MAP Pharmaceuticals, Inc.
Form 10-Q
November 05, 2010
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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, 2010

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO_____

Commission File Number 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 ¨ 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, 2010, the registrant had outstanding 30,127,041 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, 2010	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 41,816	$ 65,776
Prepaid expenses and other current assets	464	620
Total current assets	42,280	66,396
Property and equipment, net	4,903	4,164
Other assets	455	126
Restricted investment	310	310
Total assets	$ 47,948	$ 70,996
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 2,276	$ 2,916
Accrued liabilities	8,908	11,568
Current portion of long-term debt	7,845	7,283
Total current liabilities	19,029	21,767
Long-term debt, net of current	1,580	7,337
Other liabilities	123	90
Total liabilities	20,732	29,194
Commitments and contingencies (Note 6)		
Stockholders equity:		
Common stock	261	241
Additional paid-in capital	252,571	226,452
Deficit accumulated during the development stage	(225,616)	(184,891)
Total stockholders equity	27,216	41,802

Total liabilities and stockholders equity	$ 47,948	$ 70,996

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

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MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from July 3, 2003 (Inception) to September 30, 2010
	2010	2009	2010	2009	
Collaboration revenue	$	$ 35,273	$	$ 51,402	$ 54,166
Operating expenses:					
Research and development	10,009	11,912	28,037	35,615	207,731
Sales, general and administrative	3,921	3,597	11,712	9,842	58,913
Total operating expenses	13,930	15,509	39,749	45,457	266,644
Income (loss) from operations	(13,930)	19,764	(39,749)	5,945	(212,478)
Interest income	5	7	11	118	6,379
Interest expense	(284)	(519)	(1,016)	(1,672)	(6,767)
Other income (expense), net	31	7	29	(21)	(733)
Net income (loss)	(14,178)	19,259	(40,725)	4,370	(213,599)
Cumulative stock dividend attributed to preferred stockholders					(13,925)
Net income (loss) attributed to common stockholders	$ (14,178)	$ 19,259	$ (40,725)	$ 4,370	$ (227,524)
Net income (loss) per share attributed to common stockholders					
Basic	$ (0.53)	$ 0.84	$ (1.55)	$ 0.20	
Diluted	$ (0.53)	$ 0.80	$ (1.55)	$ 0.19	
Weighted average shares outstanding used in calculating net income (loss) per share attributed to common stockholders					
Basic	26,629,481	22,860,897	26,323,425	21,389,679	
Diluted	26,629,481	24,054,236	26,323,425	22,505,625	

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

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MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended September 30,		Cumulative Period from July 3, 2003 (Date of Inception) to September 30, 2010
	2010	2009	
Cash flows from operating activities:			
Net income (loss)	$ (40,725)	$ 4,370	$ (213,599)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	931	1,111	5,587
Accretion of investment discounts, net		(1)	(1,595)
Amortization of debt issuance costs			210
Accretion of debt payment premium	199	306	890
Change in carrying value of warrant liability			621
Issuance of common stock in exchange for services			51
Stock-based compensation	4,804	3,806	16,073
Loss on disposal of equipment and other non-cash items	306	675	1,373
Changes in operating assets and liabilities:			
Accounts receivable		(2,704)	
Prepaid expenses and other current assets	156	450	(689)
Other assets	83	(10)	97
Accounts payable	(640)	1,561	2,247
Accrued liabilities	(3,072)	(4,876)	8,418
Other liabilities	33	22	123
Net cash provided by (used in) operating activities	(37,925)	4,710	(180,193)
Cash flows from investing activities:			
Purchase of intangible assets and in-process research and development			(412)
Purchase of property and equipment	(1,976)	(748)	(11,417)
Purchase of short-term investments			(169,497)
Sales and maturities of short-term investments		12,740	171,411
Purchase of restricted investment			(310)
Net cash provided by (used in) investing activities	(1,976)	11,992	(10,225)
Cash flows from financing activities:			
Proceeds from issuance of convertible notes payable			4,300
Proceeds from issuance of debt			31,006
Adjustment to issuance cost related to IPO			(9)
Proceeds from sales of shares through equity plans	1,681	624	3,630

Repayment of debt	(5,394)	(4,637)	(22,571)
Proceeds from issuance of common stock resulting from equity financing transactions, net of issuance costs	19,654	31,607	113,450
Proceeds from issuance of convertible preferred stock, net of issuance costs			102,428
Net cash provided by financing activities	15,941	27,594	232,234
Net increase (decrease) in cash and cash equivalents	(23,960)	44,296	41,816
Cash and cash equivalents at beginning of period	65,776	31,927	
Cash and cash equivalents at end of period	$ 41,816	$ 76,223	$ 41,816
Supplemental disclosures of cash flow information			
Cash paid for interest	$ 818	$ 1,361	$ 5,567
Supplemental disclosures of noncash financing activities			
Accrued deferred offering costs	$ 412	$	$ 412

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

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MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

NOTE 1. THE COMPANY

MAP Pharmaceuticals, Inc., incorporated in the state of Delaware, originally was formed as a limited liability company on July 3, 2003 and converted to a corporation on December 11, 2003. Our goal is to use proprietary inhalation technologies to enhance the therapeutic benefits and commercial attractiveness of proven drugs while minimizing risk by capitalizing on their known safety, efficacy and commercialization history. Our current focus is to advance the development of our Phase 3 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 will continue to incur net losses for the next several years. We believe that our existing cash and cash equivalents, together with the net proceeds of approximately $47.1 million from our equity offering completed in October 2010 (See Note 8 Subsequent Event for more information), 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 potential commercialization of LEVADEX and to fund the development and commercialization of any future product candidates. Prior to achieving profitable operations, we intend to continue to fund operations through public or private financings, strategic partnerships or other arrangements. Such funding, if needed, may not be available on favorable terms, if at all. In the event we are unable to obtain additional capital, we may delay or reduce the scope of our current research and development programs and other expenses.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

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

The year-end condensed balance sheet at December 31, 2009 was derived from audited financial statements, but 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, 2009.

Revenue Recognition

We recognize revenue in accordance with Accounting Standards Codification, or ASC 605, *Revenue Recognition*, which requires that certain criteria must be met before revenue can be recognized: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or determinable; and collectability is reasonably assured. Determination of whether persuasive evidence of an arrangement exists and whether delivery has occurred or services have been rendered are based on management s judgments regarding the fixed nature of the fee charged for research performed and milestones met, and the collectability of those fees. Should changes in conditions cause management to determine these criteria are not met for certain future transactions, revenue recognized for any reporting period could be adversely affected.

Collaboration revenue, which is earned under agreements with third parties for research and development activities, may include nonrefundable license fees, cost reimbursements and contingent milestones and royalties. Our revenue arrangements with multiple elements are evaluated in accordance with ASC 605-*25 Revenue Recognition Multiple-Element Arrangements*, and are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value and whether there is verifiable objective and reliable evidence of the fair value of the undelivered items. The consideration we receive is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units.

