

ARENA PHARMACEUTICALS INC  
Form 10-Q  
November 09, 2009  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

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

For the quarterly period ended September 30, 2009

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 000-31161

**ARENA PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**23-2908305**  
(I.R.S. Employer Identification No.)

**6166 Nancy Ridge Drive, San Diego, CA**  
(Address of principal executive offices)

**92121**  
(Zip Code)

**858.453.7200**  
(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  No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company.

Large accelerated filer  Accelerated filer   
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 in Rule 12b-2 of the Exchange Act).  Yes  No

The number of shares of common stock outstanding as of the close of business on November 5, 2009:

Class	Number of Shares Outstanding
Common Stock, \$0.0001 par value	92,717,635

**Table of Contents**

**ARENA PHARMACEUTICALS, INC.**

**INDEX**

**PART I FINANCIAL INFORMATION**

Item 1.	<u>Financial Statements</u>	1
	<u>Condensed Consolidated Balance Sheets As of September 30, 2009 and December 31, 2008</u>	1
	<u>Condensed Consolidated Statements of Operations Three and Nine Months Ended September 30, 2009 and 2008</u>	2
	<u>Condensed Consolidated Cash Flow Statements Nine Months Ended September 30, 2009 and 2008</u>	3
	<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	4
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	12
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	19
Item 4.	<u>Controls and Procedures</u>	19

**PART II OTHER INFORMATION**

Item 1A.	<u>Risk Factors</u>	19
Item 6.	<u>Exhibits</u>	36
	<u>Signatures</u>	37

In this report, Arena Pharmaceuticals, Arena, we, us and our refer to Arena Pharmaceuticals, Inc., and our wholly owned subsidiaries, unless context otherwise provides.

Arena Pharmaceuticals®, Arena® and our corporate logo are registered service marks of Arena. CART and BRL Screening are unregistered service marks of Arena. Any other brand names or trademarks appearing in this Quarterly Report on Form 10-Q are the property of their respective holders.

**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Financial Statements.****Arena Pharmaceuticals, Inc.****Condensed Consolidated Balance Sheets****(In thousands)**

	<b>September 30, 2009 (Unaudited)</b>	<b>December 31, 2008</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 121,975	\$ 73,329
Short-term investments, available-for-sale	21,506	36,800
Accounts receivable	1,628	1,823
Prepaid expenses and other current assets	4,037	5,031
<b>Total current assets</b>	<b>149,146</b>	<b>116,983</b>
Land, property and equipment, net	96,700	102,740
Acquired technology and other intangibles, net	14,970	16,262
Other non-current assets	6,529	5,346
<b>Total assets</b>	<b>\$ 267,345</b>	<b>\$ 241,331</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and other accrued liabilities	\$ 6,220	\$ 16,989
Accrued compensation	3,034	3,758
Accrued clinical and preclinical study fees	7,639	26,042
Deferred revenues	4,049	
Current portion of lease financing obligations	651	410
<b>Total current liabilities</b>	<b>21,593</b>	<b>47,199</b>
Deferred rent	598	693
Deferred revenues		4,049
Derivative liabilities	11,715	
Note payable to Siegfried	9,078	8,567
Note payable to Deerfield (see Note below)	43,896	
Lease financing obligations, less current portion	76,970	62,657
Deferred income taxes	935	534
<b>Commitments</b>		
Stockholders' equity:		
Common stock	10	8
Additional paid-in capital	959,239	859,374
Treasury stock, at cost	(23,070)	(23,070)
Accumulated other comprehensive income	1,196	256
Accumulated deficit	(834,815)	(718,936)

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Total stockholders' equity	99,860	117,632
Total liabilities and stockholders' equity	\$ 267,345	\$ 241,331

Note: The outstanding principal balance of the note payable to Deerfield at September 30, 2009 was \$90.0 million. See Note 6.

See accompanying notes to unaudited condensed consolidated financial statements.

**Table of Contents****Arena Pharmaceuticals, Inc.****Condensed Consolidated Statements of Operations****(In thousands, except per share data)****(Unaudited)**

	<b>Three months ended</b>		<b>Nine months ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
<b>Revenues:</b>				
Manufacturing services	\$ 1,737	\$ 1,442	\$ 4,663	\$ 5,461
Collaborative agreements	882	415	3,042	1,650
Total revenues	2,619	1,857	7,705	7,111
<b>Operating Expenses:</b>				
Cost of manufacturing services	1,705	1,743	4,702	6,362
Research and development	22,147	47,475	88,972	151,050
General and administrative	5,423	5,924	18,725	21,938
Restructuring charges			3,324	
Amortization of acquired technology and other intangibles	582	580	1,721	1,748
Total operating expenses	29,857	55,722	117,444	181,098
Loss from operations	(27,238)	(53,865)	(109,739)	(173,987)
<b>Interest and Other Income (Expense):</b>				
Interest income	75	1,332	291	6,529
Interest expense	(7,339)	(1,343)	(10,991)	(4,198)
Gain from valuation of derivative liabilities	2,472		345	
Warrant settlement provision		(242)		(2,236)
Loss on extinguishment of debt	(2,479)		(2,479)	
Other	(326)	(1,509)	(859)	(1,468)
Total interest and other expense, net	(7,597)	(1,762)	(13,693)	(1,373)
Net loss	(34,835)	(55,627)	(123,432)	(175,360)
Dividends on redeemable convertible preferred stock		(557)		(1,644)
Net loss allocable to common stockholders	\$ (34,835)	\$ (56,184)	\$ (123,432)	\$ (177,004)
Net loss per share allocable to common stockholders, basic and diluted	\$ (0.38)	\$ (0.76)	\$ (1.51)	\$ (2.40)
Shares used in calculating net loss per share allocable to common stockholders, basic and diluted	90,995	73,923	81,518	73,782

See accompanying notes to unaudited condensed consolidated financial statements.

