MAP Pharmaceuticals, Inc. Form 10-Q/A March 30, 2012 Table of Contents

# 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 (State or other jurisdiction of

20-0507047 (I.R.S. Employer

incorporation or organization)

Identification No.)

2400 Bayshore Parkway, Suite 200

Mountain View, California (Address of principal executive offices)

94043 (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.

#### **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-O/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)

Current assets:	\$		
	Φ		
Cash and cash equivalents	U)	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
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 I	Ended June 30,	Six Months Er	Period from July 3, 2003 (Inception) to	
	2011	2010	2011	2010	June 30, 2011
	(as restated)		(as restated) <sup>(1)</sup>		(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	

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<sup>(1)</sup> 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.

#### ${\bf MAP\ PHARMACEUTICALS, INC.}$

(a development stage enterprise)

#### CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Six Months En	ded June 30, 2010	from In	ulative Period July 3, 2003 (Date of ception) to ne 30, 2011
	(as restated) <sup>(1)</sup>		(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	(400)	(1,317)		(169,497)
Sales and maturities of short-term investments				171,411
Purchase of restricted investment				(310)
I dichase 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	(2,2=1)	(2,002)		(=3,001)
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

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(2,161)	17,593		275,806
27.454	(10.446)		102.461
27,454 76.007	(10,446)		103,461
,	,,,,,,		
\$ 103,461	\$ 55,330	\$	103,461
\$ 198	\$	\$	198
	27,454 76,007 \$ 103,461	27,454 (10,446) 76,007 65,776 \$ 103,461 \$ 55,330	27,454 (10,446) 76,007 65,776 \$ 103,461 \$ 55,330 \$

<sup>(1)</sup> 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.

#### 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	As of June 30, 2011		
	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	
Total habilities	33,311	30,200	0,501	
Commitments and contingencies				
Communents 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 As			Six Mon	ths Ended Jun	e 30, 2011	Cumulative Period from July 3, 2003 (Date of Inception) to June 30, 2011 As			
	Previously	A.11	As	Previously	A 31	As	Previously	<b>A. 12</b>	As	
Collaboration revenue	\$ 3,513	<b>Adjustments</b> \$ (2,676)		\$ 37,675	<b>Adjustments</b> \$ (36,280)		<b>Reported</b> \$ 91,841	<b>Adjustments</b> \$ (36,280)	<b>Restated</b> \$ 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 attr	ibuted to co	mmon stock	holders:							
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)				
	+ (0.20)	+ (0.07)	+ (0.57)	- 0.20	- (1.10)	+ (0.20)				
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 Mo	onths Ended June	e 30, 2011	Cumulative Period from July 3, 2003 (Date of Inception) to June 30, 2011 As			
	previously reported	Adjustments	As restated	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	(100)		(100)	(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				17,000		17,000	
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.

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.

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) <sup>(1)</sup>			2010 2011 (as restated) <sup>(1)</sup>		2011 (as	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		30,333,126 26,480		30,272,271		20	6,167,861	
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 Jun	ne 30,
	<b>2011</b> (as restated) <sup>(1)</sup>	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 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):

			une 30, 2011
		Unrealized	Estimated
	Amortized	Gain	Fair
	Cost	(Loss)	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

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\$ 103,771

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

\$ 76,317

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

As of 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, 20	Dece	ember 31, 2010
Clinical trial related	\$ 1,2	78 \$	4,363
Payroll and related expenses	3,1	66	3,993
Professional services	8	31	998
Other		51	88
	\$ 5,3	26 \$	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, 201
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,	An	nount
2011 (remaining six months)	\$	680
2012		700
Total minimum lease payments	\$ 1	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:

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	Number of Shares	Aver	eighted age Grant 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

#### Stock Options

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

		Weighted Average	
	Number of Shares		xercise 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,				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 3		
	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%

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, should, could, would, will, projects, predicts, potential and similar expressions intended to identify anticipates, believes, estimates, 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.

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)	
	2011	2010	2011	2010	through June 30, 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 is 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	\$

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 Mor	ths Ended		%	Six Mont	hs Ended			%
	June 30,		Increase/	Increase/	Jun	Incr	ease/	Increase/	
	2011	2010	(Decrease)	(Decrease)	2011	2010	(Dec	rease)	(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 Mon	ths Ended		%	Six Mont	hs Ended	%		
	June 30,		Increase/	Increase/	June 30,		Increase/	Increase/	
	2011	2010	(Decrease)	(Decrease)	2011	2010	(Decrease)	(Decrease)	
Sales, general and administrative expenses	\$ 4,796	\$ 3,910	\$ 886	23%	\$ 9,639	\$7,791	\$ 1,848	24%	
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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 Mon	Three Months Ended			Six Mont	%		
	June	June 30,		Increase/	June 30,		Increase/	Increase/
	2011	2010	(Decrease)	(Decrease)	2011	2010	(Decrease)	(Decrease)
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 Mon	ths Ended		%	Six Month	s Ended	%		
	June	June 30,		Increase/	June 30,		Increa	se/ Increase/	
	2011	2010	(Decrease)	(Decrease)	2011	2010	(Decre	ase) (Decrease)	
Interest expense	\$ 106	\$ 339	\$ (233)	(69)%	\$ 273	\$ 732	\$ (4	(63)%	