MAP Pharmaceuticals, Inc.
Form 10-Q
November 06, 2009
Table of Contents

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, 2009

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 definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

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 November 2, 2009, the registrant had outstanding 24,494,925 shares of Common Stock.

Table of Contents

TABLE OF CONTENTS

Table of Contents

PART I FINANCIAL INFORMATION

Item 1 Financial Statements

MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)

(Unaudited)

	September 30, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 76,223	$ 31,927
Short-term investments		12,783
Accounts receivable	2,704	
Prepaid expenses and other current assets	355	805
Total current assets	79,282	45,515
Property and equipment, net	3,969	5,007
Other assets	38	28
Restricted investment	310	310
Total assets	$ 83,599	$ 50,860
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 3,192	$ 1,631
Accrued liabilities	10,569	15,445
Current portion of debt	7,105	6,348
Total current liabilities	20,866	23,424
Debt, less current portion	9,141	14,229
Other liabilities	82	60
Total liabilities	30,089	37,713
Commitments and contingencies (Note 6)		
Stockholders equity:		
Common stock	239	200
Additional paid-in capital	224,795	188,797
Deficit accumulated during the development stage	(171,524)	(175,894)
Accumulated other comprehensive income		44
Total stockholders equity	53,510	13,147

Total liabilities and stockholders equity	$ 83,599	$ 50,860

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

Table of Contents

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
	2009	2008	2009	2008	September 30, 2009
Collaboration revenue	$ 35,273	$	$ 51,402	$	$ 51,402
Operating expenses:					
Research and development	11,912	16,815	35,615	41,614	167,313
Sales, general and administrative	3,597	3,380	9,842	9,685	43,904
Total operating expenses	15,509	20,195	45,457	51,299	211,217
Income (loss) from operations	19,764	(20,195)	5,945	(51,299)	(159,815)
Interest income	7	453	118	1,894	6,367
Interest expense	(519)	(621)	(1,672)	(1,437)	(5,305)
Other income (expense), net	7		(21)	(278)	(754)
Net income (loss)	19,259	(20,363)	4,370	(51,120)	(159,507)
Cumulative stock dividend attributed to preferred stockholders					(13,925)
Net income (loss) attributed to common stockholders	$ 19,259	$ (20,363)	$ 4,370	$ (51,120)	$ (173,432)
Net income (loss) per share attributed to common stockholders					
Basic	$ 0.84	$ (1.00)	$ 0.20	$ (2.52)	
Diluted	$ 0.80	$ (1.00)	$ 0.19	$ (2.52)	
Weighted average shares outstanding used in calculating net income (loss) per share attributed to common stockholders					
Basic	22,860,897	20,398,682	21,389,679	20,308,206	
Diluted	24,054,236	20,398,682	22,505,625	20,308,206	

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

4

Table of Contents

MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended September 30,		Period from July 3, 2003 (Inception) to September 30, 2009
	2009	2008	
Cash flows from operating activities:			
Net income (loss)	$ 4,370	$ (51,120)	$ (159,507)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	1,111	906	4,291
Accretion of investment discounts, net	(1)	(663)	(1,595)
Amortization of debt issuance costs		103	210
Accretion of debt payment premium	306	187	606
Change in carrying value of warrant liability			621
Issuance of common stock in exchange for services			51
Share-based compensation	3,806	3,108	10,160
Loss on disposal and other non-cash items	675	9	1,059
Changes in operating assets and liabilities:			
Accounts receivable	(2,704)		(2,704)
Prepaid expenses and other current assets	450	554	(580)
Other assets	(10)	67	55
Accounts payable	1,561	53	3,163
Accrued liabilities	(4,876)	5,395	10,538
Other liabilities	22	41	82
Net cash provided by (used in) operating activities	4,710	(41,360)	(133,550)
Cash flows from investing activities:			
Purchase of intangible assets and in-process research and development			(412)
Purchase of property and equipment	(748)	(1,661)	(8,873)
Purchase of short-term investments		(48,648)	(169,497)
Sales and maturities of short-term investments	12,740	70,277	171,411
Maturity (purchase) of restricted investment		11	(310)
Net cash provided by (used in) investing activities	11,992	19,979	(7,681)
Cash flows from financing activities:			
Proceeds from issuance of convertible notes payable			4,300
Proceeds from issuance of debt		20,000	31,006
Proceeds from sales of shares through equity plans	624	430	1,411
Repayment of debt	(4,637)	(9,886)	(15,466)
Proceeds from issuance of common stock, net of issuance costs	31,607		93,775
Proceeds from issuance of convertible preferred stock, net of issuance costs			102,428
Net cash provided by financing activities	27,594	10,544	217,454

Net increase (decrease) in cash and cash equivalents	44,296	(10,837)	76,223
Cash and cash equivalents at beginning of period	31,927	49,116	
Cash and cash equivalents at end of period	$ 76,223	$ 38,279	$ 76,223
Supplemental disclosures of cash flow information			
Cash paid for interest	$ 1,361	$ 1,152	$ 4,383

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

Table of Contents

MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

NOTE 1. THE COMPANY

Business

MAP Pharmaceuticals, Inc., incorporated in the state of Delaware, was originally 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. We have proprietary product candidates in development that address large market opportunities, including our most advanced 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, cash equivalents and short-term investments 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 our 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.

Follow-on Public Offering

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 per share price of $9.70. 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.

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 balance sheet at December 31, 2008 has been derived from the audited financial statements at that date. 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, 2008, as amended.