**Table of Contents****Arena Pharmaceuticals, Inc.****Condensed Consolidated Cash Flow Statements****(In thousands)****(Unaudited)**

	<b>Nine months ended September 30,</b>	
	<b>2009</b>	<b>2008</b>
<b>Operating Activities</b>		
Net loss	\$ (123,432)	\$ (175,360)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	8,310	8,685
Amortization of acquired technology and other intangibles	1,721	1,748
Share-based compensation	5,366	6,050
Deferred income tax provision	401	
Gain from valuation of derivative liabilities	(345)	
Warrant settlement provision		2,236
Investment write-down		1,607
Amortization of short-term investment premium	69	292
Amortization of prepaid financing costs	278	253
Accretion of note payable to Deerfield	3,546	
Loss on extinguishment of debt	2,479	
Accretion of note payable to Siegfried	184	182
(Gain)/Loss on disposal of equipment	284	(35)
Changes in assets and liabilities:		
Accounts receivable	221	248
Prepaid expenses and other assets	(584)	3,596
Accounts payable and accrued liabilities	(27,960)	1,934
Deferred rent	(95)	(74)
Net cash used in operating activities	(129,557)	(148,638)
<b>Investing Activities</b>		
Purchases of short-term investments, available-for-sale	(20,038)	(62,029)
Proceeds from sales/maturities of short-term investments, available-for-sale	35,696	27,738
Purchase of drug product facility		(19,573)
Purchases of land, property and equipment	(3,744)	(19,232)
Proceeds from sale of equipment	261	36
Deposits, restricted cash and other non-current assets	167	(82)
Net cash provided by (used in) investing activities	12,342	(73,142)
<b>Financing Activities</b>		
Principal payments on lease financing obligations	(445)	(170)
Proceeds from issuance of note payable and related financial instruments to Deerfield	96,865	
Principal payments on note payable to Deerfield	(10,000)	
Proceeds from lease financing	15,000	1,000
Proceeds from issuance of common stock	65,121	1,415
Net cash provided by financing activities	166,541	2,245
Effect of exchange rate changes on cash	(680)	(404)
Net increase (decrease) in cash and cash equivalents	48,646	(219,939)

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Cash and cash equivalents at beginning of period	73,329	386,989
Cash and cash equivalents at end of period	\$ 121,975	\$ 167,050

See accompanying notes to unaudited condensed consolidated financial statements.



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**Table of Contents**

**Notes to Unaudited Condensed Consolidated Financial Statements**

**1. Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements of Arena Pharmaceuticals, Inc. (together with its wholly owned subsidiaries, the Company) should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's annual report on Form 10-K for the year ended December 31, 2008, as filed with the Securities and Exchange Commission, or SEC. The accompanying financial statements have been prepared in accordance with US generally accepted accounting principles, or GAAP, for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying financial statements do not include all of the information and notes required by GAAP for complete financial statements. The accompanying financial statements reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of management, necessary for a fair statement of the results for the interim periods presented. Interim results are not necessarily indicative of results for a full year.

The preparation of financial statements in accordance with GAAP requires management to make estimates and assumptions that affect amounts reported in the financial statements and notes thereto. The Company's critical accounting policies and estimates and assumptions are described in Management's Discussion and Analysis of Financial Condition and Results of Operations, which is included below in this quarterly report on Form 10-Q.

In May 2009, the Financial Accounting Standards Board, or FASB, issued new accounting guidance which requires disclosure of the date through which a company evaluated subsequent events, as well as whether that date is the date the company issued its financial statements or the date its financial statements were available for the company to issue. The Company has evaluated subsequent events after the balance sheet date of September 30, 2009 through November 9, 2009, which is the date the Company issued its financial statements. No subsequent events were identified requiring additional disclosure in the notes to these financial statements.

**2. New Accounting Guidance**

In January 2009, the Company adopted new authoritative guidance for determining whether a financial instrument or an embedded feature in a financial instrument meets the definition of a derivative financial instrument and whether such instrument is classified in the liabilities section or the stockholders' equity section of the balance sheet. The Company's adoption of this guidance resulted in the identification of warrants and other derivative instruments that were determined to be ineligible for equity classification. See Note 7 for the impact adoption of this guidance had on the Company's condensed consolidated financial statements.

In January 2009, the Company adopted new authoritative guidance that addresses whether unvested share-based payment awards that contain non-forfeitable rights to dividends or dividend equivalents are participating securities and, therefore, need to be included in the calculation of earnings per share pursuant to the required two-class method. The adoption of this guidance did not have a material impact on the Company's condensed consolidated financial statements.

In April 2009, the Company adopted new authoritative guidance related to fair value measurement, recording and disclosure, which did not have a material impact on the Company's condensed consolidated financial statements.

In September 2009, the Company adopted new authoritative guidance that established the FASB Accounting Standards Codification, or Codification, as the single official source of authoritative GAAP recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements, with the exception of guidance issued by the SEC and its staff. The Codification did not change GAAP, but reorganized the thousands of GAAP pronouncements into roughly 90 accounting topics and displays all topics using a consistent structure. The adoption of this guidance did not have a material impact on the Company's condensed consolidated financial statements.

**3. Short-term Investments, Available-for-Sale**

The Company defines short-term investments as income-yielding securities that can be readily converted to cash, and classifies such investments as available-for-sale. These securities are carried at fair value, with unrealized gains and losses reported as a separate component of accumulated other comprehensive income or loss. The cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion is included in interest income. Realized gains and losses and declines in securities judged to be other than temporary are included in other income or expense. The cost of securities sold is based on the specific identification method. Interest and dividends on available-for-sale securities are included in interest income.