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MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

Upfront payments received upon execution of collaborative agreements are recorded as deferred revenue and recognized as collaboration revenue over the research and development period pursuant to the agreement. Such period generally represents the research and development period set forth in the agreement between our third-party collaborator and us. The research and development period is estimated at the inception of the arrangement and is periodically reevaluated. Reevaluation of the research and development period may shorten or lengthen the period during which the deferred revenue is recognized. We evaluate the appropriate period based on research progress attained and reevaluate the period when significant changes occur. If the collaboration agreement is terminated, all the remaining unamortized deferred revenue will be recognized as collaboration revenue on the date of termination.

Cost reimbursements are based upon negotiated rates for our full time employee equivalents, or FTE, and actual out-of-pocket costs. They are recognized as collaboration revenue as the related research and development services are performed. The cost reimbursements are generally based on qualified expenses as defined in the collaborative agreement. FTE rates are intended to approximate our anticipated cost.

We recognize milestone payments as revenue upon achievement of the milestone provided the milestone payment is nonrefundable, substantive effort and risk is involved in achieving the milestone and the amount of the milestone is reasonable in relation to the effort expended or risk associated with the achievement of the milestone. If these conditions are not met, we defer the milestone payment and recognize it as revenue over the estimated period of performance under the contract as we complete our performance obligations.

Pre-clinical Study and Clinical Trial Accruals

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

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

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

Stock-Based Compensation

Effective January 1, 2006, we adopted ASC 718 *Compensation Stock Compensation,* using the prospective transition method, which requires the measurement and recognition of compensation expense for all stock-based payment awards granted, modified and settled to our employees and directors after January 1, 2006. Our financial statements reflect the impact of ASC 718. We chose the straight-line attribution method for

allocating compensation costs and recognized the fair value of each stock option on a straight-line basis over the requisite service period.

We account for equity instruments issued to non-employees in accordance with ASC 505-50 *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. Equity instruments issued to non-employees are recorded at their fair value on the measurement date and are subject to periodic adjustment as the underlying equity instruments vest.

Comprehensive Loss

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

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MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Net income (loss)	$ (14,178)	$ 19,259	$ (40,725)	$ 4,370
Net change in unrealized loss on available-for-sale investments				(44)
Comprehensive income (loss)	$ (14,178)	$ 19,259	$ (40,725)	$ 4,326

Net 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) 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, performance-based restricted stock units and shares issuable under our employee stock purchase plan, or ESPP, using the treasury stock method. Potential shares of common stock issuable from the exercise of outstanding stock options and warrants and pursuant to our ESPP and performance-based restricted stock units were not included in the computation of diluted net loss per share for the three and nine months ended September 30, 2010 because their inclusion would have been anti-dilutive.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Net income (loss) attributed to common stockholders	$ (14,178)	$ 19,259	$ (40,725)	$ 4,370
Basic:				
Weighted average common shares used in computing basic net income (loss) per common share	26,629,481	22,860,897	26,323,425	21,389,679
Basic income (loss) per common share	$ (0.53)	$ 0.84	$ (1.55)	$ 0.20
Diluted:				
Weighted average common shares used in computing basic net income (loss) per common share	26,629,481	22,860,897	26,323,425	21,389,679
Add: Weighted average stock options		1,122,715		1,074,667
Add: Weighted average warrants		19,451		1,176
Add: Weighted average shares issuable under employee stock purchase plan		51,173		40,103
Weighted average common shares used in computing diluted net income (loss) per common share	26,629,481	24,054,236	26,323,425	22,505,625

Diluted income (loss) per common share	$ (0.53)	$ 0.80	$ (1.55)	$ 0.19

The following outstanding common stock options, common stock issuable pursuant to the ESPP, warrants to purchase common stock and performance-based restricted stock units 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:

	As of September 30,	
	2010	2009
Options to purchase common stock	4,006,986	2,369,092
Common stock issuable pursuant to the ESPP	24,563	
Warrants to purchase common stock	26,903	
Performance-based restricted stock units	98,000	

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MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

Recent Accounting Pronouncements

On April 29, 2010, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2010-17, *Revenue Recognition Milestone Method (Topic 605): Milestone Method of Revenue Recognition* (a consensus of the FASB Emerging Issues Task Force). It establishes a revenue recognition model for contingent consideration that is payable upon the achievement of an uncertain future event, referred to as a milestone. The scope of the ASU is limited to research or development arrangements and requires an entity to record the milestone payment in its entirety in the period received if the milestone meets all the necessary criteria to be considered substantive. The ASU is effective for fiscal years (and interim periods within those fiscal years) beginning on or after June 15, 2010. Early application is permitted. Entities can apply this guidance prospectively to milestones achieved after adoption. However, retrospective application to all prior periods is also permitted. We have to adopt the new pronouncement in the first quarter of fiscal year 2011. We do not believe that the adoption of ASU 2010-17 will have a material impact on our condensed consolidated financial statements.

In September 2009, the FASB ratified Revenue Arrangements with Multiple Deliverables issued as ASU 2009-13 in early October. ASU 2009-13 updates the existing multiple-element arrangements guidance currently included in ASC 605-25, *Revenue Recognition Multiple-Element Arrangements*. The revised guidance provides for two significant changes to the existing multiple-element arrangements guidance. The first relates to the determination of when the individual deliverables included in a multiple-element arrangement may be treated as separate units of accounting. This change is significant as it will likely result in the requirement to separate more deliverables within an arrangement, ultimately leading to less revenue deferral. The second change modifies the manner in which the transaction consideration is allocated across the separately identifiable deliverables. These changes are likely to result in earlier recognition of revenue for multiple-element arrangements than under previous guidance. ASU 2009-13 also significantly expands the disclosures required for multiple-element revenue arrangements. The revised multiple-element arrangements guidance will be effective for the first annual reporting period beginning on or after June 15, 2010, and may be applied retrospectively for all periods presented or prospectively to arrangements entered into or modified after the adoption date. Early adoption is permitted provided that the revised guidance is retroactively applied to the beginning of the year of adoption. If the guidance is adopted prospectively, certain transitional disclosures are required for each reporting period in the initial year of adoption. We have to adopt the new pronouncement in the first quarter of fiscal year 2011. We do not believe that the adoption of ASU 2009-13 will have a material impact on our condensed consolidated financial statements.

NOTE 3. LICENSE AND SUPPLY AGREEMENTS

Agreement with AstraZeneca

In December 2008, we entered into an agreement with AstraZeneca AB, or the AstraZeneca Agreement, which became effective in February 2009. Pursuant to the terms of the AstraZeneca Agreement, we licensed to AstraZeneca global rights to develop and commercialize our proprietary nebulized formulation of UDB, our next generation UDB therapy and certain combination nebulization therapies for the potential treatment of asthma in children.

In February 2009, under the terms of the AstraZeneca Agreement, AstraZeneca paid us a nonrefundable upfront cash payment of $40.0 million. On February 23, 2009, we announced top-line results of our initial Phase 3 clinical trial of UDB for the potential treatment of children with asthma. We announced that the clinical trial did not meet its co-primary endpoints, asthma control as assessed by changes from baseline in nighttime and daytime composite symptom scores, in either of the doses evaluated when compared with placebo.

On July 8, 2009, we received notice from AstraZeneca of the termination of the AstraZeneca Agreement. Effective on the date of termination, all rights licensed to AstraZeneca in the AstraZeneca Agreement reverted back to us. We were jointly developing UDB with AstraZeneca, and were responsible for executing the development plan. In the third quarter of 2009 we suspended development of our UDB product candidate.