We have evaluated subsequent events through the time of filing this Form 10-Q on November 6, 2009, which is the date that the financial statements have been filed with the Securities and Exchange Commission, or SEC. All appropriate subsequent event disclosures have been made in the notes to our unaudited condensed financial statements.

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

Table of Contents

MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

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.

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 that conduct and manage pre-clinical studies and clinical trials on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven expenses and payment flows. Pre-clinical study and clinical trial expenses include the following:

fees paid to contract research organizations, or CROs, in connection with pre-clinical studies;

fees paid to CROs and investigative sites in connection with clinical trials; and

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

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

Table of Contents

MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

Share-Based Compensation

Effective January 1, 2006, we adopted ASC 718 *Compensation Stock Compensation,* or ASC 718*,* using the prospective transition method, which requires the measurement and recognition of compensation expense for all share-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.

Fair Value of Financial Instruments

The carrying amounts of certain of our financial instruments including cash, cash equivalents, short-term investments, prepaid expenses and other current assets, accounts payable and accrued liabilities approximate fair value due to their short maturities.

Comprehensive Income (loss)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Net income (loss)	$ 19,259	$ (20,363)	$ 4,370	$ (51,120)
Net change in unrealized loss on available-for-sale investments		(16)	(44)	(166)
Comprehensive income (loss)	$ 19,259	$ (20,379)	$ 4,326	$ (51,286)

Net Income (loss) per Share

Basic net income (loss) per common share and diluted net income (loss) per common share are presented in conformity with ASC 260 *Earnings per Share*, for all periods presented. Basic net income (loss) per share is computed by dividing net income (loss) by the weighted-average number of shares 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 and shares issuable under our employee stock purchase plan using the treasury stock method.

Table of Contents

MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

The following table presents the calculation of weighted average common shares 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,	
	2009	2008	2009	2008
Net income (loss) attributed to common stockholders	$ 19,259	$ (20,363)	$ 4,370	$ (51,120)
Basic:				
Weighted average common shares used in computing basic net income (loss) per common share	22,860,897	20,398,682	21,389,679	20,308,206
Basic income (loss) per common share	$ 0.84	$ (1.00)	$ 0.20	$ (2.52)
Diluted:				
Weighted average common shares used in computing basic net income (loss) per common share	22,860,897	20,398,682	21,389,679	20,308,206
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	51,172		40,103	
Weighted average common shares used in computing diluted net income (loss) per common share	24,054,236	20,398,682	22,505,625	20,308,206
Diluted income (loss) per common share	$ 0.80	$ (1.00)	$ 0.19	$ (2.52)

The following is a summary of the excluded potentially dilutive securities for the three and nine months ended September 30, 2009 and 2008, respectively, because including them would have had an anti-dilutive effect:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Options to purchase common stock	2,046,438	3,204,792	2,369,092	3,204,792
Warrants		73,989		73,989

Recent Accounting Pronouncements

In September 2009, the Financial Accounting Standards Board, or FASB ratified *Revenue Arrangements with Multiple Deliverables* issued as Accounting Standards Update, or 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. As a result, it is effective for us in the first quarter of fiscal year 2011. We currently are evaluating the impact that the adoption of ASU 2009-13 will have on our consolidated financial statements.

Table of Contents

MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

In August 2009, the FASB issued Accounting Standards Update 2009-05, *Fair Value Measurements and Disclosures (Topic 820) Measuring Liabilities at Fair Value,* or Update 2009-05. Update 2009-05 clarifies that in circumstances in which a quoted price in an active market for an identical liability is not available, a reporting entity is required to measure fair value of such liability using one or more of the of the techniques prescribed by the update. Update 2009-05 is effective for the first reporting period (including interim periods) beginning after issuance. As a result, it is effective for us in the year ending December 31, 2009. We do not believe that the adoption of Update 2009-05 will have a material impact on our financial statements.

NOTE 3. LICENSE AND SUPPLY AGREEMENTS

Agreement with AstraZeneca

In December 2008, we entered into an agreement with AstraZeneca AB, or AstraZeneca Agreement, which became effective in February 2009. Pursuant to the terms of the 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 this 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 immediately. AstraZeneca elected to terminate the AstraZeneca Agreement pursuant to Section 19.3.1(b) of the AstraZeneca Agreement, which provides that AstraZeneca could terminate the AstraZeneca Agreement in the event that the primary endpoints of the initial Phase 3 clinical trial of UDB were not met. Effective on the date of termination, all rights licensed to AstraZeneca in the agreement reverted back to us. We also announced our plan to suspend development of our UDB product candidate. We were jointly developing UDB with AstraZeneca, and were responsible for executing the development plan.

We recognized collaboration revenue of $35.3 million and $51.4 million, respectively, from AstraZeneca for the three and nine months ended September 30, 2009, compared to $0 for the same periods in 2008. The collaboration revenue includes amortization of the nonrefundable upfront payment of $40.0 million and reimbursement of qualified development expenses. The $40.0 million upfront payment initially was recognized as collaboration revenue on a straight-line basis over the term of our research and development period with respect to UDB. 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 fiscal 2009. We received $48.7 million in cash for the cumulative period from July 3, 2003 (date of inception) to September 30, 2009.