**Table of Contents**

The following table summarizes the Company's available-for-sale securities at September 30, 2009 and December 31, 2008, in thousands:

	Maturity in Years	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
<b>September 30, 2009</b>					
US government and agency obligations	Less than 1	\$ 21,038	\$ 468	\$	\$ 21,506
Total available-for-sale securities		\$ 21,038	\$ 468	\$	\$ 21,506
<b>December 31, 2008</b>					
US government and agency obligations	Less than 1	\$ 29,024	\$ 54	\$	\$ 29,078
Corporate debt securities	Less than 1	7,741	12	(31)	7,722
Total available-for-sale securities		\$ 36,765	\$ 66	\$ (31)	\$ 36,800

**4. Fair Value Disclosures**

The Company measures its financial assets and liabilities at fair value, which is defined as the exit price, or the amount that would be received for selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

The Company uses the following three-level valuation hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs to value its financial assets and liabilities:

Level 1 - Observable inputs such as unadjusted quoted prices in active markets for identical instruments.

Level 2 - Quoted prices for similar instruments in active markets or inputs that are observable for the asset or liability, either directly or indirectly.

Level 3 - Unobservable inputs based on the Company's own assumptions.

The following table presents the Company's valuation hierarchy for its financial assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2009, in thousands:

	Fair Value Measurements at September 30, 2009			
	Balance at September 30, 2009	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<i>Assets:</i>				
Money market funds (1)	\$ 105,828	\$ 105,828	\$	\$
US government and agency obligations (2)	21,506	20,506	1,000	
<i>Liabilities:</i>				
Warrants and other derivative instruments	\$ 11,715	\$	\$	\$ 11,715

(1) Included in cash and cash equivalents on the accompanying condensed consolidated balance sheet.

(2) Included in short-term investments, available-for-sale on the accompanying condensed consolidated balance sheet.



**Table of Contents**

The following table presents the activity for the Company's derivative liabilities during the nine months ended September 30, 2009, in thousands:

	<b>Significant Unobservable Inputs (Level 3)</b>
Balance at January 1, 2009 after reclassification from additional paid-in capital upon adoption of new guidance	\$ 2,118
Deerfield derivative liabilities	9,942
Gain from valuation of derivative liabilities	(345)
Balance at September 30, 2009	\$ 11,715

**5. Acquired Technology and Other Intangibles**

In January 2008, the Company acquired certain assets from Siegfried Ltd, or Siegfried, including a licensed production facility and an assembled workforce originally valued at \$12.1 million and \$1.6 million, respectively. The Company determined that the licensed production facility has an indefinite useful life since the facility is qualified to produce and package tablets broadly and is not a specific-purpose manufacturing plant. The licensed production facility is tested for impairment annually. If, in the future, the Company determines that the nature of the licensed production facility has changed to a finite useful life, amortization would begin to be recorded over the estimated useful life of the facility. The acquired workforce is being amortized over its estimated benefit of two years, which was determined based on an analysis as of the acquisition date. Using the exchange rate in effect on September 30, 2009, the Company expects to record the remaining expense of \$0.2 million in the fourth quarter of 2009 for amortization of the acquired workforce.

In February 2001, the Company acquired Bunsen Rush for \$15.0 million in cash and assumed \$0.4 million in liabilities. The Company allocated \$15.4 million to the patented Melanophore technology, its primary screening technology, acquired in such transaction. The Melanophore technology is being amortized over its estimated useful life of 10 years, which was determined based on an analysis, as of the acquisition date, of the conditions in, and the economic outlook for, the pharmaceutical and biotechnology industries and the patent life of the technology. As of September 30, 2009, the Company expects to record an expense of \$0.4 million in the remainder of 2009, \$1.5 million in 2010 and \$0.3 million in 2011 for amortization of this technology.

Acquired technology and other intangibles, net, consisted of the following at September 30, 2009, in thousands:

	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Net Carrying Amount</b>
<i>Amortizable intangible assets:</i>			
Acquired technology from Bunsen Rush	\$ 15,378	\$ (13,193)	\$ 2,185
Acquired workforce from Siegfried	1,629	(1,425)	204
	\$ 17,007	\$ (14,618)	2,389
<i>Indefinite-lived intangible assets:</i>			
Acquired licensed production facility from Siegfried			12,581
Total identifiable intangible assets, net			\$ 14,970

**6. Note Payable to Deerfield**

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In June 2009, the Company entered into a Facility Agreement with Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P., Deerfield Partners, L.P., Deerfield International Limited, Deerfield Special Situations Fund, L.P., and Deerfield Special Situations Fund International Limited, or collectively Deerfield, pursuant to which Deerfield agreed to provide the Company with a \$100.0 million secured loan and the Company agreed to issue Deerfield warrants to purchase an aggregate of 28,000,000 shares of its common stock at an exercise price of \$5.42 per share upon the closing of such loan. In July 2009, the Company received net proceeds of \$95.6 million from this loan and issued the 28,000,000 warrants to Deerfield. On or before June 17, 2011, Deerfield may make a one-time election, which the Company refers to as the Deerfield Additional Loan Election, to loan the Company up to an additional \$20.0 million under the Facility Agreement, with the additional loan maturing on the same date as the original loan, June 17, 2013. For each additional \$1.0 million that Deerfield loans the Company under the Facility Agreement, the Company will issue Deerfield warrants for 280,000 shares of common stock at an exercise price of \$5.42 per share. All of the warrants issued or issuable in connection with the Facility Agreement are exercisable until June 17, 2013. Under certain

**Table of Contents**

circumstances, Deerfield also has the right to require the Company to accelerate principal payments under the loan. At any time the Company may prepay any or all of the outstanding principal at par, and the Company may be required to make the scheduled repayments earlier in connection with certain equity issuances. At September 30, 2009, the outstanding principal balance on the Deerfield loan was \$90.0 million.