Total collaboration revenue recognized under the AstraZeneca Agreement was $0 for the three and nine months ended September 30, 2010, compared to $35.3 million and $51.4 million, respectively, for the same periods in 2009. Total collaboration revenue recognized under the AstraZeneca Agreement was $54.2 million for the cumulative period from July 3, 2003 (date of inception) to September 30, 2010. The revenue recognized in the three and nine months ended September 30, 2009 was related to the amortization of a $40.0 million upfront payment received in February 2009 and for reimbursements for UDB-related development expenses pursuant to the AstraZeneca Agreement.

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MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

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. As of September 30, 2010, we are required to make future nonrefundable milestone payments of up to $5.0 million related to products currently being developed under the Nektar Agreement, when and if certain regulatory and commercial milestones are met. We paid $0 for both the three and nine months ended September 30, 2010 and 2009. We paid $2.6 million for the cumulative period from July 3, 2003 (date of inception) to September 30, 2010. 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.

Agreement with Elan

Under the April 2004 agreement, as amended, with Elan Pharma International Limited, or the Elan Agreement, Elan granted to us a worldwide, exclusive, sub-licensable license under certain of Elan s intellectual property rights related to our UDB product candidate. 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, 2010 and 2009. We paid $4.0 million for the cumulative period from July 3, 2003 (date of inception) to September 30, 2010. Either party may terminate the Elan Agreement upon a material, uncured default of the other party. We may terminate the agreement, with or without cause, at any time upon 90 days prior written notice. We also entered into a services agreement with Elan Drug Delivery International in February 2005, amended subsequently, which describes the terms and conditions for clinical and commercial supply of product intermediate for our UDB product candidate.

In August 2010, our agreement with Elan Pharma International Limited terminated as a result of our election not to extend the agreement. Our agreement with Elan Drug Delivery International also was terminated in August 2010. We currently are not developing any product candidates requiring the technology licensed in the Elan Agreement. The termination of the Elan Agreement did not have a material impact on our condensed consolidated financial statements.

NOTE 4. FAIR VALUE MEASUREMENTS

On January 1, 2008, we adopted ASC 820, *Fair Value Measurements,* 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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MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

The following was a summary of our cash, cash equivalents and restricted investment as of September 30, 2010 and December 31, 2009, respectively (in thousands):

	As of September 30, 2010		
	Amortized Cost	Unrealized Gain (Loss)	Estimated Fair Value
Cash	$ 3,153	$	$ 3,153
Certificates of deposit	310		310
Money market funds	38,663		38,663
	$ 42,126	$	$ 42,126
Reported as:			
Cash and cash equivalents			$ 41,816
Restricted investment			310
			$ 42,126

	As of December 31, 2009		
	Amortized Cost	Unrealized Gain (Loss)	Estimated Fair Value
Cash	$ 4,620	$	$ 4,620
Certificates of deposit	310		310
Money market funds	61,156		61,156
	$ 66,086	$	$ 66,086
Reported as:			
Cash and cash equivalents			$ 65,776
Restricted investment			310
			$ 66,086

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, 2010 and December 31, 2009, 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, 2010	Level 1	Level 2	Level 3	Total
Certificates of Deposit	$	$ 310	$	$ 310
Money Market Funds	38,663			38,663
Total	$ 38,663	$ 310	$	$ 38,973

As of December 31, 2009	Level 1	Level 2	Level 3	Total
Certificates of deposit	$	$ 310	$	$ 310
Money market funds	61,156			61,156
Total	$ 61,156	$ 310	$	$ 61,466

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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MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

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.

The carrying amount for our debt reported in the condensed consolidated balance sheet as of September 30, 2010 was $9.4 million. Using a discounted cash flow technique that incorporates a market interest rate, we have determined the fair value of our debt to be $9.3 million at September 30, 2010.

NOTE 5. BALANCE SHEET COMPONENTS

Accrued liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2010	December 31, 2009
Clinical trial related	$ 4,856	$ 7,573
Payroll and related expenses	2,918	2,932
Professional services	1,052	905
Other	82	158
	$ 8,908	$ 11,568

Debt

In September 2006, we entered into a $3.0 million loan facility agreement for the purpose of financing equipment purchases, or the Equipment Loan, and borrowed $1.0 million under this facility. The Equipment Loan bore interest at an annual interest rate of 9.5% and was fully paid as of September 30, 2009.

In May 2008, we entered into an additional loan agreement, or the 2008 Working Capital Loan, for $20.0 million, in order to repay an earlier working capital loan and to support general corporate purposes. The 2008 Working Capital Loan bears interest at an annual rate of 9.95%, with an effective rate of approximately 12% after factoring in a $1.0 million payment due at the termination of this agreement. The 2008 Working Capital Loan had interest-only payments up to and including January 2009, matures in October 2011, and includes customary loan covenants. As of September 30, 2010, we were in compliance with these loan covenants.

The 2008 Working Capital Loan amounts are collateralized by all of our assets, excluding intellectual property.

Our debt consisted of the following (in thousands):

	September 30, 2010	December 31, 2009
Principal amount	$ 8,535	$ 13,929
Plus: premium, based on imputed interest rate of 12%	890	691
	9,425	14,620
Less: current portion of debt	7,845	7,283
Long-term portion	$ 1,580	$ 7,337

As of September 30, 2010, debt payments, which include interest and principal, are as follows (in thousands):

Year ending December 31,	Amount
2010 (remaining three months)	$ 2,086
2011	7,952
Total debt payments	$ 10,038

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MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

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, and in August 2006 we amended the Lease to include additional square footage within the same building. The Lease was to expire in June 2008. In March 2008, we entered into another amendment to the Lease, or the March 2008 Amendment, to extend the term of the Lease until June 2012, and to include additional square footage and options to lease additional square footage. In September 2008, we amended and restated the Lease, providing for expanded square footage and 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. The annual lease payments for the space under the amended and restated Lease were effective on July 1, 2008.

Rent expense was approximately $0.3 million and $1.0 million, respectively, for the three and nine months ended September 30, 2010, compared to $0.3 million and $0.9 million, respectively, for the same periods in 2009. Rent expense was approximately $5.5 million for the cumulative period from July 3, 2003 (date of inception) to September 30, 2010.

As of September 30, 2010, future minimum lease payments are as follows (in thousands):

Year ending December 31,	Amount
2010 (remaining three months)	$ 329
2011	1,357
2012	700
Total minimum lease payments	$ 2,386

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, 2010 and December 31, 2009.

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.

NOTE 7. STOCKHOLDERS EQUITY

Warrants

In March 2010, warrants representing 24,668 shares were exercised, resulting in a net issuance of 12,295 shares. As of September 30, 2010, we had outstanding warrants to purchase an aggregate of 26,903 shares of common stock, exercisable at a price of $7.43 per share. The remaining outstanding warrants were issued in connection with an earlier working capital loan agreement and expire in September 2013.

