MAP Pharmaceuticals, Inc.
Form 10-Q/A
March 30, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q/A

(Amendment No. 1)

(MARK ONE)

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

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2011

OR

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

FOR THE TRANSITION PERIOD FROM TO

Commission File Number 001-33719

MAP PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-0507047**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2400 Bayshore Parkway, Suite 200	
Mountain View, California	**94043**
(Address of principal executive offices)	**(Zip code)**

(650) 386-3100

(Registrant s telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

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

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

As of July 31, 2011, the registrant had outstanding 30,416,026 shares of Common Stock.

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Explanatory Note

We are filing this Amendment No. 1 on Form 10-Q/A (this Form 10-Q/A) to amend our Quarterly Report on Form 10-Q for the quarter ended June 30, 2011 (the Original Filing), as originally filed with the Securities and Exchange Commission (the SEC) on August 8, 2011 (the Original Filing Date) to reflect a restatement of the following previously filed financial statements and data (and related disclosures):

- our condensed consolidated balance sheet as of June 30, 2011, as discussed in Note 2 to the financial statements included in Item 1 of this 10-Q/A;
- our condensed consolidated statements of operations and cash flows for the three and six months ended June 30, 2011, as discussed in Note 2 to the financial statements included in Item 1 of this Form 10-Q/A; and
- our management s discussion and analysis of financial condition and results of operations as of and for the three and six months ended June 30, 2011 as discussed in Item 2 of this Form 10-Q/A.

The restatement corrects the accounting treatment for the nonrefundable $60.0 million upfront cash payment that we received in February 2011 for a license grant (the License) granted by us pursuant to a Collaboration Agreement with Allergan, Inc. and Allergan USA, Inc. (Collaboration Agreement and Allergan, respectively). In connection with (i) a review by the SEC of our Annual Report on Form 10-K for the year ended December 31, 2010 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2011 (the Staff Review) and (ii) subsequent communications between the staff of the SEC and us relating to the Staff Review, we have determined that the License deliverable does not have standalone value apart from the other deliverables under the Collaboration Agreement. As a result, all of the deliverables under the Collaboration Agreement will be treated as a single unit of accounting, and revenue recognition for the nonrefundable $60.0 million upfront cash payment will be deferred and amortized on a straight-line basis over the term of the Collaboration Agreement (as discussed in Note 2 of Item 1 of this Form 10-Q/A). This restatement will change previously reported revenue, deferred revenue, net income (loss) and earnings (loss) per share for the three and six months ended June 30, 2011.

In connection with the restatement of our financial statements described herein, we have reported a material weakness in our internal controls and procedures with regard to the evaluation of, and accounting for, complex multiple element revenue arrangements. Due to this material weakness, our principal executive officer and principal financial officer also concluded that our disclosure controls and procedures were not effective as of the end of the period covered by this report. For more information, see Item 4 included in this Form 10-Q/A.

Although this Form 10-Q/A supersedes the Original Filing in its entirety, this Form 10-Q/A amends and restates only Items 1, 2 and 4 of Part I and two risk factors set forth in Item 1A of Part II marked with an asterisk, solely as a result of, and to reflect, the restatement, and no other information in the Original Filing is amended hereby. This Form 10-Q/A speaks as of the Original Filing Date and does not reflect any events that may have occurred subsequent to the Original Filing Date. In addition, pursuant to Rule 12b-15 under the Securities Exchange Act of 1934, as amended, as a result of this Form 10-Q/A, the certifications pursuant to Section 302 and Section 906 of the Sarbanes-Oxley Act of 2002, filed and furnished, respectively, as exhibits to the Original Report have been re-executed and re-filed as of the date of this Amended Report and are included as exhibits hereto. Concurrent with the filing of this Form 10-Q/A, we are filing our Annual Report on Form 10-K for the fiscal year ended December 31, 2011.

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PART I FINANCIAL INFORMATION

Item 1 Financial Statements

MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)

(Unaudited)

	June 30, 2011 (as restated) [1]	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 103,461	$ 76,007
Accounts receivable	384	
Prepaid expenses and other current assets	516	644
Total current assets	104,361	76,651
Property and equipment, net	5,782	5,803
Other assets	27	30
Restricted investment	310	310
Total assets	$ 110,480	$ 82,794
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,843	$ 2,998
Accrued liabilities	5,326	9,442
Debt	3,715	7,581
Current portion of deferred revenue	3,349	
Total current liabilities	14,233	20,021
Deferred revenue, less current portion	55,256	
Other liabilities	105	117
Total liabilities	69,594	20,138
Commitments and contingencies (Note 7)		
Stockholders equity:		
Common stock	298	296
Additional paid-in capital	307,454	301,924
Deficit accumulated during the development stage	(266,866)	(239,564)
Total stockholders equity	40,886	62,656
Total liabilities and stockholders equity	$ 110,480	$ 82,794

(1) See Note 2 Restatement of Condensed Consolidated Financial Statements of Notes to Condensed Consolidated Financial Statements.

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

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MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,		Period from July 3, 2003 (Inception) to June 30, 2011
	2011 (as restated) (1)	2010	2011 (as restated)(1)	2010	(as restated) (1)
Collaboration revenue	$ 837	$	$ 1,395	$	$ 55,561
Operating expenses:					
Research and development	7,259	8,242	18,827	18,028	236,296
Sales, general and administrative	4,796	3,910	9,639	7,791	72,553
Total operating expenses	12,055	12,152	28,466	25,819	308,849
Loss from operations	(11,218)	(12,152)	(27,071)	(25,819)	(253,288)
Interest income	22	2	52	6	6,457
Interest expense	(106)	(339)	(273)	(732)	(7,266)
Other expense, net			(10)	(2)	(752)
Net loss	(11,302)	(12,489)	(27,302)	(26,547)	(254,849)
Cumulative stock dividend attributed to preferred stockholders					(13,925)
Net income loss attributed to common stockholders	$ (11,302)	$ (12,489)	$ (27,302)	$ (26,547)	$ (268,774)
Net income loss per share attributed to common stockholders					
Basic and diluted	$ (0.37)	$ (0.47)	$ (0.90)	$ (1.01)	
Weighted average shares outstanding used in calculating net loss per share attributed to common stockholders					
Basic and diluted	30,333	26,480	30,272	26,168	

(1) See Note 2 Restatement of Condensed Consolidated Financial Statements of Notes to Condensed Consolidated Financial Statements.

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

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MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Six Months Ended June 30,		Cumulative Period from July 3, 2003 (Date of Inception) to June 30, 2011
	2011 (as restated)[1]	2010	(as restated)[1]
Cash flows from operating activities:			
Net loss	$ (27,302)	$ (26,547)	$ (254,849)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	609	641	6,487
Accretion of investment discounts, net			(1,595)
Accretion of debt payment premium	55	142	990
Stock-based compensation	3,772	3,094	21,613
Loss on disposal of equipment and other non-cash items	10	306	2,268
Changes in operating assets and liabilities:			
Accounts receivable	(384)		(384)
Prepaid expenses and other current assets	128	165	(741)
Other assets	3	85	113
Accounts payable	(1,353)	(1,509)	526
Accrued liabilities	(4,116)	(3,136)	5,246
Deferred revenue	58,605		58,605
Other liabilities	(12)	39	105
Net cash provided by (used in) operating activities	30,015	(26,720)	(161,616)
Cash flows from investing activities:			
Purchase of intangible assets and in-process research and development			(412)
Purchase of property and equipment	(400)	(1,319)	(11,921)
Purchase of short-term investments			(169,497)
Sales and maturities of short-term investments			171,411
Purchase of restricted investment			(310)
Net cash used in investing activities	(400)	(1,319)	(10,729)
Cash flows from financing activities:			
Proceeds from issuance of convertible notes payable			4,300
Proceeds from issuance of debt			31,006
Proceeds from sales of shares through equity plans	1,758	1,479	5,980
Repayment of debt	(3,921)	(3,551)	(28,381)
Proceeds from issuance of common stock resulting from drawdown of equity line of credit, net of issuance costs		19,665	19,653
Proceeds from issuance of common stock in equity offerings, net of issuance costs	2		140,820
Proceeds from issuance of convertible preferred stock, net of issuance costs			102,428

Net cash provided by (used in) financing activities	(2,161)	17,593	275,806
Net increase (decrease) in cash and cash equivalents	27,454	(10,446)	103,461
Cash and cash equivalents at beginning of period	76,007	65,776	
Cash and cash equivalents at end of period	$ 103,461	$ 55,330	$ 103,461
Supplemental disclosures of non-cash investing activities			
Purchase of property and equipment through accounts payable	$ 198	$	$ 198

(1) See Note 2 Restatement of Condensed Consolidated Financial Statements of Notes to Condensed Consolidated Financial Statements.

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

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MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

NOTE 1. THE COMPANY

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

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

NOTE 2. RESTATEMENT OF CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Subsequent to the issuance of our condensed consolidated financial statements for the quarter ended March 31, 2011, June 30, 2011 and September 30, 2011, and in connection with (i) a review by the staff of the Securities and Exchange Commission (the Staff) of our Annual Report on Form 10-K for the year ended December 31, 2010 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2011 (the Staff Review) and (ii) subsequent communications between the Staff and us relating to the Staff Review, we, under the direction of our Audit Committee, re-evaluated our historical and then current practices with respect to the timing for recognition of revenues in accordance with accounting principles generally accepted in the United States of America. In connection with this reevaluation, we determined that our previous accounting treatment for the nonrefundable $60.0 million upfront cash payment that we had received in February 2011 pursuant to the Collaboration Agreement with Allergan was no longer appropriate for the three months ended March 31, 2011, June 30, 2011 and September 30, 2011, respectively.