In accordance with relevant guidance, the Company separately valued four components under the Facility Agreement at the July 6, 2009 issuance date, as follows:

- (1) The \$100.0 million loan was valued at \$47.9 million on a relative fair value basis and is recorded as a long-term liability on the condensed consolidated balance sheet.
- (2) The 28,000,000 warrants, net of issuance costs, were valued at \$39.0 million on a relative fair value basis. The fair value of the warrants is recorded as additional paid-in capital on the condensed consolidated balance sheet, and the resulting debt discount is being accreted to interest expense over the term of the loan using the effective interest rate method. These warrants were valued at the date of issuance using an option pricing model and the following assumptions: expected life of 3.95 years, risk-free interest rate of 2.0%, expected volatility of 66% and no dividend yield. Because these warrants are eligible for equity classification, no adjustments to the recorded value will be made on an ongoing basis.
- (3) The Deerfield Additional Loan Election, including the 5,600,000 contingently issuable warrants, was valued at \$9.5 million. The Deerfield Additional Loan Election is classified as a long-term liability on the condensed consolidated balance sheet and, accordingly, will be revalued on each subsequent balance sheet date until it is exercised or expires, with any changes in the fair value between reporting periods recorded in the interest and other income (expense) section of the accompanying condensed consolidated statements of operations (see Note 7). This allocation of proceeds under the Facility Agreement resulted in additional debt discount that is being accreted to interest expense over the term of the loan using the effective interest rate method.
- (4) Deerfield's ability to accelerate principal payments under the loan was valued at \$0.5 million. The acceleration right is classified as a long-term liability on the condensed consolidated balance sheet and, accordingly, will be revalued on each subsequent balance sheet date until it is exercised or expires, with any changes in the fair value between reporting periods recorded in the interest and other income (expense) section of the accompanying condensed consolidated statements of operations (see Note 7). This allocation of proceeds under the Facility Agreement resulted in additional debt discount that is being accreted to interest expense over the term of the loan using the effective interest rate method.

The table below reconciles the \$43.9 million recorded value of the loan to the \$90.0 million outstanding principal balance of the loan as of September 30, 2009, in thousands:

Recorded value of note payable to Deerfield	\$ 43,896
Accretion of remaining debt discount over term of loan	46,104
<b>Outstanding principal balance of note payable to Deerfield</b>	<b>\$ 90,000</b>

The loan matures on June 17, 2013, and the outstanding principal accrues interest at a rate of 7.75% per annum on the stated principal balance, payable quarterly in arrears. Total interest expense of \$5.4 million, including accretion of the debt discount attributable to the warrants and the other derivative financial instruments and amortization of capitalized issuance costs, was recognized in connection with this loan in the three and nine months ended September 30, 2009. The current effective annual interest rate on the loan is 25.6%.

As a result of the closing of the Company's public offering in July 2009 (see Note 8), the Company was required to repay Deerfield \$10.0 million that was originally scheduled to be repaid in July 2010. In connection with this \$10.0 million repayment, the Company retired a proportional share of the debt discount and issuance costs and recorded a loss on extinguishment of debt of \$2.5 million in the three and nine months ended September 30, 2009. The remainder of required principal repayments is as follows: \$20.0 million in July 2011, \$30.0 million in July 2012, and \$40.0 million at maturity.

**7. Derivative Liabilities**

In June 2006 and August 2008, the Company issued seven-year warrants, which the Company refers to as the Series B warrants, to purchase 829,856 and 1,106,344 shares of its common stock, respectively, at an exercise price of \$15.49 and \$7.71 per share, respectively. The Series B warrants are related to the Company's Series B Convertible Preferred Stock, which was redeemed and is no longer outstanding. The warrants contain an anti-dilution provision and, as a result of subsequent equity issuances at prices below the adjustment price of \$6.72 defined in the warrants, including the issuance of warrants to Deerfield (see Note 6), as of September 30, 2009 the number of Series B warrants outstanding was increased to 916,213 and 1,222,050, respectively, and the exercise price was reduced to \$14.03 and \$6.98 per share, respectively.



**Table of Contents**

In January 2009, upon adoption of new authoritative guidance and as a result of provisions in the Series B warrants that may result in an adjustment to the warrant exercise price, the Company recorded a \$9.7 million adjustment to equity, a \$2.1 million long-term liability for the fair value of the Series B warrants and a \$7.6 million adjustment to the opening accumulated deficit balance as a cumulative effect of a change in accounting principle. The Company has revalued these warrants on each subsequent balance sheet date, and will continue to do so until they are fully exercised or expire, with any changes in the fair value between reporting periods recorded as other income or expense. The warrants for 916,213 shares were valued at September 30, 2009 using an option pricing model and the following assumptions: expected life of 3.75 years, risk-free interest rate of 1.9%, expected volatility of 68% and no dividend yield. The warrants for 1,222,050 shares were valued at September 30, 2009 using an option pricing model and the following assumptions: expected life of 5.87 years, risk-free interest rate of 2.6%, expected volatility of 60% and no dividend yield.