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MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

Stock Option Activities

For the nine months ended September 30, 2010, stock option activity under our 2007 Equity Award Plan, or the 2007 Plan, was as follows:

	Number of Shares	Weighted Average Exercise Price
Balances, at December 31, 2009	3,628,845	$ 7.30
Options granted	845,281	$ 15.90
Options exercised	(392,776)	$ 3.39
Options forfeited	(66, 903)	$ 10.42
Options expired	(7,461)	$ 13.21
Balances, at September 30, 2010	4,006,986	$ 9.43

As of September 30, 2010, we had 1,959,604 shares of common stock available for grant under the 2007 Plan.

Stock-Based Compensation for Employees

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Research and development	$ 766	$ 537	$ 2,108	$ 1,529
Sales, general and administrative	944	697	2,696	2,207
	$ 1,710	$ 1,234	$ 4,804	$ 3,736

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, 2010 and 2009, respectively:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Risk-free interest rate	1.3% - 1.7%	2.3% - 2.5%	1.3% - 2.5%	1.6% - 2.5%
Expected volatility	67%	64%	62% - 67%	62% - 64%
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 our ESPP for the three and nine months ended September 30, 2010 and 2009, respectively:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Risk-free interest rate	0.2%	0.3%	0.1% - 0.2%	0.3%
Expected volatility	47%	95%	47% - 76%	95% - 99%
Expected term (in years)	0.5	0.5	0.5	0.5
Expected dividend yield	0%	0%	0%	0%

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.

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MAP PHARMACEUTICALS, INC.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

*Expected Volatility: T*he 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. We will continue to analyze the expected stock price volatility of stock options as more historical data for our common stock becomes available. Effective on January 1, 2010, the expected stock price volatility for shares from the ESPP is determined based on our own historical stock price volatilities.

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: Stock-based compensation expense is determined based on when awards are ultimately expected to vest, and it has been reduced for estimated forfeitures. ASC 718 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, 2010, there were unrecognized compensation costs of approximately $6.7 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 2.3 years.

Performance-Based Restricted Stock Units: On February 2, 2010, the Compensation Committee of the Board of Directors approved awards of 98,000 performance-based restricted stock units from the 2007 Plan to certain of our employees. These awards will convert into shares of our common stock upon vesting at the end of the performance periods, if specific performance goals set by the Compensation Committee are achieved. No performance shares will vest if the performance goals are not met. Each vested performance share will convert into one share of our common stock on the vesting dates. The fair value of the performance-based restricted stock units was determined using the stock price of our common stock on the date of the grant which was $16.19. 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 any changes to our probability assessment of the number of performance shares expected to vest as a result of our achievement of the performance goals. For the three and nine months ended September 30, 2010, we recorded compensation expense of $171,000 and $456,000, respectively, related to performance-based restricted stock units. As of September 30, 2010, there were unrecognized compensation costs of approximately $875,000, net of estimated forfeitures, related to performance-based restricted stock units.

Stock-Based Compensation for Non-Employees

Stock-based compensation expense related to stock options granted to non-employees is recognized as the stock options are earned. Management believes that the fair value of the stock options is more reliably measurable than the fair value of the service received. The fair value of stock options granted to non-employees is calculated at each grant date and remeasured at each reporting date. The stock-based compensation expense will fluctuate as the price of our common stock fluctuates. We recorded stock-based compensation expense for non-employees of $0 for the three and nine months ended September 30, 2010, compared to $8,000 and $70,000, respectively, for the same periods in 2009. We recorded stock-based compensation expense for non-employees of $0.9 million for the cumulative period from July 3, 2003 (date of inception) through September 30, 2010.

Equity Line of Credit

On November 11, 2009, we entered into a Common Stock Purchase Agreement, or the Purchase Agreement, with Azimuth Opportunity Ltd., or 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 committed to purchase up to $60 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, 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 as mutually agreed upon by Azimuth and us.

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MAP PHARMACEUTICALS, INC.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

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 the offering expenses.

NOTE 8. SUBSEQUENT EVENT

In October 2010, we completed an equity offering in which we sold 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 $47.1 million in net proceeds after deducting underwriting discounts, commissions and estimated offering expenses.

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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: 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, 2009.

Overview

Our goal is to use our proprietary inhalation technologies to enhance the therapeutic benefits and commercial attractiveness of proven drugs while minimizing risk by capitalizing on their known safety, efficacy and commercialization history. We have proprietary product candidates in development that address large market opportunities. Our current focus is to advance our Phase 3 product candidate, LEVADEX orally inhaled migraine therapy, formerly known as MAP0004, a proprietary orally inhaled version of dihydroergotamine mesylate, or DHE, for the potential treatment of migraine.

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. They 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 up to approximately 12% of the population in the United States and approximately 15% in Europe. According to the National Headache Foundation, approximately 30 million people in the United States suffer from migraine. In 2008, according to market data, approximately 29 million prescriptions were written for the treatment of migraine in the United States. Approximately 12 million of those prescriptions were written for acute migraine specific drugs. The majority of acute migraine specific drug prescriptions written were in the triptan class. In 2009, the triptan market in the United States totaled approximately $2.1 billion in revenues.

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. LEVADEX is an easy to use, at-home therapy in development that patients self-administer using our proprietary hand-held TEMPO® inhaler. 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. DHE also is available in an intranasal formulation. We believe LEVADEX has the potential to be suitable as a first-line therapy for some migraine patients.

In May 2009, we announced results of the efficacy portion of our first Phase 3 clinical trial of LEVADEX, or FREEDOM-301. The clinical trial met its four primary endpoints, pain relief and being nausea, phonophobia and photophobia free as reported two hours after dosing. Additional

endpoints showed that LEVADEX provided rapid and sustained pain relief for up to 48 hours after dosing.

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Patients taking LEVADEX therapy had statistically significant improvement at two hours compared to patients on placebo for each of the primary endpoints:

- Pain relief: 58.7% of patients who received LEVADEX compared with 34.5% for placebo ($p<0.0001$);
- Phonophobia free: 52.9% of patients who received LEVADEX compared with 33.8% for placebo ($p<0.0001$);
- Photophobia free: 46.6% of patients who received LEVADEX compared with 27.2% for placebo ($p<0.0001$); and
- Nausea free: 67.1% of patients who received LEVADEX compared with 58.7% for placebo ($p=0.02$).

A total of 792 patients were included in the primary data analysis as specified in the protocol of the FREEDOM-301 study. The patient population studied had more severe migraine pain than anticipated, with 46% reporting severe pain and 54% reporting moderate pain prior to administration of the study drug.

Results from additional pre-defined analyses include:

- LEVADEX therapy achieved statistically significant onset of pain relief at 30 minutes after dosing ($p=0.03$);
- While not statistically significant, 50% more of the patients receiving LEVADEX therapy than the patients receiving placebo reported pain relief at 10 minutes;
- LEVADEX therapy achieved statistically significant sustained pain relief from two to 24 hours ($p<0.0001$), as well as two to 48 hours ($p<0.0001$, when unadjusted for multiplicity);
- LEVADEX therapy achieved statistically significant pain freedom (pain symptom score = 0) as early as 30 minutes ($p=0.002$, when unadjusted for multiplicity); and
- LEVADEX therapy achieved sustained pain freedom from two to 24 hours, as well as two to 48 hours ($p<0.0001$ for both time points, when unadjusted for multiplicity).