In this Form 10-Q/A, we have restated to correct errors in the following previously filed financial statements and data (and related disclosures): (1) condensed consolidated balance sheet as of June 30, 2011; and (2) condensed consolidated statements of operations and cash flows for the three and six months ended June 30, 2011.

Finding from Our Review of Revenue Recognition for $60.0 Million Upfront Cash Payment

In accordance with Accounting Standards Update 2009-13, *Revenue Arrangements with Multiple Deliverables*, which was codified in Accounting Standards Codification (ASC) 605-25 and was adopted by us effective January 1, 2011, we initially determined that the License had standalone value apart from the other deliverables. As a result, we recognized $34.2 million of the nonrefundable $60.0 million upfront payment received from Allergan as collaboration revenue in the quarter ended March 31, 2011. The remaining $25.8 million was recorded as deferred revenue and would be amortized as collaboration revenue over the estimated obligation periods for the remaining deliverables.

However, in connection with (i) the Staff Review and (ii) subsequent communications between the Staff and us relating to the Staff Review, we have determined that the License deliverable does not have standalone value, because Allergan could not use the License for its intended purpose without the performance of other deliverables from us, including participating in joint committees with Allergan related to the commercialization of LEVADEX. As the License does not have standalone value, it must be combined with all the remaining deliverables to

Allergan under the Collaboration Agreement because the License could not be deemed to be fully delivered for its intended purpose unless we continue to perform our other obligations under the Collaboration Agreement. Accordingly, all of the deliverables must be treated as a single unit of accounting and revenue relating to the $60.0 million upfront cash payment would be amortized on a straight-line basis, beginning with the delivery of the first deliverable and continuing through the end date of the deliverable with the longest term. Our participation in joint committees with Allergan has the longest obligation period, requiring our participation throughout the term of the Collaboration Agreement. The term of the Collaboration Agreement is the later of (a) December 31, 2025, and (b) the date that our last patent right covering LEVADEX in the United States expires. The date that our last patent right covering LEVADEX in the United States expires is 2028. As of June 30, 2011, we anticipate amortizing the remaining $58.6 million of the initial $60.0 million through 2028.

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The effect of this restatement is to change previously reported revenue, deferred revenue, net income (loss) and earnings (loss) per share for the three and six months ended June 30, 2011. The restatement relates to the timing of revenue recognition for the nonrefundable $60.0 million upfront cash payment received from Allergan for the License but not the total amount of revenue ultimately to be recorded by us, and will have no impact on our previously reported cash position, total assets or operating expenses.

Impact of the Restatement Adjustments on our Consolidated Financial Statements

Our condensed consolidated financial statements presented in this Quarterly Report on Form 10-Q/A have been restated to reflect the impact resulting from the restatement adjustments described above, as follows:

RECONCILIATION OF CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)

(Unaudited)

	As of June 30, 2011		
	As Previously Reported	Adjustments	As Restated
ASSETS			
Current assets:			
Cash and cash equivalents	$ 103,461	$	$ 103,461
Accounts receivable	384		384
Prepaid expenses and other current assets	516		516
Total current assets	104,361		104,361
Property and equipment, net	5,782		5,782
Other assets	27		27
Restricted investment	310		310
Total assets	$ 110,480	$	$ 110,480
LIABILITIES AND STOCKHOLDERS EQUITY			
Current liabilities:			
Accounts payable	$ 1,843	$	$ 1,843
Accrued liabilities	5,326		5,326
Debt	3,715		3,715
Current portion of deferred revenue	14,400	(11,051)	3,349
Total current liabilities	25,284	(11,051)	14,233
Deferred revenue, less current portion	7,925	47,331	55,256
Other liabilities	105		105
Total liabilities	33,314	36,280	69,594
Commitments and contingencies			
Stockholders equity:			
Common stock	298		298
Additional paid-in capital	307,454		307,454
Deficit accumulated during the development stage	(230,586)	(36,280)	(266,866)

Total stockholders equity	77,166	(36,280)	40,886
Total liabilities and stockholders equity	$ 110,480	$	$ 110,480

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RECONCILIATION OF CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended June 30, 2011			Six Months Ended June 30, 2011			Cumulative Period from July 3, 2003 (Date of Inception) to June 30, 2011		
	As Previously Reported	Adjustments	As Restated	As Previously Reported	Adjustments	As Restated	As Previously Reported	Adjustments	As Restated
Collaboration revenue	$ 3,513	$ (2,676)	$ 837	$ 37,675	$ (36,280)	$ 1,395	$ 91,841	$ (36,280)	$ 55,561
Operating expenses:									
Research and development	7,259		7,259	18,827		18,827	236,296		236,296
Sales, general and administrative	4,796		4,796	9,639		9,639	72,553		72,553
Total operating expense	12,055		12,055	28,466		28,466	308,849		308,849
Income (loss) from operations	(8,542)	(2,676)	(11,218)	9,209	(36,280)	(27,071)	(217,008)	(36,280)	(253,288)
Interest income	22		22	52		52	6,457		6,457
Interest expense	(106)		(106)	(273)		(273)	(7,266)		(7,266)
Other income (expense), net				(10)		(10)	(752)		(752)
Net income (loss)	$ (8,626)	$ (2,676)	$ (11,302)	$ 8,978	$ (36,280)	$ (27,302)	$ (218,569)	$ (36,280)	$ (254,849)
Cumulative stock dividend attributed to preferred stockholders							(13,925)		(13,925)
Net income (loss) attributed to common stockholders	$ (8,626)	$ (2,676)	$ (11,302)	$ 8,978	$ (36,280)	$ (27,302)	$ (232,494)	$ (36,280)	$ (268,774)
Net income (loss) per share attributed to common stockholders:									
Basic	$ (0.28)	$ (0.09)	$ (0.37)	$ 0.30	$ (1.20)	$ (0.90)			
Diluted	$ (0.28)	$ (0.09)	$ (0.37)	$ 0.28	$ (1.18)	$ (0.90)			
Weighted average shares used in computing net income (loss) per share attributed to common stockholders:									
Basic	30,333		30,333	30,272		30,272			
Diluted	30,333		30,333	31,595	(1,323)	30,272			

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RECONCILIATION OF CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW

(In thousands)

(Unaudited)

	Three Months Ended June 30, 2011			Cumulative Period from July 3, 2003 (Date of Inception) to June 30, 2011		
	As previously reported	Adjustments	As restated	As previously reported	Adjustments	As restated
Cash flows from operating activities:						
Net income (loss)	$ 8,978	$ (36,280)	$ (27,302)	$ (218,569)	$ (36,280)	$ (254,849)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:						
Depreciation and amortization	609		609	6,487		6,487
Accretion of investment discounts, net				(1,595)		(1,595)
Accretion of debt payment premium	55		55	990		990
Stock-based compensation	3,772		3,772	21,613		21,613
Loss on disposal of equipment and other non-cash items	10		10	2,268		2,268
Changes in operating assets and liabilities:						
Accounts receivable	(384)		(384)	(384)		(384)
Prepaid expenses and other current assets	128		128	(741)		(741)
Other assets	3		3	113		113
Accounts payable	(1,353)		(1,353)	526		526
Accrued liabilities	(4,116)		(4,116)	5,246		5,246
Deferred revenue	22,325	36,280	58,605	22,325	36,280	58,605
Other liabilities	(12)		(12)	105		105
Net cash provided by (used in) operating activities	30,015		30,015	(161,616)		(161,616)
Cash flows from investing activities:						
Purchases of intangible assets and in-process research and development				(412)		(412)
Purchases of property and equipment	(400)		(400)	(11,921)		(11,921)
Purchase of short-term investments				(169,497)		(169,497)
Sales and maturities of short-term investments				171,411		171,411
Purchase of restricted investment				(310)		(310)
Net cash used in investing activities	(400)		(400)	(10,729)		(10,729)
Cash flows from financing activities:						
Proceeds from issuance of convertible notes payable				4,300		4,300
Proceeds from issuance of debt				31,006		31,006
Proceeds from sales of shares through equity plans	1,758		1,758	5,980		5,980
Repayment of debt	(3,921)		(3,921)	(28,381)		(28,381)
Proceeds from issuance of common stock resulting from drawdown of equity line of credit, net of issuance costs				19,653		19,653
Proceeds from issuance of common stock in equity offerings, net of issuance costs	2		2	140,820		140,820
Proceeds from issuance of convertible preferred stock, net of issuance costs				102,428		102,428

Net cash provided by (used in) financing activities	(2,161)		(2,161)	275,806		275,806
Net increase in cash and cash equivalents	27,454		27,454	103,461		103,461
Cash and cash equivalents at beginning of period	76,007		76,007			
Cash and cash equivalents at end of period	$ 103,461	$	$ 103,461	$ 103,461	$	$ 103,461
Supplemental disclosures of non-cash investing activities:						
Purchase of property and equipment through accounts payable	$ 198	$	$ 198	$ 198	$	$ 198

NOTE 3. 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.

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

Revenue Recognition restated

We recognize revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or determinable; and collectability is reasonably assured. Collaboration revenue, which is earned under license agreements with third parties, may include nonrefundable license fees, cost reimbursements and contingent milestones.

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

- provide updated guidance on whether multiple elements exist, how the elements in an arrangement should be separated, and how the arrangement consideration should be allocated to the separate elements;
- require an entity to allocate arrangement consideration to each element based on a selling price hierarchy, also called the relative selling price method, where the selling price for an element is based on vendor-specific objective evidence (VSOE), if available; third-party evidence (TPE), if available and VSOE is not available; or the best estimate of selling price (ESP), if neither VSOE nor TPE is available; and
- eliminate the use of the residual method and require an entity to allocate arrangement consideration using the selling price hierarchy.