Agreement with Nektar

Under the June 2004 agreement, as amended, with Nektar Therapeutics UK Limited, or 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, 2009, we are required to make future nonrefundable milestone payments of up to $5.0 million related to products currently being developed under this agreement, when and if certain regulatory and commercial milestones are met. We paid $0 for both the three and nine months ended September 30, 2009 and 2008. We paid $2.6 million for the cumulative period from July 3, 2003 (date of inception) to September 30, 2009. Either party may terminate the Nektar Agreement upon a material, uncured default of the other party. We may terminate the agreement, with or without cause, at any time upon six months prior written notice.

10

Table of Contents

MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

Agreement with Elan

Under the April 2004 agreement, as amended, with Elan Pharma International Limited, or Elan Agreement, Elan granted to us a worldwide, exclusive, sub-licensable license under Elan s intellectual property rights to use, market, distribute, sell, have sold, offer for sale, import and export certain ingredients for our UDB product candidate. We also agreed to pay royalties at specified rates based on net sales. As of September 30, 2009, we are required to make future nonrefundable milestone payments of up to $16.5 million related to products currently being developed under this agreement, when and if certain regulatory and commercial milestones under the Elan Agreement are met with respect to our UDB product candidate. We paid $0 for both the three and nine months ended September 30, 2009, compared to $0.8 million and $0.8 million, respectively, for the same periods in 2008. We paid $4.0 million for the cumulative period from July 3, 2003 (date of inception) to September 30, 2009. 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. In connection with the execution of the AstraZeneca Agreement, we amended the Elan agreements, pursuant to which AstraZeneca was granted certain rights to exercise and enforce certain of our rights with Elan prior to the expiration or termination of the AstraZeneca Agreement. The amendments to the Elan agreements did not impact our unaudited condensed consolidated financial statements. Effective on the date of termination from AstraZeneca, all rights licensed to AstraZeneca in the agreement reverted back to us.

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. In February 2008, the FASB delayed the effective date of ASC 820 *Fair Value Measurements* for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on at least an annual basis, until January 1, 2009 for calendar year-end entities. ASC 820 *Fair Value Measurements* defines fair value, establishes a framework for measuring fair value in GAAP and expands disclosures about fair value measurements.

ASC 820 *Fair Value Measurements* 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 *Fair Value Measurements* 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.

Table of Contents

MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

The following is a summary of our cash, cash equivalents, short-term investments and restricted investment as of September 30, 2009 and December 31, 2008, respectively (in thousands):

	As of September 30, 2009		
	Amortized Cost	Unrealized Gain (Loss)	Estimated Fair Value
Cash	$ 5,070	$	$ 5,070
Certificates of deposit	310		310
Money market funds	71,153		71,153
	$ 76,533	$	$ 76,533
Reported as:			
Cash and cash equivalents			$ 76,223
Restricted investment			310
			$ 76,533

	As of December 31, 2008		
	Amortized Cost	Unrealized Gain	Estimated Fair Value
Cash	$ 3,021	$	$ 3,021
Certificates of deposit	310		310
Money market funds	27,895		27,895
Corporate debt securities	2,684	6	2,690
U.S. government and its agencies securities	11,066	38	11,104
	$ 44,976	$ 44	$ 45,020
Reported as:			
Cash and cash equivalents			$ 31,927
Short-term investments			12,783
Restricted investment			310
			$ 45,020

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, 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 was as follows (in thousands):

	Level 1	Level 2	Level 3	Total
Certificates of deposit	$	$ 310	$	$ 310
Money market funds	71,153			71,153
Total	$ 71,153	$ 310	$	$ 71,463

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 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.

Table of Contents

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 related to our lease agreements.

The carrying amount for our debt reported in the consolidated balance sheet as of September 30, 2009 is $16.2 million. Using a discounted cash flow technique that incorporates a market interest rate, we have determined the fair value of our debt to be $15.7 million at September 30, 2009.

NOTE 5. BALANCE SHEET COMPONENTS

Accrued liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2009	December 31, 2008
Clinical trial related	$ 5,923	$ 11,329
Payroll and related expenses	2,886	2,791
Professional services and other	1,759	1,325
	$ 10,569	$ 15,445

Debt

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

In September 2006, we entered into a $10.0 million loan facility agreement for the purpose of financing working capital, or 2006 Working Capital Loan, and borrowed all $10.0 million under the facility agreement during the year ended December 31, 2006. The 2006 Working Capital Loan bears interest at an annual interest rate of 11.9% and matured in 2010. In May 2008, we entered into a new loan agreement, or 2008 Working Capital Loan, for $20.0 million, in order to repay the 2006 Working Capital Loan and to support general corporate purposes. The 2008 Working Capital Loan bore 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 the agreement. The 2008 Working Capital Loan has interest-only payments up to and including January 2009, maturing in October 2011, and includes customary loan covenants. As of September 30, 2009, we were in compliance with the loan covenants.

The 2008 Working Capital Loan amounts are collateralized by all of our assets, excluding intellectual property, while Equipment Loan amounts are collateralized by our equipment purchased by such borrowed funds.

Our debt consisted of the following (in thousands):

	September 30, 2009	December 31, 2008

Principal amount	$ 15,640	$ 20,277
Plus: premium, based on imputed interest rate of 12%	606	300
	16,246	20,577
Less: current portion of debt	7,105	6,348
Long-term portion	$ 9,141	$ 14,229

Table of Contents

MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

As of September 30, 2009, debt payments, which include interest and principal, are as follows (in thousands):

Year ending December 31,	Amount
2009 (remaining three months)	$ 2,086
2010	8,343
2011	7,952
Total debt payments	$ 18,381

Suspended UDB program

During the third quarter of 2009, we suspended the development of our UDB product candidate. As a result, we recorded wind-down costs and writedown of fixed assets charges of approximately $2.8 million, which are included in research and development expenses for the third quarter of 2009.