The Company separately valued the Deerfield Additional Loan Election, including the 5,600,000 contingently issuable warrants, as of the July 6, 2009 issuance date of the Deerfield loan (see Note 6). The value of the Deerfield Additional Loan Election is classified as a long-term liability on the condensed consolidated balance sheet and, accordingly, will be revalued on each subsequent balance sheet date until it is fully exercised or expires, with any changes in the fair value between reporting periods recorded as other income or expense. In July 2009, the Deerfield Additional Loan Election was valued using an option pricing model and the following assumptions: expected life of 2 to 3 years, risk-free interest rate of 2.0%, expected volatility of 66% and no dividend yield. At September 30, 2009, these warrants were revalued using an option pricing model and the following assumptions: expected life of 2 to 3 years, risk-free interest rate of 1.8%, expected volatility of 68% and no dividend yield.

The Company separately valued Deerfield's right to require the Company to accelerate principal payments of the loan under certain circumstances at \$0.5 million as of the July 6, 2009 issuance date of the Deerfield loan (see Note 6). The value of this acceleration right is classified as a long-term liability on the condensed consolidated balance sheet and, accordingly, will be revalued on each subsequent balance sheet date, with any changes in the fair value between reporting periods recorded as other income or expense. In July 2009 and at September 30, 2009, this acceleration right was valued using a discounted cash flow model.

The Company's derivative liabilities consisted of the following, as of September 30, 2009, in thousands:

Series B warrants	\$ 3,474
Deerfield Additional Loan Election	7,796
Deerfield acceleration right	445
Total derivative liabilities	\$ 11,715

The change in the fair value of the Company's derivative liabilities is recorded in the interest and other income (expense) section of the accompanying condensed consolidated statements of operations. The following table presents the gain (loss) recorded for the three and nine months ended September 30, 2009, in thousands:

	Three months ended September 30, 2009	Nine months ended September 30, 2009
Series B warrants	\$ 771	\$ (1,356)
Deerfield Additional Loan Election	1,687	1,687
Deerfield acceleration right	14	14
Total gain (loss) due to revaluation of derivative liabilities	\$ 2,472	\$ 345

**8. Stockholders' Equity**

In July 2009, the Company received net proceeds of \$49.7 million from a public offering of 12,500,000 shares of its common stock at \$4.17 per share.

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In July 2009, the Company issued to Deerfield warrants to purchase an aggregate of 28,000,000 shares of its common stock at an exercise price of \$5.42 per share in connection with the receipt of a \$100.0 million loan. The Company valued these warrants, which are classified as additional paid-in capital on the condensed consolidated balance sheet, at \$39.0 million as of the July 6, 2009 issuance date, net of allocated issuance costs (see Note 6).

**Table of Contents**

The following table presents a summary of the Company's outstanding warrants as of September 30, 2009:

	<b>Balance Sheet Classification</b>	<b>Number of Warrants</b>	<b>Exercise Price</b>	<b>Expiration Date</b>
Deerfield warrants	Equity	28,000,000	\$ 5.42	June 17, 2013
Series B warrants	Liability	1,222,050	\$ 6.98	August 14, 2015
Series B warrants	Liability	916,213	\$ 14.03	June 30, 2013
Total number of warrants outstanding		30,138,263		

**9. Share-based Activity*****Equity Compensation Plans***

In June 2009, the Company's stockholders approved the Company's 2009 Long-Term Incentive Plan, or 2009 LTIP. When the Company's 2006 Long-Term Incentive Plan, as amended, or 2006 LTIP, was adopted, the Company's Amended and Restated 1998 Equity Compensation Plan, Amended and Restated 2000 Equity Compensation Plan, and 2002 Equity Compensation Plan (or together with the 2006 LTIP, the Prior Plans) were terminated. Upon stockholder approval of the 2009 LTIP, the 2006 LTIP was also terminated. However, notwithstanding such termination of the Prior Plans, all outstanding awards under the Prior Plans will continue to be governed under the terms of the Prior Plans.

There were 6,488,112 shares available for issuance under the 2009 LTIP as of the date of stockholder approval and 6,548,244 shares available for issuance at September 30, 2009. Such shares may be granted as incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and performance awards. Subject to certain limited exceptions, (i) stock options and stock appreciation rights granted under the 2009 LTIP reduce the available number of shares by one share for every share issued while awards other than stock options and stock appreciation rights granted under the 2009 LTIP reduce the available number of shares by 1.3 shares for every share issued, and (ii) shares that are released from awards granted under the Prior Plans or the 2009 LTIP because the awards expire, are forfeited or are settled for cash will increase the number of shares available under the 2009 LTIP by one share for each share released from a stock option or stock appreciation right and by 1.3 shares for each share released from a restricted stock award or restricted stock unit award.

Stock options granted under the 2009 LTIP generally vest 25% a year for four years and are exercisable for up to 10 years from the date of grant. The recipient of a restricted stock award has all rights of a stockholder at the date of grant, subject to certain restrictions on transferability and a risk of forfeiture. The minimum performance period under a performance award is 12 months. Neither the exercise price of an option nor the grant price of a stock appreciation right may be less than 100% of the fair market value of the common stock on the date such option is granted, except in specified situations. The 2009 LTIP prohibits repricings of options and stock appreciation rights (other than to reflect stock splits, spin-offs or certain other corporate events) unless stockholder approval is obtained.

***Employee Stock Purchase Plan***

In June 2009, the Company's stockholders approved the Company's 2009 Employee Stock Purchase Plan, or 2009 ESPP, which provides for the issuance of up to 1,500,000 shares of the Company's common stock and qualifies under Section 423 of the Internal Revenue Code. As of September 30, 2009, a total of 1,319,256 shares of common stock were available for issuance under the 2009 ESPP.