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

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

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

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

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

Our process for determining ESPs involves management s judgment. Our process considers multiple factors such as discounted cash flows, estimated direct expenses and other costs and available data, which may vary over time, depending upon the circumstances, and relate to each

deliverable. If the estimated obligation period of one or more deliverables should change, the future amortization of the revenue would also change. We regularly review ESP and maintain internal controls over the establishment and updates of the estimates.

The Allergan Agreements entered into in February 2011 contain multiple elements, including a license to commercialize our product candidate, regulatory approval and manufacturing for our product candidate, and various committee participations. We received an upfront cash payment of $60.0 million from Allergan upon execution of the Allergan Agreements. In accordance with ASU 2009-13, we evaluated whether there is standalone value for each of the various deliverables. As we have determined that the license and other non-contingent deliverables do not have standalone value, they must be combined with all the remaining deliverables to Allergan because the license could not be deemed fully delivered for its intended purpose unless we continue to perform our other obligations under the Collaboration Agreement. Accordingly, they do not meet the separation criteria, resulting in these deliverables being considered a single unit of account. As a result, revenue relating to the upfront cash payment is deferred and will be recognized on a straight-line basis over the term of the Allergan Agreements through 2028, which represents the estimated obligation period. See Note 2 of Item 1 of this Form 10-Q/A Note 2 with respect to the accounting treatment of the upfront cash payment.

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

Pre-clinical Study and Clinical Trial Accruals

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

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

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

Stock-Based Compensation

Effective January 1, 2006, we adopted ASC 718 *Compensation Stock Compensation,* , or ASC718, using the prospective transition method, which requires the measurement and recognition of compensation expense for all stock-based payment awards granted, modified and settled to our employees and directors after January 1, 2006. Our financial statements reflect the impact of ASC 718. We chose the straight-line attribution method for allocating compensation costs and recognized the fair value of each stock option on a straight-line basis over the requisite service period.

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

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

Comprehensive Loss

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

For both of the three and six months ended June 30, 2011 and 2010, there was no difference between net loss and comprehensive loss.

Net Loss per Share

Basic net loss per share is computed by dividing net loss attributed to common stockholders by the weighted average number of common shares outstanding during the period. Our potential dilutive shares, which include outstanding common stock options, RSUs with time-based vesting, common stock issuable pursuant to our employee stock purchase plan, or ESPP, warrants to purchase common stock and RSUs with performance-based vesting have not been included in the computation of diluted net loss per share for all the periods as the result would be anti-dilutive. Such potentially dilutive shares are excluded when the effect would be to reduce a net loss per share.

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The numerator and denominator used in the calculation of basic and diluted net loss per share were as follows (in thousands, except share and per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011 (as restated)[1]	2010	2011 (as restated)[1]	2010
Numerator				
Net loss attributed to common stockholders	$ (11,302)	$ (12,489)	$ (27,302)	$ (26,547)
Denominator				
Weighted average common shares outstanding	30,333,126	26,480,166	30,272,271	26,167,861
Basic and diluted net loss per share	$ (0.37)	$ (0.47)	$ (0.90)	$ (1.01)

(1) See Note 2 Restatement of Condensed Consolidated Financial Statements of Notes to Condensed Consolidated Financial Statements.

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

	As of June 30,	
	2011 (as restated)[1]	2010
Options to purchase common stock	4,391,696	4,081,932
RSUs with time-based vesting	128,242	
Common stock issuable pursuant to the ESPP	7,452	9,080
Warrants to purchase common stock	26,903	26,903
RSUs with performance-based vesting	81,000	98,000

(1) See Note 2 Restatement of Condensed Consolidated Financial Statements of Notes to Condensed Consolidated Financial Statements.

Recent Accounting Pronouncements

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

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

the adoption of ASU 2011-05 will have a material impact on our condensed consolidated financial statements.

NOTE 4. LICENSE AND SUPPLY AGREEMENTS

Agreement with Allergan

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

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

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

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

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

In February 2011, Allergan paid us an upfront payment of $60.0 million, out of which $0.8 million and $1.4 million were recognized as collaboration revenue for the three and six months ended June 30, 2011, respectively. The remaining $58.6 million is deferred and will be amortized as collaboration revenue through the end date of the deliverable under the Collaboration Agreement with the longest term. Our participation in joint committees with Allergan has the longest obligation period, requiring our participation throughout the term of the Collaboration Agreement. The term of the Collaboration Agreement is the later of (a) December 31, 2025, and (b) the date that our last patent right covering LEVADEX in the United States expires. The date that our last patent right covering LEVADEX in the United States expires is 2028. As a result, we will amortize the remaining $58.6 million of the initial $60.0 million through 2028.

In August 2011, we announced that the FDA accepted for filing our LEVADEX NDA. As a result, pursuant to the terms of our Collaboration Agreement with Allergan, the acceptance for filing of the LEVADEX NDA triggers a milestone payment of $20.0 million from Allergan. Please refer to Note 8. Subsequent Event for further details.

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

Sales, general and administrative expenses for both the three and six months ended June 30, 2011, as well as for the cumulative period from July 3, 2003 (date of inception) to June 30, 2011, was net of $0.4 million of costs reimbursed or reimbursable by Allergan under cost sharing provisions in our Collaboration Agreement.

Agreement with Nektar

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

We paid $0 and $1.0 million for the three and six months ended June 30, 2011, respectively. For the six months ended June 30, 2011, we paid Nektar a milestone payment of $1.0 million as a result of entering into the Allergan Agreements, and recorded it as research and development

expenses on our condensed consolidated statements of operations for the six months ended June 30, 2011. We paid $0 for both the three and six months ended June 30, 2010. We have paid $3.6 million for the cumulative period from July 3, 2003 (date of inception) to June 30, 2011. Either party may terminate the Nektar Agreement upon a material, uncured default of the other party. We may terminate the Nektar Agreement, with or without cause, at any time upon six months prior written notice.

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NOTE 5. FAIR VALUE MEASUREMENTS

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

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

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

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

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

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

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

	As of June 30, 2011		
	Amortized Cost	Unrealized Gain (Loss)	Estimated Fair Value
Cash	$ 5,225	$	$ 5,225
Certificates of deposit	310		310
Money market funds	98,236		98,236
	$ 103,771	$	$ 103,771
Reported as:			
Cash and cash equivalents			$ 103,461
Restricted investment			310
			$ 103,771

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

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

As of June 30, 2011	Level 1	Level 2	Level 3	Total
Certificates of deposit	$	$ 310	$	$ 310
Money market funds	98,236			98,236
Total	$ 98,236	$ 310	$	$ 98,546

As of December 31, 2010	Level 1	Level 2	Level 3	Total
Certificates of deposit	$	$ 310	$	$ 310
Money market funds	73,680			73,680
Total	$ 73,680	$ 310	$	$ 73,990

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

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

The carrying amount for our debt reported in the consolidated balance sheet as of June 30, 2011 was $3.7 million. Using a discounted cash flow technique that incorporates a market interest rate, we have determined the fair value of our debt to be $3.7 million at June 30, 2011.

NOTE 6. BALANCE SHEET COMPONENTS

Accounts receivable

	June 30, 2011	December 31, 2010
Accounts receivable	$ 384	$
	$ 384	$

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The increase in the accounts receivable balance as of June 30, 2011 as compared to December 31, 2010 was due to the amount reimbursable to us from Allergan under cost sharing provisions in our Collaboration Agreements.

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	June 30, 2011	December 31, 2010
Clinical trial related	$ 1,278	$ 4,363
Payroll and related expenses	3,166	3,993
Professional services	831	998
Other	51	88
	$ 5,326	$ 9,442

Debt

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

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

Our debt consisted of the following (in thousands):

	June 30, 2011	December 31, 2010
Principal amount	$ 2,724	$ 6,646
Plus: premium, based on imputed interest rate of 12%	991	935
	3,715	7,581
Less: current portion of debt	3,715	7,581
Long-term portion	$	$

As of June 30, 2011, debt payments, which include interest and principal, are as follows (in thousands):

Year ending December 31,	Amount
2011 (remaining four months, from July 2011 to the maturity date in October 2011)	3,781
Total debt payments	$ 3,781

NOTE 7. COMMITMENTS AND CONTINGENCIES

Operating Leases

In June 2004, we entered into a lease agreement for laboratory and office facilities in Mountain View, California, or the Lease, and in August 2006 we amended the Lease to include additional square footage within the same building. The Lease was to expire in June 2008. In March 2008, we entered into another amendment to the Lease, or the March 2008 Amendment, to extend the term of the Lease until June 2012, and to include additional square footage and options to lease additional square footage. In September 2008, we amended and restated the Lease, providing for expanded square footage and certain renewal options. Under the Lease, we pay operating costs, including property taxes, insurance and maintenance, in addition to monthly rent. Rent is subject to an annual increase for the duration of the Lease, which we recognize on a straight-line basis. The annual lease payments for the space under the amended and restated Lease were effective on July 1, 2008.

Rent expense was approximately $0.3 million and $0.6 million, respectively, for the three and six months ended June 30, 2011, compared to $0.3 million and $0.7 million, respectively, for the same periods in 2010. Rent expense was approximately $6.4 million for the cumulative period from July 3, 2003 (date of inception) to June 30, 2011.

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As of June 30, 2011, future minimum lease payments are as follows (in thousands):

Year ending December 31,	Amount
2011 (remaining six months)	$ 680
2012	700
Total minimum lease payments	$ 1,380

In accordance with the terms of the Lease, we are obligated to maintain an irrevocable letter of credit from a bank as a security deposit. As collateral for the letter of credit, we are required to maintain a bank deposit account of $0.3 million, which is shown as a restricted investment on our condensed consolidated balance sheets at June 30, 2011 and December 31, 2010.