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 and in August 2006, we amended our lease agreement to include additional square footage within the same building. In March 2008, we further amended our lease agreement, which we refer to as the March 2008 Amendment, to extend the term of the agreement until June 2012, and to include additional square footage and options to lease additional square footage. In September 2008, we amended and restated the March 2008 Amendment, providing for expanded square footage and certain renewal options. The facility lease requires us to 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 leased under the amended and restated lease agreement were effective as of July 1, 2008.

Rent expense was approximately $0.3 million and $0.9 million, respectively, for the three and nine months ended September 30, 2009, compared to $0.3 million and $0.7 million, respectively, for the same periods in 2008. Rent expense was approximately $4.3 million for the cumulative period from July 3, 2003 (date of inception) to September 30, 2009.

As of September 30, 2009, future minimum lease payments are as follows (in thousands):

Year ending December 31,	Amount
2009 (remaining three months)	$ 262
2010	1,293
2011	1,357
2012	700

Total minimum lease payments	$ 3,612

In accordance with the terms of the lease agreements 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 deposit account with the bank of $0.3 million at September 30, 2009 and December 31, 2008, which is shown as a restricted investment on our unaudited condensed consolidated balance sheets.

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 general indemnifications. Our exposure under these agreements is unknown because it involves claims that may be

Table of Contents

MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

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. STOCK-BASED COMPENSATION

Stock Option Activities

For the nine months ended September 30, 2009, stock option activity under our plans is as follows:

	Shares Available for Grant	Outstanding Options Number of Shares	Outstanding Options Weighted Average Exercise Price
Balances, at December 31, 2008	1,697,112	3,178,837	$ 5.83
Additional shares reserved	1,000,000		
Options granted	(1,048,500)	1,048,500	$ 9.80
Options exercised		(310,881)	$ 1.10
Options cancelled	153,351	(153,351)	$ 9.12
Balances, at September 30, 2009	1,801,963	3,763,105	$ 7.19

Stock-Based Compensation for Employees

The following table summarizes the stock-based compensation expense for stock options and our employee stock purchase plan that we recorded in the condensed statements of operations in accordance with ASC 718 *Compensation Stock Compensation* for the three and nine months ended September 30, 2009 and 2008, respectively (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Research and development	$ 537	$ 336	$ 1,529	$ 1,013
Sales, general and administrative	697	520	2,207	1,582
	$ 1,234	$ 856	$ 3,736	$ 2,595

We used the following assumptions to estimate the fair value of options granted under our stock option plans for the three and nine months ended September 30, 2009 and 2008, respectively:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Risk-free interest rate	2.3% - 2.5%	3.0% - 3.6%	1.6% - 2.5%	2.7% - 3.6%
Expected volatility	64%	63%	62% - 64%	63%
Expected term (in years)	5	5.5	5	5.5
Expected dividend yield	0%	0%	0%	0%

Table of Contents

MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

We used the following assumptions to estimate the fair value of shares purchased under our employee stock purchase plan for the three and nine months ended September 30, 2009 and 2008, respectively:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Risk-free interest rate	0.3%	1.9%	0.3%	1.9% - 2.9%
Expected volatility	95%	83%	95% - 99%	81% - 83%
Expected term (in years)	0.5	0.5	0.5	0.5 - 0.6
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.

Expected Volatility: The expected stock price volatility for our common stock 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 any significant 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.

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 historical stock price volatility and expected term assumptions as more historical data for our common stock becomes available.

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

Forfeitures: As stock-based compensation expense recognized in the condensed consolidated statement of operations for the three and nine months ended September 30, 2009 and 2008 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. ASC 718 *Compensation Stock Compensation* requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on our historical experience.

As of September 30, 2009, there were unrecognized compensation costs of approximately $7.0 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.

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 $8,000 and $70,000, respectively, for the three and nine months ended September 30, 2009, compared to $259,000 and

$513,000, respectively, for the same periods in 2008. 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, 2009.

NOTE 8. SUBSEQUENT EVENT

On October 13, 2009, we received confirmation that AstraZeneca was in agreement with the final reimbursement of costs associated with the termination of the AstraZeneca Agreement and suspension of our UDB program. As a result, we expect to receive and record $2.8 million as collaboration revenue in the fourth quarter of 2009.

Table of Contents

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, 2008, as amended.

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, including our most advanced product candidate, LEVADEX , formerly known as MAP0004, our proprietary orally inhaled version of dihydroergotamine for the potential treatment of migraine. LEVADEX is designed to provide faster onset and longer lasting pain relief than triptans, the class of drugs most often prescribed for treating migraine.

For our LEVADEX migraine program, we initiated a Phase 3 clinical program in July 2008 pursuant to a special protocol assessment, or SPA, from the U.S. Food and Drug Administration, or FDA. In May 2009, we announced results of the efficacy portion of our first Phase 3 clinical trial of LEVADEX. We announced that 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.

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 percent of patients who received LEVADEX compared with 34.5 percent for placebo ($p<0.0001$);

Phonophobia free: 52.9 percent of patients who received LEVADEX compared with 33.8 percent for placebo ($p<0.0001$);

Photophobia free: 46.6 percent of patients who received LEVADE compared with 27.2 percent for placebo ($p<0.0001$); and

Nausea free: 67.1 percent of patients who received LEVADEX compared with 58.7 percent 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 expected, with 46 percent reporting severe pain and 54 percent 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;

Table of Contents

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).

