

^ XBRL (Extensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, and is not otherwise subject to liability under those sections.

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SIGNATURES

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

Date: November 6, 2012

MAP PHARMACEUTICALS, INC.

By: /s/ TIMOTHY S. NELSON
Timothy S. Nelson

President and Chief Executive Officer

(Principal Executive Officer)

By: /s/ CHRISTOPHER Y. CHAI
Christopher Y. Chai

Senior Vice President and Chief Financial Officer

(Principal Financial and Accounting Officer)