Contingencies

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

Indemnification

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

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

NOTE 8. STOCKHOLDERS EQUITY

Restricted Stock Units

The Compensation Committee of the Board of Directors approved awards of RSUs with time-based vesting from our 2007 Equity Award Plan, or the 2007 Plan, to certain of our employees. Each RSU represents one equivalent share of our common stock to be awarded after the vesting period. These RSUs vest over four years at a rate of 25% annually. The fair value for these RSUs is based on the closing price of our common stock on the date of grant. We measure compensation expense for these RSUs at fair value on the date of grant and recognize the expense over the expected vesting period. The RSUs do not entitle participants to the rights of holders of common stock, such as voting rights, until the shares are issued.

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

For the six months ended June 30, 2011, activity for RSUs under the 2007 Plan was as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
RSUs Outstanding at December 31, 2010	98,000	$ 16.19
RSUs granted	137,042	$ 16.06
RSUs vested		
RSUs forfeited	(25,800)	$ 16.18
Unvested RSUs outstanding at June 30, 2011	209,242	$ 16.10

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Stock Options

For the six months ended June 30, 2011, activity for stock options under the 2007 Plan was as follows:

	Number of Shares	Weighted Average Exercise Price
Balances, at December 31, 2010	4,071,903	$ 9.64
Options granted	614,625	$ 16.09
Options exercised	(183,762)	$ 7.13
Options forfeited	(109,938)	$ 13.69
Options expired	(1,132)	$ 16.19
Balances, at June 30, 2011	4,391,696	$ 10.54

As of June 30, 2011, we had 2,244,722 shares of common stock available for grant under the 2007 Plan.

Warrants

We issued warrants to purchase 73,989 shares of common stock to selected lenders in connection with an earlier working capital loan which was fully paid in May 2008 and an equipment loan which was fully paid in September 2009. The warrants are exercisable at a price of $7.43 per share and expire in September 2013. In October 2009 and March 2010, warrants to purchase 22,418 shares and 24,668 shares were exercised, respectively, resulting in a net issuance of 5,817 shares and 12,295 shares, respectively. As of June 30, 2011, warrants to purchase the remaining 26,903 shares of common stock were outstanding.

Stock-Based Compensation for Employees

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Research and development	$ 693	$ 736	$ 1,697	$ 1,342
Sales, general and administrative	954	872	2,075	1,752
	$ 1,647	$ 1,608	$ 3,772	$ 3,094

We used the following assumptions to estimate the fair value of options granted under our stock option plan for the three and six months ended June 30, 2011 and 2010, respectively:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Risk-free interest rate	1.6% - 2.2%	1.9% - 2.5%	1.6% - 2.2%	1.9% - 2.5%
Expected volatility	69%	62%	69% - 70%	62% - 63%
Expected term (in years)	5	5	5	5
Expected dividend yield	0%	0%	0%	0%

We used the following assumptions to estimate the fair value of shares purchased under our ESPP for the three and six months ended June 30, 2011 and 2010, respectively:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Risk-free interest rate	0.1% - 0.2%	0.1% - 0.2%	0.1% - 0.2%	0.1% - 0.2%
Expected volatility	30% - 38%	47% - 76%	30% - 38%	47% - 76%
Expected term (in years)	0.5	0.5	0.5	0.5
Expected dividend yield	0%	0%	0%	0%

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

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

Expected Volatility: The expected stock price volatility of stock options was determined by examining the historical volatilities for industry peers and using an average of the historical volatilities of our industry peers as we did not have sufficient trading history for our common stock. Industry peers consist of several public companies in the biopharmaceutical industry similar to us in size, stage of life-cycle and financial leverage. We will continue to analyze the expected stock price volatility of stock options as more historical data for our common stock becomes available. Effective on January 1, 2010, the expected stock price volatility for shares from the ESPP is determined based on our own historical volatilities.

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

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

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

As of June 30, 2011, there were unrecognized compensation costs of approximately $7.2 million related to non-vested stock option awards granted after January 1, 2006 that will be recognized on a straight-line basis over the weighted average remaining period of 2.2 years.

NOTE 9. SUBSEQUENT EVENT

In August 2011, we announced that the FDA accepted for filing our LEVADEX NDA. As a result, pursuant to the terms of our Collaboration Agreement with Allergan, the acceptance for filing of the LEVADEX NDA triggers a milestone payment of $20.0 million from Allergan. We will record the $20.0 million milestone payment as collaboration revenue on our condensed consolidated statements of operations for the three months ended September 30, 2011.

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

This quarterly report on Form 10-Q/A 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/A 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/A. You should read this quarterly report on Form 10-Q/A 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/A 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, 2010.

Restatement of Condensed Consolidated Financial Statements

We have restated the condensed consolidated balance sheet as of June 30, 2011, condensed consolidated statements of operations and cash flows for the three and six months ended June 30 2011, including the applicable notes as reflected in this Form 10-Q/A. For additional information about the restatement, please see the Explanatory Note regarding restatement immediately preceding Part I, Item 1 and Note 2 of the Notes to Condensed Consolidated Financial Statements, Restatement of Condensed Consolidated Financial Statements.

The following discussion and analysis of our financial condition and results of operations incorporates the restated amounts.

Overview

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

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

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

Our current focus is to advance our lead product candidate, LEVADEX (MAP0004) orally inhaled migraine therapy, a proprietary orally inhaled version of dihydroergotamine mesylate, or DHE, for the potential acute treatment of migraine. We completed clinical development for LEVADEX in 2010 and submitted a NDA to the U.S. Food and Drug Administration, or FDA, in May 2011. In collaboration with Allergan, Inc., we plan to commercialize LEVADEX directly to neurologists and pain specialists in the United States and Canada. We are also evaluating options to commercialize LEVADEX to primary care physicians in the United States and Canada and to physicians in markets outside the United States and Canada.

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Our Lead Product Candidate

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

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

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

In 2008, according to market data, approximately 29 million prescriptions were written for the treatment of migraine in the United States. Approximately 12 million of those prescriptions were written for acute migraine specific drugs. The majority of acute migraine specific drug prescriptions written were in the triptan class. In 2010, the triptan market in the United States totaled approximately $1.6 billion in revenues.

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

In May 2009, we announced results of the efficacy portion of our Phase 3 clinical trial of LEVADEX, or FREEDOM-301. We announced that the clinical trial met its four primary endpoints, pain relief and being phonophobia, photophobia and nausea 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% of patients who received LEVADEX compared with 34.5% for placebo ($p<0.0001$);
- Phonophobia free: 52.9% of patients who received LEVADEX compared with 33.8% for placebo ($p<0.0001$);
- Photophobia free: 46.6% of patients who received LEVADEX compared with 27.2% for placebo ($p<0.0001$); and
- Nausea free: 67.1% of patients who received LEVADEX compared with 58.7% for placebo ($p=0.02$).

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

Results from additional pre-defined analyses include:

LEVADEX therapy achieved statistically significant onset of pain relief at 30 minutes after dosing (p=0.03);

While not statistically significant, 50% more of the patients receiving LEVADEX therapy than the patients receiving placebo reported pain relief at 10 minutes;

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LEVADEX therapy achieved statistically significant sustained pain relief from two to 24 hours ($p<0.0001$), as well as two to 48 hours ($p<0.0001$, when unadjusted for multiplicity);

LEVADEX therapy achieved statistically significant pain freedom (pain symptom score = 0) as early as 30 minutes ($p=0.002$, when unadjusted for multiplicity); and

LEVADEX therapy achieved sustained pain freedom from two to 24 hours, as well as two to 48 hours ($p<0.0001$ for both time points, when unadjusted for multiplicity).

LEVADEX was well tolerated, with the most common adverse event reported being medication aftertaste at 6%, with 2% of patients receiving placebo also reporting medication aftertaste. The next most common adverse event was nausea at 5%, compared with 2% for placebo. Symptoms or sensitivities typically associated with commonly used triptan migraine treatments, such as chest discomfort (1%) or chest pain (0%), were rare and comparable to placebo. There were no mean decreases in lung function, as measured by spirometry, between the active and placebo groups. There were no drug-related serious adverse events reported in the trial. These data were presented in September 2009 in a late-breaking session of the 14th Congress of the International Headache Society.

In 2010, we announced that a second Phase 3 clinical trial would not be required for the LEVADEX NDA submission, completed and announced successful results from a pharmacokinetic, or PK, trial in smokers, a pharmacodynamics, or PD, trial evaluating pulmonary artery pressure using echocardiogram and a thorough QT trial. In addition, we completed our 12 month open-label safety extension of the Phase 3 FREEDOM 301 trial. In our clinical trials conducted for LEVADEX, no drug related serious adverse events have been reported. The LEVADEX clinical development program evaluated the efficacy, safety, PK and PD of LEVADEX in approximately 1,000 patients.

In May 2011, we submitted an NDA to the FDA for our LEVADEX orally inhaled migraine drug for the potential acute treatment of migraine. In August 2011, we announced that the FDA accepted for filing our LEVADEX NDA.

Other Product Technologies

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

We also have technologies which we may leverage including:

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

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

Nebulized Corticosteroid Particle Technology: We have expertise in the formulation and administration of nebulized corticosteroids for the treatment of pediatric asthma. We have created novel versions of budesonide that are designed to be administered more quickly and to provide efficacy at lower doses than conventional nebulized budesonide. Conventional nebulized budesonide is an inhaled corticosteroid approved by the FDA for treating asthma in children from 12 months up to eight years of age. We have developed novel morphologies of corticosteroid particles which may allow for faster delivery and efficacy at a lower dose, which together may offer improved safety, compliance and convenience.