There were no drug-related serious adverse events reported in the trial. 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 (0 percent), were rare and comparable to placebo. There were no decreases in lung function, as measured by spirometry, between the active and placebo groups. These data were presented in a late-breaking session of the 14th Congress of the International Headache Society.

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 order to obtain regulatory approval for LEVADEX, we will need to conduct additional Phase 3 and Phase 2 clinical trials. We anticipate initiating our second Phase 3 clinical trial of LEVADEX in the first quarter of 2010. 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 both inside and outside of the United States.

In December 2008 we entered into a worldwide collaboration with AstraZeneca AB, or AstraZeneca Agreement, to develop and commercialize Unit Dose Budesonide, or UDB, our proprietary nebulized version of budesonide for the potential treatment of asthma in children, 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, related to the UDB product candidate, effective immediately. We announced plans to suspend 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.

In February 2009, under the terms of the AstraZeneca Agreement, AstraZeneca paid us a nonrefundable upfront cash payment of $40.0 million. The $40.0 million upfront payment initially was recognized as collaboration revenue on a straight-line basis over the term of our research and development period with respect to UDB. 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 fiscal 2009.Our product portfolio also includes two earlier stage product candidates, both of which, we believe, highlight the broad applicability of our technologies to a diverse range of potential future products. MAP0005 is our proprietary combination of an inhaled corticosteroid and a long-acting beta-agonist for the potential treatment of asthma and chronic obstructive pulmonary disease and MAP0001 is our proprietary form of insulin for the potential treatment of Type 1 and Type 2 diabetes via pulmonary delivery using our proprietary Tempo® inhaler. 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 partnership opportunities for further development and commercialization of these two product candidates.

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 $171.5 million as of September 30, 2009. We have financed our operations through equity financing, debt financing, the issuance of convertible notes and collaboration payments. Prior to our initial public offering, or 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 2006, we entered into a loan facility agreement and borrowed $10.0 million to finance working capital, or the 2006 Working Capital Loan, and a $1.0 million loan facility to finance equipment purchases. In May 2008, we entered into an agreement to borrow $20.0 million, or the 2008 Working Capital Loan, in order to repay the 2006 Working Capital Loan and to support general corporate purposes. We received $40.0 million as a nonrefundable upfront payment from AstraZeneca in February 2009 and $8.7 million in cash for reimbursement of qualified development expenses during 2009. 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 an issue 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.

Table of Contents

Although we have net income for the three and nine months ended September 30, 2009, we expect to have a net loss for the year ending December 31, 2009. We expect to continue to incur net losses for 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 Estimates

With the exception of the Revenue Recognition policy discussed below, there have been no other significant changes in our critical accounting policies during the nine months ended September 30, 2009, 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, 2008, as amended.

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.

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.

Table of Contents

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. Total collaboration revenue recognized under the AstraZeneca Agreement was $35.3 million and $51.4 million, respectively, for the three and nine months ended September 30, 2009, compared to $0 for the same periods in 2008.

The $40.0 million upfront payment initially was recognized as collaboration revenue on a straight-line basis over the term of our research and development period with respect to UDB. 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 fiscal 2009.

Research and Development Expenses

Research and development expenses consist of: (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, 2009, we incurred approximately $167.3 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 clinical trials. We plan to increase our 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, effective February 2, 2009 and terminated on July 8, 2009, AstraZeneca reimbursed our development costs related to the UDB program.

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, 2009 and 2008, 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 is allocated based on management estimates.

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from July 3, 2003 (Inception) through September 30, 2009
	2009	2008	2009	2008	
Our most advanced product candidates:					
LEVADEX	59%	46%	58%	42%	49%
UDB (suspended)	25%	47%	32%	50%	43%
Other projects	16%	7%	10%	8%	8%
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.

Table of Contents

Sales, General and Administrative Expenses

Sales, general and administrative expenses consist primarily of compensation for executive, finance, marketing, legal and administrative personnel, including share-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, 2009, we incurred approximately $43.9 million in sales, general and administrative expenses since our inception in 2003.

Results of Operations

Comparison of Three and Nine Months Ended September 30, 2009 and 2008

Collaboration Revenue

Collaboration revenue includes amortization of the nonrefundable upfront payment and reimbursement of qualified development expenses. The collaboration revenue as compared to the prior year is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Collaboration revenue	$ 35,273	$	$ 51,402	$

For the three and nine months ended September 30, 2009 compared to the same periods in 2008, the increase in collaboration revenue was due to the AstraZeneca Agreement, which became effective on February 2, 2009 and was terminated effective on July 8, 2009. The $40.0 million upfront payment initially was recognized as collaboration revenue on a straight-line basis over the term of our research and development period with respect to UDB. 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 fiscal 2009.

On October 13, 2009, we received confirmation that AstraZeneca was in agreement with the final reimbursement of costs associated with the termination of the AstraZeneca Agreement and suspension of our UDB program. As a result, we expect to receive and record $2.8 million as collaboration revenue in the fourth quarter of 2009.

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,			
	2009	2008	Increase/ (Decrease)	% Increase/ (Decrease)	2009	2008	Increase/ (Decrease)	% Increase/ (Decrease)
Research and development expenses	$ 11,912	$ 16,815	$ (4,903)	(29)%	$ 35,615	$ 41,614	$ (5,999)	(14)%

For the three months ended September 30, 2009 compared to the same period in 2008, the decrease in research and development expenses was driven primarily by a decrease of $3.9 million in clinical and other related expenses to support the UDB Phase 3 clinical program, a decrease of $1.2 million in clinical and other related expenses to support the LEVADEX Phase 3 clinical program and a decrease of $0.2 million in expenses related to other projects.