LEVADEX was well tolerated, with the most common adverse event reported being medication aftertaste at six percent, with two percent of patients receiving placebo also reporting medication aftertaste. The next most common adverse event was nausea at five percent, compared with two percent for placebo. Symptoms or sensitivities typically associated with commonly used triptan migraine treatments, such as chest discomfort (one percent) or chest pain (zero percent), were rare and comparable to placebo. There were no mean decreases in lung function, as measured by spirometry, between the active and placebo groups. There were no drug-related serious adverse events reported in the trial. These data were presented in September 2009 in a late-breaking session of the 14th Congress of the International Headache Society.

In September 2009, we announced that post-hoc analysis of data from this Phase 3 trial shows the potential of LEVADEX to be effective in treating acute migraine as well as a broad spectrum of migraine, including migraine subpopulations that are often resistant to current therapies such as triptans, migraine with moderate and severe pain, migraine with nausea and vomiting and migraine with and without aura.

In October 2009, we announced that we had completed a planned interim safety review of the open-label, long-term safety extension of the FREEDOM 301 clinical trial. At the time of the interim review, more than 400 patients had completed at least six months of treatment and over

7,800 headaches had been treated in the safety extension. No drug-related serious adverse events had been reported.

In January 2010, we announced that the U.S. Food and Drug Administration, or the FDA, had informed us that a second pivotal efficacy study would not be required for the LEVADEX new drug application, or NDA, submission, if the topline efficacy results we submitted are confirmed during the review of our NDA. We had previously anticipated initiating a second pivotal efficacy study in the first quarter of 2010.

In May 2010, we announced that we currently expected to file an NDA, for LEVADEX with the FDA during the first half of 2011.

In July 2010, we announced results from a clinical trial comparing the pharmacokinetics, or PK, and safety of LEVADEX orally inhaled migraine therapy with intravenous DHE in 23 smokers and 24 non-smokers. The trial was designed to measure whether systemic absorption and exposure in smokers is greater 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.

In September 2010, we announced results from a pharmacodynamics trial evaluating pulmonary artery pressure in approximately 24 healthy volunteers using echocardiogram. The trial compared 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.

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In September 2010, we also announced the following in connection with our ongoing open-label safety trial: more than 400 patients had completed at least six months of treatment and more than 200 patients had completed twelve months of treatment; all non-asthmatic patients and a subset of asthmatic patients had completed treatment; LEVADEX was well tolerated and no drug-related serious adverse events had been reported; and no clinically significant trends had been reported for LEVADEX in the evaluation of cardiovascular measurements and pulmonary function. The remaining patients are expected to complete treatment in 2010. In addition, we have completed patient treatment in a thorough QT trial evaluating whether LEVADEX has an effect on QT interval as measured by electrocardiograms in support of our application to the FDA for regulatory approval.

We hold worldwide commercialization rights for LEVADEX and our goal is to market LEVADEX in the United States through our own focused sales force targeting neurologists and headache specialists. We may establish partnerships with pharmaceutical companies to market and sell to primary care physicians and specialists inside and outside of the United States.

Nebulized Budesonide

Unit Dose Budesonide, or UDB, is our proprietary nebulized version of budesonide intended to treat asthma in children from 12 months to eight years of age. UDB is designed to be administered more quickly and to provide efficacy at lower doses than conventional nebulized budesonide. Conventional nebulized budesonide is an inhaled corticosteroid approved by the FDA for treating asthma in children from 12 months up to eight years of age. Our UDB product candidate has been designed to achieve a particle size smaller than previously possible with budesonide. We believe this smaller particle size may allow for faster delivery and efficacy at a lower dose, which together may offer improved safety, compliance and convenience.

In December 2008 we entered into a worldwide collaboration with AstraZeneca AB to develop and commercialize UDB, or the AstraZeneca Agreement, which became effective on February 2, 2009. 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 when compared to placebo. On July 8, 2009, we received a notice of termination of the AstraZeneca Agreement. Subsequently, we suspended development of UDB. We are considering options for our pediatric asthma program moving forward, by leveraging our experience with budesonide and our expertise in particle technology, including the development of a next generation therapy with budesonide.

Other Pipeline Products

Our product portfolio also includes the two earlier stage product candidates listed below, both of which highlight the broad applicability of our technologies to a diverse range of potential future products. While we do not plan to make further significant direct investment in these two product candidates, we plan to evaluate other potential product candidates which may utilize these technologies, as well as potential partnership opportunities for further development and commercialization of these two product candidates.

Combination Particle Technology: We can apply our proprietary particle formulation technologies to deliver the optimal ratio of multiple drugs in a reproducible and consistent manner. We combine two or more drugs together into a single micron sized particle at consistent and reproducible ratios, which may improve the delivery profile and stability of the resultant combination therapy. We believe our proprietary technologies in this area have potential broad applicability for a number of small molecule combination product candidates in diverse indications via inhalation and other routes of delivery.

MAP0005: We demonstrated this combination particle capability with MAP0005, our proprietary single particle combination of an inhaled corticosteroid and a long-acting beta-agonist, or LABA, for the potential treatment of asthma and chronic obstructive pulmonary disease, or COPD, using our proprietary TEMPO inhaler. In April 2008, we announced positive results from a Phase 2a clinical trial evaluating MAP0005 in adult asthmatics.

Stable Protein & Peptide Technology: We have also demonstrated our ability to apply our proprietary technologies to formulate and stabilize biologically active proteins and peptides. We design and incorporate our protein formulations to avoid the need for excipients or other additives, to be stored for months at room temperature and to deliver multiple doses of medicine accurately without needle injections.

MAP0001: We demonstrated this stable protein and peptide capability with MAP0001, our proprietary formulation of insulin for the potential treatment of Type 1 and Type 2 diabetes via pulmonary delivery using our proprietary TEMPO inhaler. This approach may overcome many of the issues currently associated with the invasive delivery of proteins by injection or infusion in general, and with inhalable insulin therapies in particular.

We have not filed an investigational new drug application, or IND, with the FDA for MAP0005 or MAP0001 because our clinical trials were not conducted in the United States.

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A core part of our strategy is to reduce the risk of drug development by focusing on the development of proven drugs with established safety and efficacy profiles. The compounds underlying our product candidates are well characterized and have been previously approved by the FDA for other sponsors and in other dosage forms and formulations. As a result, we may seek FDA marketing approval of our product candidates under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FFDCA, which, if available to us, would allow any new drug application, or NDA, we file with the FDA to rely in part on data in the public domain or the FDA s prior conclusions regarding the safety and efficacy of approved compounds. This may expedite the development program for our product candidates by potentially decreasing the overall scope of work we must do ourselves.

We are a development stage company and have not generated any product revenues. Since our inception, we have incurred losses and have an accumulated deficit of $225.6 million as of September 30, 2010. We have financed our operations through equity financing, debt financing, the issuance of convertible notes and collaboration payments. We expect to continue to incur net losses for at least the next several years as we continue to develop our current product candidates, develop, acquire or in-license additional products or product candidates, expand clinical trials for our product candidates in development, expand our research and development activities, seek regulatory approvals and engage in commercialization preparation activities in anticipation of potential FDA approval of our product candidates. We will need to raise additional capital and expand our commercial organization to launch any products. Significant capital is required to launch a product, and many expenses are incurred before revenues are received. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

Critical Accounting Policies and Significant Judgments and Estimates

There have been no significant changes in critical accounting policies during the nine months ended September 30, 2010, 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, 2009.