A component of our strategy is to reduce the risk of drug development by focusing on the development of proven drugs with established safety and efficacy profiles. The compounds underlying our product candidates are well characterized and have been previously approved by the FDA or foreign agencies for other sponsors and in other dosage forms and formulations. As a result, we may seek FDA marketing approval of our product candidates under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FFDCA, which, if available to us, would allow any 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. This may expedite the development program for our product candidates by potentially decreasing the overall scope of

work we must do ourselves.

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Allergan Collaboration

On January 28, 2011, we entered into a Collaboration Agreement (the Collaboration Agreement) and a Co-Promotion Agreement (the Co-Promotion Agreement, and together with the Collaboration Agreement, the Allergan Agreements) with Allergan, Inc., Allergan USA, Inc. and Allergan Sales, LLC (collectively, Allergan). Pursuant to the terms of the Allergan Agreements, we have granted Allergan a co-exclusive license to market and promote LEVADEX, our proprietary novel migraine therapy for delivery by inhalation, to neurologists and pain specialists in the United States in collaboration with us. In July 2011, Allergan exercised its option to expand the Collaboration Agreement to include Canada for neurologists and pain specialists. Under the Allergan Agreements, we retain the right to market and promote LEVADEX to other physicians within the United States and Canada and also retain all rights to LEVADEX in all other countries. We and Allergan will each provide sales representatives and other sales support for such marketing and promotional efforts. The Allergan Agreements specify minimum annual sales detail requirements to be provided by each party, and establish maximum annual amounts of detailing costs that each party will be obligated to incur pursuant to a commercialization plan. The parties will collaborate in the development of LEVADEX for the treatment of migraine in adolescents 12 to 18 years of age, and for at least one other indication. We may develop LEVADEX for certain other indications independently of the collaboration if Allergan does not agree to develop LEVADEX for such indications pursuant to the Allergan Agreements. We will be responsible for manufacturing and supplying LEVADEX, and for distributing the product and recording product revenues from sales of LEVADEX resulting from the parties collaboration. The parties will share profits and losses resulting from the collaboration equally. We will be solely responsible for payment of all remaining costs of obtaining regulatory approval of LEVADEX for the acute treatment of migraine in adults, except that if the FDA notifies us that additional development or manufacturing activities costing in excess of a certain threshold amount will be required for such regulatory approval, the parties will share any such excess costs. The parties generally will share equally all other costs of developing LEVADEX under the Allergan Agreements, except that neither party shall be obligated for more than a certain threshold amount in a given year, or for more than a certain threshold amount in the aggregate, for development or manufacturing costs or expenses incurred by us for such activities.

In February 2011, Allergan paid us an upfront payment of $60.0 million, out of which $0.8 million and $1.4 million was recognized as collaboration revenue for the three and six months ended June 30, 2011, respectively. The remaining $58.6 million is deferred and will be amortized as collaboration revenue through the end date of the deliverable with the longest term. Our participation in joint committees with Allergan has the longest obligation period, requiring our participation throughout the term of the Collaboration Agreement. The term of the Collaboration Agreement is the later of (a) December 31, 2025, and (b) the date that our last patent right covering LEVADEX in the United States expires. The date that our last patent right covering LEVADEX in the United States expires is 2028. As a result, we will amortize the remaining $58.6 million of the initial $60.0 million through 2028.

Sales, general and administrative expenses for both of the three and six months ended June 30, 2011, as well as for the cumulative period from July 3, 2003 (date of inception) to June 30, 2011, was net of $0.4 million of costs reimbursed or reimbursable by Allergan under cost sharing provisions in our Collaboration Agreement.

In August 2011, we announced that the FDA accepted for filing our LEVADEX NDA. As a result, pursuant to the terms of our Collaboration Agreement with Allergan, the acceptance for filing of the LEVADEX NDA triggers a milestone payment of $20.0 million from Allergan.

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

Critical Accounting Policies and Significant Judgments and Estimates

With the exceptions of the discussion below, there have been no significant changes in critical accounting policies during the three and six months ended June 30, 2011, 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, 2010.

Revenue Recognition

We recognize revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or determinable; and collectability is reasonably assured. Collaboration revenue, which is earned under license agreements with third parties, may include nonrefundable license fees, cost reimbursements and contingent milestones.

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

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

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

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

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

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

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

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

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

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

The Allergan Agreements entered into in February 2011 contain multiple elements, including a license to commercialize our product candidate, regulatory approval and manufacturing for our product candidate, and various committee participations. We received an upfront cash payment of $60.0 million from Allergan upon execution of the Allergan Agreements. In accordance with ASU 2009-13, we evaluated whether there is standalone value for each of the various deliverables. As we have determined that the license and other non-contingent deliverables do not have standalone value, they must be combined with all the remaining deliverables to Allergan because the License could not be deemed to be fully delivered for its intended purpose unless we continue to perform our other obligations under the Collaboration Agreement. Accordingly, they do not meet the separation criteria, resulting in these deliverables being considered a single unit of account. As a result, revenue relating to the upfront cash payment is deferred and will be recognized on a straight-line basis over the term of the Allergan Agreements through 2028, which represents the estimated obligation period, as discussed in Note 2 of Item 1 of this Form 10-Q/A.

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

Financial Overview

Collaboration Revenue

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

Research and Development Expenses

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

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Conducting a significant amount of research and development is central to our business model. Through June 30, 2011, we had incurred approximately $236.3 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 later-stage clinical trials. We plan to incur substantial research and development expenses for the foreseeable future in order to complete development of our most advanced product candidate, LEVADEX, and to conduct earlier-stage research and development projects.

The following table summarizes the percentages of our research and development expenses related to our LEVADEX program, our Unit Dose Budesonide, or UDB, program, which has been suspended, and other earlier stage projects for the three and six months ended June 30, 2011 and 2010, respectively. The percentages summarized in the following table reflect costs directly attributable to each development candidate, which are tracked on a project basis. A portion of our internal costs, including indirect costs relating to our product candidates, is not tracked on a project basis and has been allocated based on management estimates.

	Three Months Ended June 30,		Six Months Ended June 30,		Period from July 3, 2003 (Inception) through June 30,
	2011	2010	2011	2010	2011
Our most advanced product candidates:					
LEVADEX	86%	89%	91%	89%	60%
UDB (suspended)					30%
Other projects	14%	11%	9%	11%	10%
Total	100%	100%	100%	100%	100%

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

Sales, General and Administrative Expenses

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

Through June 30, 2011, we incurred approximately $72.6 million in sales, general and administrative expenses since our inception in 2003.

Results of Operations

Collaboration Revenue

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

	Three Months Ended June 30,	Six Months Ended June 30,

	2011	2010	2011	2010
Collaboration revenue	$ 837	$	$ 1,395	$

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The increase in collaboration revenue was due to the Allergan Agreements effective on January 28, 2011. In February 2011, Allergan paid us an upfront payment of $60.0 million, out of which $0.8 million and $1.4 million was recognized as collaboration revenue for the three and six months ended June 30, 2011, respectively. The remaining $58.6 million is deferred and will be amortized as collaboration revenue over the estimated obligation period (through 2028), as discussed in Note 2 of Item 1 of this Form 10-Q/A.

In August 2011, we announced that the FDA accepted for filing our LEVADEX NDA. As a result, pursuant to the terms of our Collaboration Agreement with Allergan, the acceptance for filing of the LEVADEX NDA triggers a milestone payment of $20.0 million from Allergan.

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 June 30,			%	Six Months Ended June 30,			%
	2011	2010	Increase/ (Decrease)	Increase/ (Decrease)	2011	2010	Increase/ (Decrease)	Increase/ (Decrease)
Research and development expenses	$ 7,259	$ 8,242	$ (983)	(12)%	$ 18,827	$ 18,028	$ 799	4%

For the three months ended June 30, 2011 compared to the same period in 2010, the decrease in research and development expenses was due primarily to a decrease of $1.3 million in clinical and other project expenses to support the LEVADEX Phase 3 clinical program, partially offset by an increase of $0.5 million in personnel related expenses including stock-based compensation.

For the six months ended June 30, 2011 compared to the same period in 2010, the increase in research and development expenses was due primarily to an increase of $1.4 million in personnel related expenses including stock-based compensation, partially offset by a decrease of $0.6 million from loss on disposal of assets and other expenses.

Sales, General and Administrative Expenses

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

	Three Months Ended June 30,			%	Six Months Ended June 30,			%
	2011	2010	Increase/ (Decrease)	Increase/ (Decrease)	2011	2010	Increase/ (Decrease)	Increase/ (Decrease)
Sales, general and administrative expenses	$ 4,796	$ 3,910	$ 886	23%	$ 9,639	$ 7,791	$ 1,848	24%

Sales, general and administrative expenses for both of the three and six months ended June 30, 2011 was net of $0.4 million of costs reimbursed or reimbursable by Allergan under cost sharing provisions in our Collaboration Agreement.

For the three months ended June 30, 2011 compared to the same period in 2010, the increase in sales, general and administrative expenses was due primarily to an increase of $0.5 million in personnel related expenses including stock-based compensation, and an increase of $0.2 million in professional services.

For the six months ended June 30, 2011 compared to the same period in 2010, the increase in sales, general and administrative expenses was due primarily to an increase of $1.1 million in personnel related expenses including stock-based compensation, and an increase of $0.6 million in professional services.

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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 June 30,		Increase/ (Decrease)	% Increase/ (Decrease)	Six Months Ended June 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2011	2010			2011	2010		
Interest income	$ 22	$ 2	$ 20	*	$ 52	$ 6	$ 46	*

* Percentage is not meaningful.