During the third quarter of 2009, we suspended the development of our UDB product candidate. As a result, we recorded wind-down costs and writedown of fixed assets charges of approximately $2.8 million.

For the nine months ended September 30, 2009 compared to the same period in 2008, the decrease in research and development expenses was driven primarily by a decrease of $8.7 million in clinical and other related expenses to support the UDB Phase 3 clinical program, partially offset by an increase of $1.6 million in clinical and other related expenses to support the LEVADEX Phase 3 clinical program and by an increase of

$1.3 million in personnel related expenses.

Table of Contents

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,			
	2009	2008	Increase/ (Decrease)	% Increase/ (Decrease)	2009	2008	Increase/ (Decrease)	% Increase/ (Decrease)
Sales, general and administrative expenses	$ 3,597	$ 3,380	$ 217	6%	$ 9,842	$ 9,685	$ 157	2%

For the three months ended September 30, 2009 compared to the same period in 2008, the increase in sales, general and administrative expenses was related primarily to an increase of $0.2 million in stock-based compensation and an increase of $0.1 million in professional services, partially offset by a decrease of $0.2 million in other miscellaneous fees.

For the nine months ended September 30, 2009 compared to the same period in 2008, the increase in sales, general and administrative expenses was related primarily to an increase of $0.6 million in stock-based compensation, partially offset by a decrease of $0.3 million in other miscellaneous fees and by a decrease of $0.3 million in professional services.

Interest Income

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

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2009	2008	Increase/ (Decrease)	% Increase/ (Decrease)	2009	2008	Increase/ (Decrease)	% Increase/ (Decrease)
Interest income	$ 7	$ 453	$ (446)	(99)%	$ 118	$ 1,894	$ (1,776)	(94)%

For the three and nine months ended September 30, 2009 compared to the same periods in 2008, interest income decreased due primarily to a decrease in market interest rates.

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

Interest Expense

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

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2009	2008	Increase/ (Decrease)	% Increase/ (Decrease)	2009	2008	Increase/ (Decrease)	% Increase/ (Decrease)
Interest expense	$ 519	$ 621	$ (102)	(16)%	$ 1,672	$ 1,437	$ 235	16%

Interest expense for the three and nine months ended September 30, 2009 compared to the same periods in 2008 were relatively unchanged.

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

Other Income (expense), net

Other income (expense), net 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)
	2009	2008			2009	2008		
Other income (expense), net	$ 7	$	$ 7		$ (21)	$ (278)	$ (257)	(92)%

For the three months ended September 30, 2009 compared to the same period in 2008, other income was relatively unchanged.

For the nine months ended September 30, 2009 compared to the same period in 2008, other expense decreased due primarily to the fact that in the second quarter of 2008, we incurred a debt issuance cost of $394,000 upon the retirement of the 2006 Working Capital Loan and commencement of the 2008 Working Capital Loan. We did not incur such expenses in the second quarter of 2009.

Table of Contents

Liquidity and Capital Resources

Liquidity

We have incurred losses since our inception in July 2003 and as of September 30, 2009 we had an accumulated deficit of $171.5 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 the next several years. We expect to incur increased research and development and sales, general and administrative expenses related to our development 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. 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 2006, we entered into the 2006 Working Capital Loan, and a $1.0 million loan facility to finance equipment purchases. In May 2008, we entered into the 2008 Working Capital Loan, in order to repay the 2006 Working Capital Loan and to support general corporate purposes. We received $40.0 million as a nonrefundable upfront payment from AstraZeneca in February 2009 and $8.7 million in cash for reimbursement of qualified development expenses during 2009. On July 8, 2009, we received notice from AstraZeneca of the termination of the license agreement, effective immediately. 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 an issue 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.

As of September 30, 2009, we had approximately $76.2 million in cash, cash equivalents and short-term investments. Our cash, cash equivalents and short-term investments are primarily held in money market funds. Cash in excess of immediate requirements is invested in accordance with our investment policy with a view toward capital preservation and liquidity.

Cash Flow

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

	Nine Months Ended September 30,	
	2009	**2008**
Cash provided by (used in):		
Operating activities	$ 4,710	$ (41,360)
Investing activities	11,992	19,979
Financing activities	27,594	10,544

Net cash provided by (used in) operating activities. We received $4.7 million of cash from operating activities for the nine months ended September 30, 2009 compared to the usage of cash of $41.4 million for the same period in 2008. 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, 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. The usage of cash of $41.4 million for the nine months ended September 30, 2008 was due primarily to a net loss of $51.1 million, partially offset by an increase in accrued liabilities of $5.4 million.

Net cash provided by (used in) investing activities. We received $12.0 million of cash from investing activities for the nine months ended September 30, 2009 compared to receiving cash of $20.0 million for the same period in 2008. 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 investing activities for the nine months ended September 30, 2008 was primarily related to investment activity, with more sales and maturities than purchases of investments.

Net cash provided by financing activities. We received $27.6 million of cash from financing activities for the nine months ended September 30, 2009 compared to receiving cash of $10.5 million for the same period in 2008. 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. The cash provided by financing activities for the nine months ended September 30, 2008 was primarily attributable to the issuance of $20.0 million in debt in May 2008, partially offset by the repayment of $8.3 million for the 2006

Working Capital Loan.