Upon stockholder approval of the 2009 ESPP, the Company's 2001 Employee Stock Purchase Plan, as amended, or 2001 ESPP, was terminated. However, notwithstanding such termination of the 2001 ESPP, all offering periods existing under the 2001 ESPP on the effective date of the 2009 ESPP continue in effect under the 2009 ESPP, but in accordance with the terms of the 2001 ESPP.

Under the 2009 ESPP, substantially all US employees can choose to have up to 15% of their annual compensation withheld to purchase up to 625 shares of common stock per purchase period, subject to certain limitations. The shares of common stock may be purchased over an offering period with a maximum duration of 24 months and at a price of not less than 85% of the lesser of the fair market value of the common stock on (i) the first trading day of the applicable offering period or (ii) the last trading day of the applicable three-month purchase period.



**Table of Contents****Share-based Compensation**

The Company recognized share-based compensation expense as follows, in thousands, except per share data:

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
Research and development	\$ 1,054	\$ 1,065	\$ 2,878	\$ 3,273
General and administrative	571	680	2,182	2,777
Restructuring charges			306	
Total share-based compensation expense and impact on net loss allocable to common stockholders	\$ 1,625	\$ 1,745	\$ 5,366	\$ 6,050
Impact on net loss per share allocable to common stockholders, basic and diluted	\$ 0.02	\$ 0.02	\$ 0.06	\$ 0.08

The Company uses the Black-Scholes option pricing model to estimate the grant-date fair value of share-based awards in determining the share-based compensation expense recognized. The table below sets forth the weighted-average assumptions and estimated fair value of stock options granted under the Company's equity compensation plans during the three and nine-month periods ended September 30, 2009 and 2008:

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
Risk-free interest rate	2.8%	2.5%	2.0%	2.5%
Dividend yield	0%	0%	0%	0%
Expected volatility	80%	57%	86%	57%
Expected life (years)	5.72	5.50	5.72	5.50
Weighted-average estimated fair value of stock options granted	\$ 3.06	\$ 3.18	\$ 2.87	\$ 3.65

The table below sets forth the weighted-average assumptions and estimated fair value of options to purchase stock granted under the applicable employee stock purchase plan for multiple offering periods during the three- and nine-month periods ended September 30, 2009 and 2008:

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
Risk-free interest rate	0.1% - 4.2%	1.4% - 5.1%	0.1% - 5.1%	1.4% - 5.3%
Dividend yield	0%	0%	0%	0%
Expected volatility	53% - 82%	53% - 69%	53% - 82%	53% - 69%
Expected life (years)	0.25 - 2.0	0.25 - 2.0	0.25 - 2.0	0.25 - 2.0
Weighted-average estimated fair value of options granted under employee stock purchase plans	\$1.45 - 4.70	\$2.14 - 5.46	\$1.45 - 4.70	\$2.14 - 5.46

Expected volatility is based on a combination of 75% historical volatility of the Company's common stock and 25% market-based implied volatilities from traded options on its common stock, with historical volatility being more heavily weighted due to the low volume of traded options on its common stock. The expected life of options is determined based on historical experience of similar awards, giving consideration to the contractual terms of the share-based awards, vesting schedules and post-vesting terminations. The risk-free interest rates are based on the US Treasury yield curve, with a remaining term approximately equal to the expected term used in the option pricing model.

Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Based on historical experience, forfeitures of unvested options were estimated to be 8.5% at September 30, 2009 and 5.1% at September 30, 2008. If actual forfeitures vary from estimates, the Company will recognize the difference in compensation expense in the period the actual forfeitures occur or when stock options vest.



**Table of Contents****Share-based Award Activity**

The following table summarizes the Company's stock option activity during the nine months ended September 30, 2009:

	Options	Weighted-Average Exercise Price
Outstanding at January 1, 2009	6,556,630	\$ 9.74
Granted	1,238,519	4.02
Exercised	(60,750)	0.60
Forfeited/cancelled/expired	(484,838)	8.21
Outstanding at September 30, 2009	7,249,561	\$ 8.95

The following table summarizes activity with respect to the Company's performance-based restricted stock unit awards during the nine months ended September 30, 2009:

	Performance Units	Weighted-Average Grant-Date Fair Value
Outstanding at January 1, 2009	1,950,100	\$ 12.30
Granted		
Vested		
Forfeited/cancelled	(232,250)	11.34
Outstanding at September 30, 2009	1,717,850	\$ 12.43

**10. Concentration of Credit Risk and Major Customers**

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist primarily of cash, cash equivalents and short-term investments. The Company limits its exposure to credit loss by, in accordance with its board-approved investment policy, placing its cash and investments in US government, agency and government-sponsored enterprise obligations and in corporate debt instruments that are rated investment grade.

The Company manufactures drug products for Siegfried under a manufacturing services agreement, and all of the Company's manufacturing services revenues are attributable to Siegfried. Percentages of the Company's total revenues derived from its manufacturing services agreement and from its two most significant collaborators are as follows:

Source of Revenue	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
Manufacturing services agreement with Siegfried	66.3%	77.7%	60.5%	76.8%
Collaboration with Ortho-McNeil-Janssen Pharmaceuticals, Inc.	33.1%	21.8%	39.0%	22.8%
Collaboration with Merck & Co., Inc.	0.6%	0.5%	0.5%	0.4%
	100.0%	100.0%	100.0%	100.0%

**11. Restructuring Charges**

In June 2009, the Company completed a previously announced reduction of its US workforce of approximately 31%, or a total of approximately 130 employees, to preserve cash and to focus on its clinical development program for lorcaserin and select earlier-stage research and development programs. The Company recognized a liability for all restructuring costs when the liability was incurred. As a result of this workforce reduction, the Company recorded a charge of \$3.3 million in the three months ended June 30, 2009, including non-cash, share-based compensation charges of \$0.3 million, which is reflected as a separate line item in the accompanying condensed consolidated statements of operations. As of September 30, 2009, less than \$2,000 of the restructuring charge remains to be paid.