For the three and six months ended June 30, 2011 compared to the same periods in 2010, the increase in interest income was both due primarily to an increase in interest rates related to our investments and higher cash balances. We expect our interest income to fluctuate in the future due to changes in average investment balances and market interest rates.

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 June 30,		Increase/ (Decrease)	% Increase/ (Decrease)	Six Months Ended June 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2011	2010			2011	2010		
Interest expense	$ 106	$ 339	$ (233)	(69)%	$ 273	$ 732	$ (459)	(63)%

The decrease in interest expense was due primarily to lower debt balances related to the 2008 Working Capital Loan. We expect our interest expense to fluctuate in the future with average debt balances.

Other Expense, Net

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

	Three Months Ended June 30,		Increase/ (Decrease)	% Increase/ (Decrease)	Six Months Ended June 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2011	2010			2011	2010		
Other expense, net	$	$	$		$ 10	$ 2	$ 8	*

* Percentage is not meaningful.

Liquidity and Capital Resources

We have incurred losses since our inception in July 2003 and as of June 30, 2011 we had an accumulated deficit of $266.9 million. We will continue to incur losses until we generate sufficient revenue to offset our expenses, and we anticipate that we may continue to incur net losses for at least the next several years. We expect to incur increased research and development and sales, general and administrative expenses related to our development and potential commercialization of LEVADEX and, as a result, we will need to generate significant net product sales, royalty and other revenues to achieve profitability.

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

Equity

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

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

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

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

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

Debt

In September 2006, we entered into a loan facility agreement and borrowed $10.0 million to finance working capital and a $1.0 million loan facility to finance equipment purchases;

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

Collaboration

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

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

As of June 30, 2011, we had approximately $103.5 million in cash and cash equivalents. Our cash and cash equivalents are held primarily in money market funds. Cash in excess of immediate requirements is invested in accordance with our investment policy with a view toward capital preservation and liquidity.

Cash Flows

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

	Six Months Ended June 30,	
	2011	**2010**
Cash provided by (used in):		
Operating activities	$ 30,015	$ (26,720)
Investing activities	(400)	(1,319)
Financing activities	(2,161)	17,593

Net cash provided by (used in) operating activities. We received $30.0 million of cash from operating activities for the six months ended June 30, 2011 compared to the usage of cash of $26.7 million for the corresponding period in 2010. The cash provided by operating activities for the six months ended June 30, 2011 was due primarily to a $60.0 million nonrefundable upfront payment we received from Allergan in February 2011, which resulted in an increase in deferred revenue by $58.6 million, and stock-based compensation of $3.8 million, partially offset by a net loss of $27.3 million and a decrease in accrued liabilities of $4.1 million as a result of the payment of expenses related to the LEVADEX Phase 3 clinical program. The usage of cash of $26.7 million for the six months ended June 30, 2010 was due primarily to a net loss of $26.5 million and a decrease in accrued liabilities of $3.1 million as a result of paying down expenses related to the LEVADEX Phase 3 clinical program, and UDB program, which was suspended in the third quarter of 2009, partially offset by stock-based compensation of $3.1 million.

Net cash used in investing activities. We used $0.4 million and $1.3 million of cash for investing activities for the six months ended June 30, 2011 and 2010, respectively. The usage of cash for both the six months ended June 30, 2011 and 2010 was due to purchase of property and equipment.

Net cash provided by (used in) financing activities. We used $2.2 million of cash for financing activities for the six months ended June 30, 2011, compared to receiving cash of $17.6 million for the corresponding period in 2010. The usage of cash of $2.2 million for the six months ended June 30, 2011 was due primarily to the repayment of $3.9 million of outstanding debt in the six months ended June 30, 2011, partially offset by the proceeds from sales of shares through equity plans of $1.8 million. The cash provided by financing activities for the six months ended

June 30, 2010 was due primarily to the net proceeds of approximately $19.7 million from the issuance of our common stock from the drawdown of the equity line of credit with Azimuth Opportunity Ltd., or Azimuth, and proceeds from sales of shares through equity plans of $1.5 million, partially offset by the repayment of debt of $3.6 million.

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Equity Line of Credit

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

In January 2010 we accessed our equity line of credit and sold 1,527,695 shares of common stock at a price of approximately $13.70 per share less a discount of approximately 4.5% per share for a net price of approximately $13.09 per share. The total purchase price for all these shares was $20.0 million or approximately $19.7 million after deducting the offering expenses. As of June 30, 2011, we have $40 million remaining under the equity line of credit for future use.

Agreement with Allergan

Under the Collaboration Agreement with Allergan effective January 28, 2011, we are responsible for manufacturing and supplying LEVADEX, and for distributing the product and recording product revenues from sales of LEVADEX resulting from the parties collaboration. The parties share profits and losses resulting from the collaboration equally. We are solely responsible for payment of all remaining costs of obtaining regulatory approval of LEVADEX for the acute treatment of migraine in adults, except that if the FDA notifies us that additional development or manufacturing activities costing in excess of a certain threshold amount will be required for such regulatory approval, the parties will share any such excess costs. The parties generally share equally all other costs of developing LEVADEX under the Allergan Agreements, except that neither party shall be obligated for more than a certain threshold amount in a given year, or for more than a certain threshold amount in the aggregate, for development or manufacturing costs or expenses incurred by us for such activities. We have agreed to indemnify Allergan against any losses incurred in connection with, among other things, any negligence, recklessness or wrongful intentional acts by us, any breach by us of the Allergan Agreements, the development and commercialization of LEVADEX actually conducted by or for us or our affiliates or sublicensees, allegations that the manufacture, use or commercialization of LEVADEX infringes third party intellectual property rights, or allegations that personal injury or death or property damage was caused by a defect in LEVADEX manufactured by or for us. The Collaboration Agreement may be terminated (i) by Allergan, at will, after first commercial sale of LEVADEX in the United States, upon 180 days prior written notice, (ii) by Allergan, upon written notice to us, if we receive a complete response letter or equivalent communication from the FDA, that Allergan determines will extend potential approval beyond a certain date or requires a certain minimum level of additional investment, (iii) by us, upon written notice to Allergan, if Allergan commercializes a competing product in the United States or Canada and (iv) by us, upon written notice to Allergan, if Allergan challenges or opposes patent rights licensed to Allergan pursuant to the Collaboration Agreement. Additionally, either party may terminate the Collaboration Agreement in the event of an uncured material breach. The Co-Promotion Agreement will terminate upon termination of the Collaboration Agreement.

Operating Capital and Capital Expenditure Requirements

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

- the initiation, progress, timing and completion of clinical trials for our product candidates and potential product candidates;
- the outcome, timing and cost of regulatory approvals and the regulatory approval process;
- delays that may be caused by changing regulatory requirements;

the number of product candidates that we pursue;

the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;

the timing and terms of future in-licensing and out-licensing transactions;

the cost and timing of establishing commercial infrastructure including sales, marketing, manufacturing and distribution capabilities;

the cost of procuring clinical and commercial supplies of our product candidates;

the cost of maintaining adequate working capital;

the extent to which we acquire or invest in businesses, products or technologies; and

the possible costs of litigation.

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We believe that our existing cash and cash equivalents will be sufficient to fund our projected operating requirements for at least 12 months. We will need substantial additional capital in the future in order to complete the development and commercialization of LEVADEX and to fund the development and commercialization of any future product candidates. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Such funding, if needed, may not be available on favorable terms, if at all. In the event we are unable to obtain additional capital, we may delay or reduce the scope of our current research and development programs and other expenses.

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

Recent Accounting Pronouncements

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

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

Off-Balance Sheet Arrangements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

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

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

At the time that our Quarterly Report on Form 10-Q for the quarter ended June 30, 2011 was filed on August 8, 2011, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of June 30, 2011. Subsequent to that evaluation, as a result of the restatement described in Note 2 to the financial statements included in this report, a re-evaluation was carried out under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of our disclosure controls and procedures, as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Based on that re-evaluation, our principal executive officer and principal financial officer concluded that, as a result of the material weakness in internal control over financial reporting described below, our disclosure controls and procedures were not effective as of June 30, 2011 to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

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Material Weakness in Internal Control over Financial Reporting

A material weakness in internal control over financial reporting is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company s annual or interim financial statements will not be prevented or detected on a timely basis. Based on our re-evaluation, management determined that they had not maintained effective controls over complex multiple element revenue arrangements. Specifically, effective controls were not designed and in place with regard to the evaluation of, and accounting for, complex multiple element revenue arrangements. This control deficiency resulted in a restatement of revenues and deferred revenues, related to an upfront payment received from Allergan, for the first three quarterly periods during the year ended December 31, 2011. Additionally, this control deficiency could result in further misstatement of the aforementioned account balances or disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected. Accordingly, the Company s management has determined the control deficiency constitutes a material weakness.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended June 30, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Plan of Remediation of Material Weakness

Subsequent to the identification of the material weakness related to the evaluation of, and accounting for, complex multiple element revenue arrangements, we are re-evaluating our accounting and financial reporting controls for complex multiple element revenue arrangements, including the application of the provisions of Accounting Standard Codification Topic 605-25 Revenue Recognition Multiple-Element Arrangements to any future agreements that include complex multiple elements.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not a party to any material legal proceeding.