Table of Contents

Agreement with AstraZeneca

In December 2008, we entered into an agreement with AstraZeneca AB, or AstraZeneca Agreement, which became effective in February 2009. Pursuant to the terms of the 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 this 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 immediately. AstraZeneca elected to terminate the AstraZeneca Agreement pursuant to Section 19.3.1(b) of the AstraZeneca Agreement, which provides that AstraZeneca could terminate the AstraZeneca Agreement in the event that the primary endpoints of the initial Phase 3 clinical trial of UDB were not met. Effective on the date of termination, all rights licensed to AstraZeneca in the agreement reverted back to us. We also announced our plan to suspend development of our UDB product candidate. We were jointly developing UDB with AstraZeneca, and were responsible for executing the development plan.

We recognized collaboration revenue of $35.3 million and $51.4 million, respectively, from AstraZeneca for the three and nine months ended September 30, 2009, compared to $0 for the same periods in 2008. The collaboration revenue includes amortization of the nonrefundable upfront payment of $40.0 million and reimbursement of qualified development expenses. The $40.0 million upfront payment initially was recognized as collaboration revenue on a straight-line basis over the term of our research and development period with respect to UDB. 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 fiscal 2009. We received $48.7 million in cash for the cumulative period from July 3, 2003 (date of inception) to September 30, 2009.

Agreement with Nektar

Under the June 2004 agreement, as amended, with Nektar Therapeutics UK Limited, or 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, 2009, we are required to make future nonrefundable milestone payments of up to $5.0 million related to products currently being developed under this agreement, when and if certain regulatory and commercial milestones are met. We paid $0 for both the three and nine months ended September 30, 2009 and 2008. We paid $2.6 million for the cumulative period from July 3, 2003 (date of inception) to September 30, 2009. Either party may terminate the Nektar Agreement upon a material, uncured default of the other party. We may terminate the 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 Elan Agreement, Elan granted to us a worldwide, exclusive, sub-licensable license under Elan s intellectual property rights to use, market, distribute, sell, have sold, offer for sale, import and export certain ingredients for our UDB product candidate. We also agreed to pay royalties at specified rates based on net sales. As of September 30, 2009, we are required to make future nonrefundable milestone payments of up to $16.5 million related to products currently being developed under this agreement, when and if certain regulatory and commercial milestones under the Elan Agreement are met with respect to our UDB product candidate. We paid $0 for both the three and nine months ended September 30, 2009, compared to $0.8 million and $0.8 million, respectively, for the same periods in 2008. We paid $4.0 million for the cumulative period from July 3, 2003 (date of inception) to September 30, 2009. 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. In connection with the execution of the AstraZeneca Agreement, we amended the Elan agreements, pursuant to which AstraZeneca was granted certain rights to exercise and enforce certain of our rights with Elan prior to the expiration or termination of the AstraZeneca Agreement. The amendments to the Elan agreements did not impact our unaudited condensed consolidated financial statements. Effective on the date of termination from AstraZeneca, all rights licensed to AstraZeneca in the agreement reverted back to us.

24

Table of Contents

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;
- 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, cash equivalents and short-term investments 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 our 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.

As widely reported, financial markets in the United States, Europe and Asia have been experiencing extreme disruption in recent months, including, among other things, extreme volatility in security prices, severely diminished liquidity and credit availability, rating downgrades of certain investments and declining valuations of others. Governments have taken unprecedented actions intended to address extreme market conditions that include severely restricted credit and declines in real estate values. Concern about the stability of the markets generally and the strength of counterparties specifically has led many lenders and institutional investors to reduce, and in some cases, cease to provide funding to borrowers. Continued turbulence in the U.S. and international markets and economies may limit our ability to access the capital markets to meet our funding requirements. 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

In September 2009, the Financial Accounting Standards Board, or FASB, ratified *Revenue Arrangements with Multiple Deliverables* issued as Accounting Standards Update, or 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. As a result, it is effective for us in the first quarter of fiscal year 2011. We currently are evaluating the impact that the adoption of ASU 2009-13 will have on our consolidated financial statements.

Table of Contents

In August 2009, the FASB issued ASU 2009-05, *Fair Value Measurements and Disclosures (Topic 820) Measuring Liabilities at Fair Value,* or Update 2009-05. Update 2009-05 clarifies that in circumstances in which a quoted price in an active market for an identical liability is not available, a reporting entity is required to measure fair value of such liability using one or more of the of the techniques prescribed by the update. Update 2009-05 is effective for the first reporting period (including interim periods) beginning after issuance. As a result, it is effective for us in the year ending December 31, 2009. We do not believe that the adoption of Update 2009-05 will have a material impact on our 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, 2009.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures: As required by paragraph (b) of Exchange Act Rules 13a-15 or 15d-15, 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, 2009, 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.

Table of Contents

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 $25.8 million, $40.1 million and $72.9 million, for the years ended December 31, 2006, 2007 and 2008, respectively. As of September 30, 2009, we had a deficit accumulated during development stage of approximately $171.5 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 our expenses to increase 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 incur substantial and increasing 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 increased 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, debt financings and collaboration payments. 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, effective immediately, of our license agreement with AstraZeneca 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 UDB development activities conducted for the U.S. registration, subject to the terms and conditions of the license agreement. Following the termination of the license agreement, we suspended development of UDB. If we are unable to develop and commercialize our other product candidates 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;

Table of Contents

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

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

our ability to manage our supply chain for the study drug, other clinical materials and potentially approved products;

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

the FDA s determination of the special protocol assessment, or SPA, we entered into for LEVADEX;

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

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

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

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

guidelines and recommendations of therapies published by various organizations;

the ability of patients to obtain coverage of or sufficient reimbursement for our products;
the ability to receive regulatory approval or commercialize our products;

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

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.