**12. Net Loss Per Share**

Basic and diluted net loss per share are computed using the weighted-average number of shares of common stock outstanding during the period, less any shares subject to repurchase or forfeiture, for all periods presented.



**Table of Contents**

There were no shares of common stock outstanding excluded from the calculation of basic and diluted net loss per share because no shares were subject to repurchase or forfeiture for each of the three and nine months ended September 30, 2009. For each of the three and nine months ended September 30, 2008, there were 29,000 shares excluded from the calculation of basic and diluted net loss per share because they were subject to repurchase or forfeiture. Because the Company is in a net loss position, the Company has excluded all unvested performance-based restricted stock unit awards, which are subject to forfeiture, outstanding stock options, preferred stock and warrants from the calculation of basic and diluted net loss per share allocable to common stockholders because these securities are antidilutive for all periods presented. Had they been dilutive, such shares would have been included in the computation of diluted net loss per share allocable to common stockholders.

**13. Comprehensive Income (Loss)**

The Company reports all components of comprehensive income (loss), including foreign currency translation gain and loss and unrealized gains and losses on investment securities, in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Below is a reconciliation, in thousands, of net loss to comprehensive loss for all periods presented.

	Three months ended		Nine months ended	
	September 30, 2009	September 30, 2008	September 30, 2009	September 30, 2008
Net loss	\$ (34,835)	\$ (55,627)	\$ (123,432)	\$ (175,360)
Foreign currency translation gain (loss)	1,348	(2,796)	507	(389)
Unrealized gain (loss) on available-for-sale securities and other investments	462	(81)	433	(122)
Comprehensive loss	\$ (33,025)	\$ (58,504)	\$ (122,492)	\$ (175,871)

**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

This discussion and analysis should be read in conjunction with our financial statements and notes thereto included in this quarterly report on Form 10-Q, or Quarterly Report, and the audited consolidated financial statements and notes thereto included in our annual report on Form 10-K for the year ended December 31, 2008, or 2008 Annual Report, as filed with the Securities and Exchange Commission, or SEC. Operating results are not necessarily indicative of results that may occur in future periods.

This Quarterly Report includes forward-looking statements, which involve a number of risks and uncertainties. These forward-looking statements can generally be identified as such because the context of the statement will include words such as may, will, intend, plan, believe, anticipate, expect, estimate, predict, potential, continue, likely, or opportunity, the negative of these words or other similar words. Statements that describe our future plans, strategies, intentions, expectations, objectives, goals or prospects and other statements that are not historical facts are also forward-looking statements. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Readers of this Quarterly Report are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the time this Quarterly Report was filed with the SEC. These forward-looking statements are based largely on our expectations and projections about future events and future trends affecting our business, and are subject to risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. These risks and uncertainties include, without limitation, the risk factors identified in our SEC reports, including this Quarterly Report. In addition, past financial or operating performance is not necessarily a reliable indicator of future performance, and you should not use our historical performance to anticipate results or future period trends. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of operations and financial condition. Except as required by law, we undertake no obligation to update publicly or revise our forward-looking statements.

**OVERVIEW AND RECENT DEVELOPMENTS**

We are a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing oral drugs in four major therapeutic areas: cardiovascular, central nervous system, inflammatory and metabolic diseases. Our most advanced drug candidate, lorcaserin hydrochloride, or lorcaserin, is being investigated in a Phase 3 clinical trial program for weight management. We have a broad pipeline of novel compounds targeting G protein-coupled receptors, or GPCRs, an important class of validated drug targets, which includes compounds being evaluated independently and with partners, including Merck & Co., Inc., or Merck, and Ortho-McNeil-Janssen Pharmaceuticals, Inc., or

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Ortho-McNeil-Janssen. We incorporated on April 14, 1997 in the state of Delaware and commenced operations in July 1997.

Our recent developments include:

Announced positive, highly significant top-line results from the BLOSSOM (Behavioral modification and Lorcaserin Second Study for Obesity Management) Phase 3 trial. Lorcaserin patients achieved highly significant categorical and absolute weight loss over 52 weeks of treatment. About two-thirds (63.2%) of lorcaserin patients dosed twice daily who

**Table of Contents**

completed the trial according to protocol lost at least 5% of their weight, compared to 34.9% of patients on placebo, and more than one-third (35.1%) of these lorcaserin patients lost at least 10% of their weight, compared to 16.1% for placebo. The average weight loss for lorcaserin patients dosed twice daily was 17.0 pounds, compared to 8.7 pounds for placebo. The top quartile of lorcaserin patients who completed the trial according to protocol and had their Week 52 weight recorded lost an average of 35.1 pounds. Lorcaserin was very well tolerated and no excess depression or suicidal ideation was observed with lorcaserin treatment. The incidence of new FDA-defined valvulopathy from the integrated echocardiographic data set from BLOSSOM and BLOOM did not differ from placebo.

Announced a late-breaking oral presentation from the pivotal BLOSSOM trial and additional positive data from the pivotal BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) Phase 3 trial at the 27<sup>th</sup> Annual Scientific Meeting of The Obesity Society. The new BLOSSOM data demonstrate improvements in patients' body composition, cardiovascular risk factors and quality of life. The new BLOOM data demonstrate that lorcaserin significantly improved markers of cardiovascular risk and glycemic parameters and was not associated with depression or suicidal ideation. Lorcaserin patients who completed the BLOOM trial according to protocol lost 31% of their excess body weight, compared to 12% for the placebo group.