ITEM 1A. RISK FACTORS

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

Risks Relating to Our Financial Position and Need for Additional Capital

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

We are not profitable and do not expect to be profitable on a sustained basis in the foreseeable future. We have incurred significant net losses and negative cash flow in each year since our inception, including net losses of approximately $54.7 million, $9.0 million and $72.9 million for the years ended December 31, 2010, 2009 and 2008, respectively, net losses of $11.3 million and $27.3 million for the three and six months ended June 30, 2011, respectively. As of June 30, 2011, we had a deficit accumulated during development stage of approximately $266.9 million. We have devoted most of our financial resources to research and development, including our pre-clinical development activities, clinical trials and manufacturing-related activities. We have not obtained regulatory approval for, or commercialized any product candidate and have therefore not generated any product revenues. In that regard, we expect to incur additional expenses as we pursue our new drug application, or NDA, for LEVADEX, our most advanced product candidate, with the U.S. Food and Drug Administration, or the FDA. In addition, if we are required by the FDA to perform studies in addition to those we have conducted, our expenses will increase beyond expectations and the timing of any potential product approval may be delayed. We also expect an increase in our expenses associated with our manufacturing work and with preparing for commercialization. In addition, we expect to continue to incur costs to support operations as a public company. As a result, we may continue to incur substantial net losses and negative cash flow for the foreseeable future. These losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders equity and working capital.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of substantial expenses or when, or if, we will be able to achieve or maintain profitability. We have financed our operations primarily through the sale of equity securities, collaboration payments and debt financings. The size of our future net losses will depend, in part, on the rate of growth of our expenses and the rate of growth, if any, of our revenues. Revenues from potential strategic partnerships are uncertain because we may not enter into any additional strategic partnerships. On January 28, 2011, we entered into a collaboration agreement with Allergan, Inc., or Allergan, pursuant to which Allergan will co-promote LEVADEX with us in the United States to neurologists and pain specialists. In addition to the $60.0 million upfront payment already received from Allergan, we are eligible to receive additional payments upon achievement of regulatory milestones and first commercial sale. If we do not meet these milestones, we will not receive additional payments and, under certain circumstances, Allergan may terminate our collaboration. On July 8, 2009, we received a notice of termination of our license agreement with AstraZeneca AB, or the AstraZeneca Agreement, related to our Unit Dose Budesonide, or UDB, product candidate. Under the AstraZeneca Agreement, AstraZeneca had agreed to fund our remaining development activities for UDB and to reimburse us for costs we incur with respect to future development activities conducted for the U.S. registration of our UDB product candidate, subject to the terms and conditions of the AstraZeneca Agreement. Following the termination of the AstraZeneca Agreement, we suspended development of UDB. If we are unable to develop and commercialize our other product candidates, including pursuant to strategic partnerships, or if sales revenue from any product candidate that receives marketing approval is insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability.

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

Our operations to date have been primarily limited to organizing and staffing our company, developing our technology and undertaking pre-clinical studies, clinical trials and manufacturing-related activities 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

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operating results have varied significantly in the past and will continue to fluctuate from quarter-to-quarter and year-to-year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following factors, among others:

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

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

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

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

practice guidelines and recommendations of therapies published by various organizations;

potential product liability claims;

potential liabilities associated with hazardous materials;

our ability to maintain adequate insurance policies;

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

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

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

costs related to and outcomes of potential intellectual property litigation;

compliance with obligations under intellectual property licenses with third parties;

our ability to adequately support future growth; and

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

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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. While we have completed our clinical development program for LEVADEX for the acute treatment of migraine in adults, we expect to have continued expenses in connection with our ongoing activities, particularly as we focus on and proceed with our NDA submission for 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 have conducted, in which case the timing of any potential product approval may be delayed. We believe that our existing cash and cash equivalents will be sufficient to fund our projected operating requirements for at least 12 months. We will need substantial additional capital in the future in order to commercialize LEVADEX and to fund the development and commercialization of future product candidates. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, including our collaboration with Allergan. Such funding, if needed, may not be available on favorable terms, if at all. In the event we are unable to obtain additional capital, we may delay or reduce the scope of our current research and development programs and other expenses

If adequate funds are not available, we may be required to delay, 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 including any potential delays that may occur;
- 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, including our current collaboration agreement with Allergan;.
- the cost and timing of commercial-scale manufacturing and distribution activities;
- the costs of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval; and

rate of market adoption of our product candidates for which we obtain regulatory approval.

Risks Relating to the Development, Regulatory Approval and

Commercialization of Our Product Candidates

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

We have invested a significant portion of our efforts and financial resources in the development of LEVADEX and UDB. In February 2009, we announced top-line results from our first Phase 3 trial of UDB, indicating that the trial did not meet its co-primary endpoints in either dose evaluated when compared to placebo. In July 2009, we announced that we were suspending development of UDB, after our partner AstraZeneca terminated our license agreement. We are now largely dependent on the success of one product candidate, LEVADEX, for which we have completed a Phase 3 clinical development program and for which we have submitted an

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

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

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

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

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

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

We may enter into additional collaborations with third parties to develop and commercialize our product candidates, including LEVADEX. For example, we may enter into a collaboration with a third party in the Unites States to commercialize LEVADEX to primary care physicians and/or to develop and commercialize LEVADEX outside the United States. Our dependence on current and future partners for development and commercialization of our product candidates will subject us to a number of risks, including:

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

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

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

partners may experience financial difficulties;

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

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

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

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

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

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

reaching agreements on acceptable terms with prospective contract research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

obtaining regulatory approval to commence a clinical trial;

obtaining institutional review board, or IRB, approval to conduct a clinical trial at numerous prospective sites;

recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our study and competition from other clinical trial programs for the same indication as our product candidates;

retaining patients who have initiated a clinical trial but may be prone to withdraw due to the treatment protocol, lack of efficacy, personal issues or side effects from the therapy or who are lost to further follow-up;

maintaining and supplying clinical trial material on a timely basis; and

collecting, analyzing and reporting final data from the clinical trials.

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

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

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

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

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

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

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.

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

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

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

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

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

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

All of our product candidates in development require regulatory review and approval prior to commercialization, including review of pre-clinical data, clinical data and inspection of manufacturing facilities and processes. Any delays in the regulatory review or approval of our product candidates in development would delay market launch, increase our cash requirements and result in additional operating losses.

The process of obtaining FDA and other required regulatory approvals, including foreign approvals, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. Furthermore, this approval process is extremely complex, expensive and uncertain. We or our partners may not be able to maintain our proposed schedules for the submission of any NDA in the United States or any marketing approval application or other foreign applications for any of our products. If we or our partners submit any NDA, including any amended NDA or supplemental NDA, to the FDA seeking marketing approval for any of our product candidates, the FDA must decide whether to either accept or reject the submission for filing. We cannot be certain that any of these submissions will be accepted for filing and reviewed by the FDA, or that our marketing approval application submissions to any other regulatory authorities will be accepted for filing and review by those authorities. We cannot be certain that we or our partners will be able to respond to any regulatory requests during the review period in a timely manner without delaying potential regulatory action. We also cannot be certain that any of our product candidates will receive favorable recommendation from any FDA advisory committee or foreign regulatory bodies or be approved for marketing by the FDA or foreign regulatory authorities. In addition, delays in approvals or rejections of marketing applications may be based upon many factors, including regulatory requests for additional analyses, reports, data and/or studies, regulatory questions regarding data and results, changes in regulatory policy during the period of product development and/or the emergence of new information regarding our products or other products.

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

In addition, the environment in which our regulatory submissions may be reviewed changes over time. For example, average review times at the FDA for marketing approval applications have fluctuated over the last ten years, and we cannot predict the review time for any of our

submissions with any regulatory authorities. In addition, review times can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

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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 expected, and we would also have to conduct more clinical trials than we had anticipated.

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

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

a product s FDA-approved labeling as well as limitations or warnings contained in the labeling;

changes in the standard of care for the targeted indications for any of our product candidates, which could reduce the marketing impact of any claims that we could make following FDA approval;

limitations inherent in the approved indication and product labeling for any of our product candidates compared to more commonly understood or addressed medical conditions;

lower demonstrated efficacy and a less favorable safety or tolerability profile compared to other products;

device-related difficulties associated with our TEMPO inhaler;

prevalence and severity of adverse effects;

ineffective marketing and distribution efforts;

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

lack of cost-effectiveness;

timing of market introduction and perceived effectiveness of competitive products;

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

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

potential product liability claims.

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

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

We plan to market or co-promote our products where appropriate and build our own specialized sales force in the United States. We currently do not have significant internal sales, distribution and marketing capabilities. For example, in order to commercialize LEVADEX, we intend to develop a specialized sales force and marketing capabilities in the United States directed at high prescribers including specialists such as neurologists and pain specialists. We have entered into a collaboration with Allergan pursuant to which we will co-promote LEVADEX to neurologists and pain specialists in the United States, following potential FDA approval of LEVADEX. The development of a 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 specialized sales force in the United States that is sufficient in size or has adequate expertise in the medical markets that we intend to target, including neurology. If we are unable to establish our specialized sales force and marketing capability for our most advanced product candidate, we may not be able to generate any product revenue, may generate increased expenses and may never become profitable.

We 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
- sales and marketing resources and experience.

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

marketing their products.

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

If approved for the acute treatment of migraine, we anticipate that LEVADEX would compete against other marketed migraine therapies and may compete with products currently under development by both large and small companies. The majority of marketed prescription products for the treatment of migraine are in the triptan class. In 2010, the triptan market in the United States totaled approximately $1.6 billion in revenue. The triptan with the largest market share is sumatriptan with 2010 prescriptions of approximately 6.1 million in the United States. There are at least six other branded triptan therapies being sold by pharmaceutical companies. Alternative formulations of triptans are available that may have faster onset of action than solid oral dosage forms. In April 2008, GlaxoSmithKline s Treximet, a combination oral formulation of sumatriptan and naproxen sodium, was approved by the FDA for the acute treatment of migraine. In July 2009, Zogenix, Inc s Sumavel DosePro needle-free sumatriptan was approved by the

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

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

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

Successful sales of our products depend on the availability of adequate coverage and reimbursement from third-party payors. Healthcare providers that purchase medicine or medical products for treatment of their patients generally rely on third-party payors to reimburse all or part of the costs and fees associated with the products. Adequate coverage and reimbursement from governmental payors, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Patients are unlikely to use our products if they do not receive reimbursement adequate to cover the cost of our products.