Financial Overview

Collaboration Revenue

We recognize revenues from collaborative research and development activities. Collaboration revenue, which is earned under agreements with third parties for research and development activities, may include nonrefundable upfront payments, cost reimbursements and milestone payments.

Research and Development Expenses

Research and development costs 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, 2010, we had incurred approximately $207.7 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 our most advanced product candidate, LEVADEX, and to conduct earlier-stage research and development projects. Pursuant to the AstraZeneca Agreement, AstraZeneca reimbursed our development costs related to the UDB program beginning on the effective date of February 2, 2009. The agreement was terminated on July 8, 2009, and we suspended development of UDB in the third quarter of 2009.

The following table summarizes the percentages of our research and development expenses related to our two most advanced product candidates and other earlier stage projects for the three and nine months ended September 30, 2010 and 2009, respectively. 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.

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	Three Months Ended September 30,		Nine Months Ended September 30,		Period from July 3, 2003 (Inception) through September 30, 2010
	2010	2009	2010	2009	
Our most advanced product candidates:					
LEVADEX	94%	59%	91 %	58%	56%
UDB (suspended)		25%		32%	35%
Other projects	6%	16%	9%	10%	9%
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. However, we will need substantial additional capital in the future in order to complete the development and potential commercialization of LEVADEX and other product candidates.

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. Through September 30, 2010, we had incurred approximately $58.9 million in sales, general and administrative expenses since our inception in 2003.

Results of Operations

Collaboration Revenue

Collaboration revenue in 2009 includes amortization of the nonrefundable upfront payment and reimbursement of qualified development expenses from AstraZeneca. Collaboration revenue for the three and nine months ended September 30, 2010, as compared to the same periods in 2009, is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Collaboration revenue	$	$ 35,273	$	$ 51,402

Revenue was $0 for the three and nine months ended September 30, 2010, compared to $35.3 million and $51.4 million, respectively, for the same periods in 2009. The revenue recognized in the three and nine months ended September 30, 2009 related to the amortization of a $40.0 million upfront payment received in February 2009 and to reimbursements for UDB-related development expenses, pursuant to the AstraZeneca Agreement. The AstraZeneca Agreement was terminated in July 2009, and we suspended development of UDB in the third quarter of 2009. Effective on the date of termination, the remaining unamortized deferred revenue of $33.1 million was recognized as collaboration revenue in the third quarter of 2009.

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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,			
	2010	2009	Increase/ (Decrease)	% Increase/ (Decrease)	2010	2009	Increase/ (Decrease)	% Increase/ (Decrease)
Research and development expenses	$ 10,009	$ 11,912	$ (1,903)	(16)%	$ 28,037	$ 35,615	$ (7,578)	(21)%

For the three months ended September 30, 2010 compared to the same period in 2009, the decrease in research and development expenses was due primarily to a decrease of $2.3 million in clinical and other project expenses to support the UDB Phase 3 clinical program as a result of suspending the development of our UDB product candidate in the third quarter of 2009, partially offset by an increase of $0.7 million in clinical and other project expenses to support the LEVADEX Phase 3 clinical program.

For the nine months ended September 30, 2010 compared to the same period in 2009, the decrease in research and development expenses was due primarily to a decrease of $7.6 million in clinical and other project expenses to support the UDB Phase 3 clinical program as a result of suspending the development of our UDB product candidate in the third quarter of 2009 and a decrease of $0.3 million in clinical and other project expenses to support the LEVADEX Phase 3 clinical program, partially offset by an increase of $0.4 million in personnel related expenses, including stock-based compensation.

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,				Nine Months Ended September 30,			
	2010	2009	Increase/ (Decrease)	% Increase/ (Decrease)	2010	2009	Increase/ (Decrease)	% Increase/ (Decrease)
Sales, general and administrative expenses	$ 3,921	$ 3,597	$ 324	9%	$ 11,712	$ 9,842	$ 1,870	19%

For the three months ended September 30, 2010 compared to the same period in 2009, the increase in sales, general and administrative expenses was due primarily to an increase of $0.4 million in personnel related expenses, including stock-based compensation, partially offset by a decrease of $0.2 million in professional services.

For the nine months ended September 30, 2010 compared to the same period in 2009, the increase in sales, general and administrative expenses was due primarily to an increase of $0.9 million in personnel related expenses, including stock-based compensation, an increase of $0.5 million in other expenses and an increase of $0.4 million in professional services and LEVADEX related marketing activities.

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,			
	2010	2009	Increase/ (Decrease)	% Increase/ (Decrease)	2010	2009	Increase/ (Decrease)	% Increase/ (Decrease)
Interest income	$ 5	$ 7	$ (2)	(29)%	$ 11	$ 118	$ (107)	(91)%

For the three months ended September 30, 2010 compared to the same period in 2009, the decrease in interest income was due primarily to a decrease in cash and cash equivalents balances. For the nine months ended September 30, 2010 compared to the same period in 2009, the decrease in interest income was due primarily to the decreased market interest rates.

We expect our interest income to fluctuate in the future due to changes in market interest rates and average investment balances.

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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,		Increase/ (Decrease)	% Increase/ (Decrease)	Nine Months Ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2010	2009			2010	2009		
Interest expense	$ 284	$ 519	$ (235)	(45)%	$ 1,016	$ 1,672	$ (656)	(39)%

For the three and nine months ended September 30, 2010 compared to the same periods in 2009, the decrease in interest expense was due primarily to lower debt balances related to the 2008 Working Capital Loan.

We expect our interest expense to fluctuate in the future with average debt balances.

Liquidity and Capital Resources

Liquidity

We have incurred losses since our inception in July 2003 and as of September 30, 2010 we had an accumulated deficit of $225.6 million. We will continue to incur losses until we generate sufficient revenue to offset our expenses, and we anticipate that we will 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;

In January 2010, we accessed our equity line of credit with 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 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 $47.1 million in net proceeds after deducting underwriting discounts and commissions and estimated 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;

In May 2008, we entered into an agreement to borrow $20.0 million in order to repay the earlier working capital loan and to support general corporate purposes; and

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.

As of September 30, 2010, we had approximately $41.8 million in cash and cash equivalents. In October 2010, we completed an equity offering and raised a total of approximately $47.1 million in net proceeds. 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.

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Cash Flows

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

	Nine Months Ended September 30,	
	2010	2009
Cash provided by (used in):		
Operating activities	$ (37,925)	$ 4,710
Investing activities	(1,976)	11,992
Financing activities	15,941	27,594

Net cash provided by (used in) operating activities. We used $37.9 million of cash for operating activities for the nine months ended September 30, 2010, compared to receiving cash of $4.7 million for the corresponding period in 2009. The usage of cash of $37.9 million for the nine months ended September 30, 2010 was due primarily to a net loss of $40.7 million and a decrease in accrued liabilities of $3.1 million as a result of paying down expenses related to the LEVADEX Phase 3 clinical program, and the UDB program, which was suspended in the third quarter of 2009, partially offset by stock-based compensation of $4.8 million. The cash provided by operating activities for the nine months ended September 30, 2009 was due primarily to net income of $4.4 million resulting from a $40.0 million nonrefundable upfront payment received from AstraZeneca and stock-based compensation of $3.8 million, partially offset by a decrease in accrued liabilities of $4.9 million and by an increase in accounts receivable of $2.7 million from AstraZeneca.