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 our research and development expenses to increase in connection with our ongoing activities, particularly as we focus on and proceed with our Phase 3 clinical program and conduct our other clinical trials 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, cash equivalents and short-term investments 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

Table of Contents

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.

As widely reported, financial markets in the United States, Europe and Asia have been experiencing extreme disruption in recent months, including, among other things, extreme volatility in security prices, severely diminished liquidity and credit availability, rating downgrades of certain investments and declining valuations of others. Governments have taken unprecedented actions intended to address extreme market conditions that include severely restricted credit and declines in real estate values. Concern about the stability of the markets generally and the strength of counterparties specifically has led many lenders and institutional investors to reduce, and in some cases, cease to provide funding to borrowers. Continued turbulence in the U.S. and international markets and economies may limit our ability to access the capital markets to meet our funding requirements.

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 outsourced 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 UDB and LEVADEX. In July 2009 we announced that we were suspending development of UDB, after our partner AstraZeneca terminated our license agreement. 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. Our contract with AstraZeneca provided a right of termination in the event that the trial failed to meet its co-primary endpoints and in July 2009, AstraZeneca notified us of the termination of the collaboration, effective immediately. 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 and regulatory approval 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 subset of subjects from this trial are continuing in a long-term safety extension of the study and we are continuing to recruit and enroll subjects in the safety extension. We also expect to conduct a second, confirmatory Phase 3 clinical trial as well as additional Phase 2 trials, including a pharmacokinetic trial in approximately 24 adult smokers comparing them to non-smokers and a

Table of Contents

pharmacodynamic trial in approximately 24 healthy adults compared to placebo, studying echocardiographic effects, of LEVADEX before submitting an application to the FDA for regulatory approval. 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 a new drug application, or 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 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.

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 begin on time or 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:

Table of Contents

- 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;

- complying with design protocols of any applicable SPAs; 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 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.

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 currently are conducting a Phase 3 clinical program for LEVADEX and will need to conduct additional Phase 3 and Phase 2 clinical trials in order to obtain regulatory approval for this product candidate. We may not be able to obtain approval for indications that are as broad as intended or we may obtain approval for indications different than those indications for which we seek approval. Furthermore we may not be able to obtain approval for any of our other product candidates.

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

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 first Phase 3 trial of LEVADEX, indicating that the trial met all four of its co-primary endpoints when LEVADEX was compared to placebo. A subset of subjects from this trial is continuing in a long-term safety extension of the study and we are continuing to recruit and enroll subjects for this safety extension. In order to obtain regulatory approval for LEVADEX, we will need to conduct additional Phase 3 and Phase 2 clinical trials. 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

Table of Contents

candidates, we do not know whether subsequent Phase 3 or other clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates. For example, 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, AstraZeneca terminated our collaboration. We have suspended development of our UDB product candidate.

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

To receive regulatory approval for the commercial sale of LEVADEX or any other product candidates, we must conduct adequate and well-controlled clinical trials to demonstrate efficacy and safety in humans. Clinical testing is expensive, takes many years and has an uncertain outcome. Clinical failure can occur at any stage of the testing. Our clinical trials may produce negative or inconclusive results. In such cases, we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing, or we may decide not to pursue further development of a product candidate, such as the case of our UDB product candidate, where top-line results of our initial Phase 3 clinical trial indicated that the trial failed to meet the primary endpoints. 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. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion, or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

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

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. 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-to-drug interactions that could impact potential product safety. At this point in time, we have not been requested to perform drug-to-drug interaction studies, but any such request may delay any potential product approval and will increase our expenses associated with our clinical programs. Furthermore, regulatory attitudes

32

Table of Contents

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.

While we have negotiated an SPA with the FDA for our first Phase 3 clinical trial of LEVADEX for the potential treatment of migraine, the SPA does not guarantee any particular outcome from regulatory review of the study or the product candidate.

The FDA s SPA process creates a written agreement between the sponsoring company and the FDA regarding clinical trial design and other clinical trial issues that can be used to support approval of a product candidate. The SPA is intended to provide assurance that if the agreed upon clinical trial protocols are followed and the trial endpoints are achieved, the data may serve as the primary basis for an efficacy claim in support of an NDA. However, the SPA agreement is not a guarantee of an approval of a product or any permissible claims about the product. In particular, the SPA is not binding on the FDA if public health concerns unrecognized at the time of the SPA agreement is entered into become evident, other new scientific concerns regarding product safety or efficacy arise or if the sponsor company fails to comply with the agreed upon trial protocols. In January 2008, we announced that we reached agreement with the FDA on a SPA for the first Phase 3 clinical trial of our LEVADEX product candidate for the potential treatment of migraine. 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 subset of subjects from this trial is continuing in a long-term safety extension of the study and we are continuing to recruit and enroll subjects for this safety extension of the study. We cannot assure you that the safety extension of the Phase 3 clinical trial will be successful. In addition, we do not know how the FDA will interpret the commitments under the SPA agreement, how it will interpret the data and results or whether it will approve our LEVADEX product candidate for the treatment of migraine. As a result, we cannot guarantee any particular outcome from regulatory review of the first LEVADEX Phase 3 trial.

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;
- 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;

Table of Contents

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 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 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