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

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

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

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

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

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

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

regulatory authorities may require the addition of labeling statements, specific warnings, contraindications or field alerts to physicians and pharmacies;

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

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

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

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

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

- issue warning letters or untitled letters identifying violations;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;

impose other civil or criminal penalties;

suspend regulatory review of pending NDAs or approval of new products;

suspend any ongoing clinical trials;

refuse to approve pending applications or supplements to approved applications filed by us;

impose restrictions on operations, including costly new manufacturing requirements; or

seize or detain products or require a product recall.

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

Any trade name we or our potential partners intend to use for our product candidates will require approval from the FDA regardless of whether we or our partners have secured a formal trademark registration from the U.S. Patent and Trademark Office. The FDA typically conducts a rigorous review of proposed product names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims. If the FDA objects to our product names, we may be required to adopt an alternative name for our product candidates. If we or our partners adopt an alternative name, we or our partners would lose the benefit of our existing trademark applications and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We or our partners may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

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

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

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

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

withdrawal of clinical trial participants;

termination of clinical trial sites or entire trial programs;

costs of related litigation;

substantial monetary awards to patients or other claimants;

decreased demand for our product candidates;

impairment of our business reputation;

loss of revenues; and

the inability to commercialize our product candidates.

We have obtained limited product liability insurance coverage for our clinical trials domestically and in selected foreign countries where we conduct clinical trials. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

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

Our research and development processes involve the controlled use of hazardous materials, including chemicals. Our operations produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge or injury from these materials. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these

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materials. We could be subject to civil damages in the event of an improper or unauthorized release of, or exposure of individuals, including employees, to hazardous materials. In addition, claimants may sue us for injury or contamination that results from our use of these materials and our liability may exceed our total assets. We maintain limited insurance for the use of hazardous materials which may not be adequate to cover any claims. Compliance with environmental and other laws and regulations may be expensive and current or future regulations may impair our research, development or production efforts.

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

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

Risks Related to Our Dependence on Third Parties

We have no experience manufacturing large clinical-scale or commercial-scale pharmaceutical products and we do not own or operate a manufacturing facility. As a result, we are dependent on numerous third parties for the manufacture of our product candidates and our supply chain, and if we experience problems with any of these suppliers the manufacturing of our products could be delayed.

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

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

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

Any of these factors could cause the delay or suspension of initiation or completion of clinical trials, regulatory submissions, required approvals or commercialization of our products, cause us to incur higher costs and could prevent us from commercializing our product candidates successfully. Furthermore, if our contract manufacturers fail to deliver the required commercial quantities of finished product on a timely basis and at commercially reasonable prices and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality and on a timely basis, we would likely be unable to meet demand for our products and we would lose potential revenue. It may take a significant period of time to establish an alternative source of supply for our product

candidates and to have any such new source approved by the FDA.

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

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

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

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

Risks Relating to Our Intellectual Property

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

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

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

The patent positions of pharmaceutical and biopharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biopharmaceutical patents has emerged to date in the United States. The biopharmaceutical patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents we own

or to which we have a license from a third-party. Further, if any of our patents are deemed invalid and unforceable, it could impact our ability to commercialize or license our technology.

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

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

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

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

If we or our partners choose to go to court to stop someone else from using the inventions claimed in our patents, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop a third party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to prevent the other party s activities on the ground that such other party s activities do not infringe our rights to these patents. In addition, the U.S. Supreme Court has recently invalidated some tests used by the U.S. Patent and Trademark Office in granting patents over the past 20 years. As a consequence, several issued patents may be found to contain invalid claims according to the newly revised standards. Some of our own or in-licensed patents may be subject to challenge and subsequent invalidation in a re-examination proceeding before the U.S. Patent and Trademark Office or during litigation under the revised criteria which make it more difficult to obtain patents.

Furthermore, a third party may claim that we or our manufacturing or commercialization partners are using inventions covered by the third party s patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. We are aware that claims in patents owned by others may relate to our business and technologies. If we are sued for patent

infringement, we would need to demonstrate that our products or methods of use either do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. If we are sued for patent infringement, there is a risk that a court would order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court will order us or our partners to pay the other party damages for having violated the other party s patent rights. We have agreed to indemnify certain of our commercial partners against certain patent infringement claims brought by third parties. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any

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such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents by others covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions.

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

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

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

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

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Employee Matters, Managing Growth and Accounting Matters

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

As of June 30, 2011, we had 102 full-time employees. We may need to expand our managerial, operational, administrative and other resources in order to manage and fund our operations, continue our development activities and commercialize our product candidates. To support this growth, we may hire additional employees within the next 12 months. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we:

- manage our development program for LEVADEX, including manufacturing and regulatory activities in support of the NDA process with the FDA, and potential approval from the FDA;
- begin activities related to commercialization as we prepare for a potential product launch of LEVADEX; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

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

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

We may not be able to attract or retain qualified management, scientific and clinical personnel in the future due to competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the Silicon Valley region of California. If we are not able

to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the development, regulatory, commercialization and product acquisition expertise of our senior management, particularly Timothy S. Nelson, our President and Chief Executive Officer, and Thomas A. Armer, our co-founder and Chief Scientific Officer. If we lose one or more of these key employees, our ability to implement our business strategy successfully could be seriously harmed. Replacing key

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employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, obtain regulatory approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel.

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

Management s determination that there was a material weakness in our internal control over financial reporting could have a material adverse impact on the Company.*

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

In Part I. Item 4 of this report, management determined that there was a material weakness in our internal control over the evaluation of, and accounting for, complex multiple element arrangements, in this case timing of recognition of revenue related to an upfront payment from Allergan, which timing had no impact on our cash position, total assets or operating expenses. Due to this material weakness, our principal executive officer and principal financial officer also concluded that our disclosure controls and procedures were not effective as of the end of the period covered by this report. Consequently, and pending our remediation of the matters that caused the control deficiencies underlying the material weaknesses, our business and results of operations could be harmed, we may be unable to report properly or timely the results of our operations, and investors may lose faith in the reliability of our financial statements. Accordingly, the price of our securities may be adversely and materially impacted.

The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and we cannot assure you that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become ineffective because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. We cannot assure you that we or our independent registered public accounting firm will not identify any additional material weaknesses in our internal controls in the future.

Risks Relating to Owning Our Common Stock

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

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

- actual or anticipated fluctuations in our financial condition and operating results;
- status and/or results of our clinical trials;
- results of clinical trials of our competitors products;
- regulatory actions with respect to our products or our competitors products;

actions and decisions by our collaborators or partners;

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

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

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

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

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

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

market conditions for biopharmaceutical stocks in general; and

general economic and market conditions.

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

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

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

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

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

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

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

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

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

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

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

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

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

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biotechnology and biopharmaceutical companies. These broad market fluctuations may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock

price volatility in recent years. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management s attention and resources, which could adversely affect our business.

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ITEM 6. EXHIBITS

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant (filed as Exhibit 3.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2007 and incorporated herein by reference).
3.2	Amended and Restated Bylaws of the Registrant (filed as Exhibit 3.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2007 and incorporated herein by reference).
4.1	Specimen Stock Certificate (filed as Exhibit 4.1 to the Registrant s Registration Statement on Form S-1-A (File No. 333-143823), filed on September 20, 2007, and incorporated herein by reference).
10.1	Collaboration Agreement by and among MAP Pharmaceuticals, Inc., Allergan Sales, LLC, Allergan USA, Inc. and Allergan, Inc. dated January 28, 2011 (filed as Exhibit 10.1 to the Registrant s Current Report on Form 8-K/A filed on February 16, 2011, and incorporated herein by reference).
10.2	Co-Promotion Agreement by and between MAP Pharmaceuticals, Inc., Allergan USA, Inc., dated January 28, 2011 (filed as Exhibit 10.2 to the Registrant s Current Report on Form 8-K/A filed on February 16, 2011, and incorporated herein by reference).
10.3	First Amendment to Loan and Security Agreement among Silicon Valley Bank, Oxford Finance Corporation and the Registrant dated October 28, 2008 (filed as Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2011 and incorporated herein by reference).
10.4	Second Amendment to Loan and Security Agreement among Silicon Valley Bank, Oxford Finance Corporation and the Registrant dated April 15, 2011(filed as Exhibit 10.4 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2011 and incorporated herein by reference).
10.5*	First Amendment to Collaboration Agreement by and among MAP Pharmaceuticals, Inc., Allergan Sales, LLC, Allergan USA, Inc. and Allergan, Inc. dated January 28, 2011.
31.1	Certification of Principal Executive Officer Required under Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer Required under Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of Principal Executive Officer and Principal Financial Officer Required under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.
101.INS^	XBRL Instance Document
101.SCH^	XBRL Taxonomy Extension Schema Document
101.CAL^	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB^	XBRL Taxonomy Extension Label Linkbase Document
101.PRE^	XBRL Taxonomy Extension Presentation Linkbase Document

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Confidential treatment has been granted as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.

* Confidential treatment requested for certain portions.

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

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SIGNATURES

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

Date: March 30, 2012

MAP PHARMACEUTICALS, INC.

By: /s/ TIMOTHY S. NELSON
Timothy S. Nelson
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ CHRISTOPHER Y. CHAI
Christopher Y. Chai
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)