Net cash provided by (used in) investing activities. We used $2.0 million of cash for investing activities for the nine months ended September 30, 2010, compared to receiving cash of $12.0 million for the corresponding period in 2009. The usage of cash of $2.0 million for the nine months ended September 30, 2010 was due primarily to purchase of property and equipment. Net cash provided by investing activities for the nine months ended September 30, 2009 was due primarily to sales and maturities of our short-term investments of $12.7 million.

Net cash provided by financing activities. We received $15.9 million of cash from financing activities for the nine months ended September 30, 2010, compared to receiving cash of $27.6 million for the corresponding period in 2009. The cash provided by financing activities for the nine months ended September 30, 2010 was due primarily to the net proceeds of approximately $19.7 million from the issuance of our common stock from the drawdown of the equity line of credit with Azimuth and proceeds from sales of shares through equity plans of $1.7 million, partially offset by the repayment of debt of $5.4 million for the 2008 Working Capital Loan. Net cash provided by financing activities for the nine months ended September 30, 2009 was due primarily to net proceeds of $31.6 million from our follow-on offering, partially offset by the repayment of $4.6 million for the 2008 Working Capital Loan.

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 committed to purchase up to $60 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, 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 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 estimated offering expenses.

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. As of September 30, 2010, we are required to make future nonrefundable milestone payments of up to $5.0 million related to products currently being developed under the Nektar Agreement, when and if certain regulatory and commercial milestones are met. We paid $0 for both the three and nine months ended September 30, 2010 and 2009. We paid $2.6 million for the cumulative period from July 3, 2003 (date of inception) to September 30, 2010. 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.

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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 outcome, timing and cost of regulatory approvals and the regulatory approval process;
- 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 future in-licensing and out-licensing transactions;
- the cost and timing of establishing sales, marketing, manufacturing and distribution capabilities;
- the cost of procuring clinical and commercial supplies of our product candidates;
- 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, together with the net proceeds of approximately $47.1 million from our equity offering completed in October 2010, 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.

Recent Accounting Pronouncements

On April 29, 2010, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2010-17, *Revenue Recognition Milestone Method (Topic 605): Milestone Method of Revenue Recognition* (a consensus of the FASB Emerging Issues Task Force). It establishes a revenue recognition model for contingent consideration that is payable upon the achievement of an uncertain future event, referred to as a milestone. The scope of the ASU is limited to research or development arrangements and requires an entity to record the milestone payment in its entirety in the period received if the milestone meets all the necessary criteria to be considered substantive. The ASU is effective for fiscal years (and interim periods within those fiscal years) beginning on or after June 15, 2010. Early application is permitted. Entities can apply this guidance prospectively to milestones achieved after adoption. However, retrospective application to all prior periods is also permitted. We have to adopt the new pronouncement in the first quarter of fiscal year 2011. We do not believe that the adoption of ASU 2010-17 will have a material impact on our condensed consolidated financial statements.

In September 2009, the FASB ratified Revenue Arrangements with Multiple Deliverables issued as ASU 2009-13 in early October. ASU 2009-13 updates the existing multiple-element arrangements guidance currently included in ASC 605-25, *Revenue Recognition Multiple-Element Arrangements*. The revised guidance provides for two significant changes to the existing multiple-element arrangements guidance. The first relates to the determination of when the individual deliverables included in a multiple-element arrangement may be treated as separate units of accounting. This change is significant as it will likely result in the requirement to separate more deliverables within an arrangement, ultimately leading to less revenue deferral. The second change modifies the manner in which the transaction consideration is allocated across the separately identifiable deliverables. These changes are likely to result in earlier recognition of revenue for multiple-element arrangements than under previous guidance. ASU 2009-13

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also significantly expands the disclosures required for multiple-element revenue arrangements. The revised multiple-element arrangements guidance will be effective for the first annual reporting period beginning on or after June 15, 2010, and may be applied retrospectively for all periods presented or prospectively to arrangements entered into or modified after the adoption date. Early adoption is permitted provided that the revised guidance is retroactively applied to the beginning of the year of adoption. If the guidance is adopted prospectively, certain transitional disclosures are required for each reporting period in the initial year of adoption. We have to adopt the new pronouncement in the first quarter of fiscal year 2011. We do not believe that the adoption of ASU 2009-13 will have a material impact on our condensed consolidated financial statements.

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 primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. We do not have any foreign currency or other derivative financial instruments.

We believe that there have been no significant changes in our market risk exposures for the three and nine months ended September 30, 2010.

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, 2010, 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

Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this report as well as our other public filings with the Securities and Exchange Commission.

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 expect to 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 in the foreseeable future. We have incurred significant net losses and negative cash flow in each year since our inception, including net losses of approximately $40.1 million, $72.9 million and $9.0 million, for the years ended December 31, 2007, 2008 and 2009, respectively and $14.2 million and $40.7 million for the quarter and nine months ended September 30, 2010, respectively. As of September 30, 2010, we had a deficit accumulated during development stage of approximately $225.6 million. We have devoted most of our financial resources to research and development, including our pre-clinical development activities and clinical trials. We have not completed development of, or commercialized any product candidate and have therefore not generated any product revenues. In that regard, we expect to have substantial expenses as we continue with our Phase 3 clinical program for LEVADEX, our most advanced product candidate, and conduct other clinical trials. In addition, if we are required by the U.S. Food and Drug Administration, or the FDA, to perform studies in addition to those we currently anticipate, our expenses will increase beyond expectations and the timing of any potential product approval may be delayed. We also 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. On July 8, 2009, we received a notice of termination of our license agreement with AstraZeneca AB, or the AstraZeneca Agreement, related to our Unit Dose Budesonide, or UDB, product candidate. Under the AstraZeneca Agreement, AstraZeneca had agreed to fund our remaining development activities for UDB and to reimburse us for costs we incur with respect to future development activities conducted for the U.S. registration of our UDB product candidate, subject to the terms and conditions of the AstraZeneca Agreement. Following the termination of the AstraZeneca Agreement, we suspended development of UDB. 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 and undertaking pre-clinical studies and clinical trials of our product candidates. 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;

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the need to obtain regulatory approval of our most advanced product candidate, LEVADEX for the potential treatment of migraine;

potential risks related to any collaborations we may enter into for our product candidates, including LEVADEX;

delays in the commencement, enrollment and completion of clinical testing, as well as the analysis and reporting of results from such clinical testing;

the success of clinical trials of our LEVADEX product candidate or future product candidates;

any delays in regulatory review and approval of product candidates in development;

our ability to receive regulatory approval or commercialize our product candidates;

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;

market acceptance of our product candidates for which we obtain regulatory approval;

our ability, and our partners ability, to establish an effective sales and marketing infrastructure;

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

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

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

regulatory difficulties relating to products that have already received regulatory approval;

guidelines and recommendations of therapies published by various organizations;

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 ability to adequately support future growth; 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.

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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, is expensive. We expect to have substantial research and development expenses in connection with our ongoing activities, particularly as we focus on and proceed with our Phase 3 clinical program of LEVADEX, our most advanced product candidate. In addition, our expenses could increase beyond expectations if the FDA requires that we perform additional studies to those that we currently anticipate, in which case the timing of any potential product approval may be delayed. We believe that our existing cash and cash equivalents, together with the net proceeds of approximately $47.1 million from our equity offering completed in October 2010, 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 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 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 scope, rate of progress and cost of our clinical trials and other research and development activities;
- the costs and timing of regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effect of competing technological and market developments;
- the terms and timing of any collaboration, licensing or other arrangements that we may establish;.
- the cost and timing of completion of clinical and commercial-scale manufacturing activities; and
- the costs of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval.

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 UDB. 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. In July 2009, we announced that we were suspending development of UDB, after our partner AstraZeneca terminated our license agreement. We are now largely dependent on the success of one product candidate, LEVADEX, for which we are conducting a Phase 3 clinical development program. Our ability to generate product revenue, which we do not expect will occur for at least the next several years, if ever, will depend heavily on the successful development, regulatory approval and commercialization of this product candidate. We may have inadequate financial or other resources to advance LEVADEX through the clinical trial 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 is ongoing. 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 topline 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

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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 also 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. In addition we have completed patient treatment in a thorough QT trial evaluating whether LEVADEX has an effect on QT interval as measured by electrocardiograms in support of our application to the FDA for regulatory approval. We expect treatment in our remaining LEVADEX clinical trials to be completed in 2010. 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 in our planned clinical trials, 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 product candidate in late stage development. 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 a next generation budesonide therapy for the treatment of asthma in children, should we pursue these activities. 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 submitted an NDA or received marketing approval for any of our product candidates. 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 may enter into 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 collaborations with third parties to develop and commercialize our product candidates, including LEVADEX. Our dependence on 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;
- 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.

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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. We do not know whether planned clinical trials for LEVADEX will be completed on schedule, if at all. 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.

We are conducting a Phase 3 clinical program to support our NDA for LEVADEX. In October 2009, we submitted our topline efficacy results for the double-blind efficacy portion of our pivotal Phase 3 study. We recently completed a pharmacokinetics trial in healthy adult smokers and non-smokers and a pharmacodynamics trial measuring pulmonary artery pressure in healthy adults. We are currently completing the long-term safety extension of our pivotal Phase 3 trial and have completed treatment in a thorough QT 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 Agency 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 topline 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.

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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.

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.

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. A long-term safety extension of this Phase 3 trial is ongoing, and we expect to complete patient treatment by the end of the year. 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. We also announced that we completed patient treatment in a thorough QT trial. In order to obtain regulatory approval for LEVADEX, we need to complete the long-term safety extension trial and the analysis of the results of the thorough QT trial. The data collected from our clinical trials may not be adequate to support regulatory approval of LEVADEX or any of our other product candidates. 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.

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.

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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.

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 manufacturing facilities and processes. 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.

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.

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. At this point in time, we have not been requested to perform drug-drug interaction studies, but any such requirement may delay any potential product approval and will increase our expenses associated with our clinical programs. 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 a longer development program and more costly trials than we anticipate.

We may not be able to seek FDA marketing approval of our product candidates under Section 505(b)(2) of the FFDCA. Section 505(b)(2), if applicable to us, would allow an NDA we file with the FDA to rely in part on data in the public domain or the FDA s prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the overall scope of work we must do ourselves. If we are unable to rely on Section 505(b)(2), the development program for our product candidates would be longer than we expect, and we would also have to conduct more costly trials than we anticipate.

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;

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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 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;

ineffective marketing and distribution efforts;

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

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;

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 recently 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 focused 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 focused sales force in the United States. We currently do not have significant internal sales, distribution and marketing capabilities. For example, in order to commercialize LEVADEX, we intend to develop a focused sales force and marketing capabilities in the United States directed at high prescribers including specialists such as

neurologists and headache specialists. The development of a focused sales and marketing infrastructure for our domestic operations will require substantial resources, will be expensive and time consuming and could negatively impact our commercialization efforts, including delay of any product launch. Many of these costs will be incurred in advance of notice to us that any of our product candidates has been approved. In addition, we may not be able to hire a focused 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 focused 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 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, time to market, price, extent of adverse side effects and convenience of treatment

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procedures. One or more of our competitors may develop products based upon the principles underlying our proprietary technologies earlier than us, obtain approvals for such products from the FDA more rapidly than us or develop alternative products or therapies that are safer, more effective and/or more cost effective than any products developed by 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 treatment of acute 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. The majority of marketed prescription products for the treatment of migraine are in the triptan class. The largest selling triptan is sumatriptan with 2009 sales of approximately $800 million in the United States, including approximately $600 million from generics and $200 million from branded Imitrex from GlaxoSmithKline. 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 treatment of acute migraine 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 are product candidates under development by large pharmaceutical companies, such as Merck & Co., Inc., and other smaller companies, that could potentially be used to treat acute 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 acute 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.

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. 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 equivalent 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 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.

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 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 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 or change the labeling of the product;
- 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.

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

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product s 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 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 assure 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 approval;
- 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 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 at all, 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:

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;

decreased demand for our product candidates;

impairment of our business reputation;

loss of revenues; and

the inability to commercialize our product candidates.

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

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 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 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 or suspension of initiation or completion of clinical trials, regulatory submissions, required approvals or commercialization of our products, cause us to incur higher costs and could prevent us from commercializing our product candidates successfully. 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.

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

We plan to establish marketing, sales and distribution collaborations with third parties where appropriate. For example, if we choose to expand the marketing and sales of LEVADEX to primary care physicians beyond high prescribers, including specialists such as neurologists and headache specialists, we may establish partnerships with other companies to maximize the potential of the commercialization opportunity. Outside the United States, we may establish commercial partnerships for LEVADEX in order to effectively reach target markets in order to maximize its commercial opportunities. We also expect to face competition in our efforts to identify appropriate collaborators or partners to help commercialize LEVADEX in our target commercial areas. 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 may not be successful in maintaining or establishing development collaborations, which could adversely affect our ability to develop certain of our product candidates.

On July 8, 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 MAP0005 and MAP0001. We have no current intention to further develop either 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

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for further development and commercialization of these two 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 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.

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 unforceable, 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; or

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.

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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 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 number of license agreements, including with Nektar Therapeutics UK Limited, pursuant to which we license key intellectual property, including intellectual property relating to our most advanced product candidate. 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.

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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 and Managing Growth

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

As of September 30, 2010, we had 102 full-time employees. We may need to expand our managerial, operational, administrative and other resources in order to manage and fund our operations and clinical trials, continue our development activities and commercialize our product candidates. To support this growth, we may 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 Phase 3 development program for LEVADEX, including clinical, manufacturing and regulatory activities in support of an NDA submission to the FDA and commercialization activities as we prepare for a potential product launch; 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, scientific and clinical personnel in the future due to competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the Silicon Valley area 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.

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 condition and operating results;

status and/or results of our clinical trials;

results of clinical trials of our competitors products;

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

actions and decisions by our collaborators or partners;

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

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 substantial 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 substantial 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 substantial 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.

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 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

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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.

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.

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ITEM 6. EXHIBITS

Exhibit

No.	**Description**
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.

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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 5, 2010

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

Chief Financial Officer

(Principal Financial Officer)