Completed dosing in all lorcaserin clinical trials we expect to be included in the NDA we plan to submit to the FDA by the end of 2009.

Completed a public offering of 12.5 million shares of common stock, resulting in net proceeds to us of \$49.7 million.

Received net proceeds of \$95.6 million from a \$100.0 million loan provided by Deerfield Management. The outstanding principal accrues interest until maturity in June 2013 at a rate of 7.75% per annum. In connection with the loan, we issued Deerfield warrants for 28 million shares of our common stock at an exercise price of \$5.42 per share. On or before June 17, 2011, Deerfield may make a one-time election to provide us with up to an additional \$20.0 million under similar terms, with the additional loan also maturing in June 2013. For each additional \$1.0 million in funding, we will issue Deerfield additional warrants for 280,000 shares of our common stock at an exercise price of \$5.42 per share. We repaid Deerfield the first scheduled principal repayment of \$10.0 million upon completion of our public offering in July.

**RESULTS OF OPERATIONS**

We are providing the following summary of our revenues, research and development expenses and general and administrative expenses to supplement the more detailed discussion below. The following tables are stated in millions.

**Revenues**

Source of revenue	Three months ended		Nine months ended	
	September 30, 2009	September 30, 2008	September 30, 2009	September 30, 2008
Manufacturing services agreement	\$ 1.7	\$ 1.5	\$ 4.7	\$ 5.5
Collaborative agreements	0.9	0.4	3.0	1.6
<b>Total revenues</b>	<b>\$ 2.6</b>	<b>\$ 1.9</b>	<b>\$ 7.7</b>	<b>\$ 7.1</b>

**Research and development expenses**

Three months ended	Nine months ended
September 30,	September 30,

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Type of expense	2009	2008	2009	2008
External clinical and preclinical study fees and expenses	\$ 7.7	\$ 27.9	\$ 39.8	\$ 90.9
Salary and other personnel costs (excluding non-cash share-based compensation)	7.7	10.3	27.3	31.3
Facility and equipment costs	3.8	4.1	11.7	12.0
Other	1.1	1.7	3.6	5.2
Non-cash share-based compensation	1.0	1.1	2.9	3.3
Research supplies	0.8	2.4	3.7	8.3
<b>Total research and development expenses</b>	<b>\$ 22.1</b>	<b>\$ 47.5</b>	<b>\$ 89.0</b>	<b>\$ 151.0</b>

**Table of Contents****General and administrative expenses**

Type of expense	Three months ended		Nine months ended	
	September 30, 2009	September 30, 2008	September 30, 2009	September 30, 2008
Salary and other personnel costs (excluding non-cash share-based compensation)	\$ 1.9	\$ 2.3	\$ 6.5	\$ 7.4
Legal, accounting and other professional fees	1.7	1.1	6.0	6.6
Facility and equipment costs	0.8	1.0	2.7	2.7
Non-cash share-based compensation	0.6	0.7	2.2	2.8
Other	0.4	0.8	1.3	2.4
Total general and administrative expenses	\$ 5.4	\$ 5.9	\$ 18.7	\$ 21.9

**THREE MONTHS ENDED SEPTEMBER 30, 2009 AND 2008**

**Revenues.** We recorded revenues of \$2.6 million during the three months ended September 30, 2009, compared to \$1.9 million during the three months ended September 30, 2008. Our revenues for the three months ended September 30, 2009 included \$1.7 million under our manufacturing services agreement with Siegfried Ltd, or Siegfried, an increase of \$0.2 million from the \$1.5 million of manufacturing services revenues recorded in the three months ended September 30, 2008. Our revenues for the three months ended September 30, 2009 also included \$0.9 million for patent activities and additional sponsored research from our collaborations with Ortho-McNeil-Janssen and Merck, compared to \$0.4 million for patent activities in the three months ended September 30, 2008.

Absent any new collaborations or achievement of a milestone in one of our existing collaborations, we expect our 2009 revenues will consist primarily of reimbursement for patent activities from our collaborators and manufacturing services revenue under our manufacturing services agreement with Siegfried. Under such Siegfried agreement, until at least December 31, 2010, Siegfried may sub-contract to us the manufacture of certain drug products it previously manufactured for its customers, and we agreed to perform such manufacturing up to certain specified amounts. Also under such agreement, Siegfried guarantees a minimum level of cost absorption, which we will record as revenues, of CHF 1.8 million in the remaining quarter of 2009 and CHF 6.6 million in 2010. Using the exchange rate in effect on September 30, 2009, this would translate to approximately \$1.8 million and \$6.4 million in manufacturing services revenues for the balance of 2009 and 2010, respectively.

Revenues from our collaborators for milestones that may be achieved in the future are difficult to predict, and our revenues may vary significantly from quarter to quarter and year to year. We expect that any significant revenues for at least the short term will depend on the clinical success of our partnered programs as well as whether we partner lorcaseerin or any of our other current or future drug candidates. Ultimately, we expect our revenues in the long term to primarily depend upon the regulatory approval and commercialization of our partnered or internally developed drugs.

**Cost of manufacturing services.** Cost of manufacturing services is comprised of direct costs associated with manufacturing drug products for Siegfried under our manufacturing services agreement, including related salaries, other personnel costs and machinery depreciation costs. Cost of manufacturing services of \$1.7 million was recorded for each of the three-month periods ended September 30, 2009 and 2008.

**Research and development expenses.** Research and development expenses, which account for the majority of our expenses, consist primarily of costs associated with external clinical and preclinical study fees, manufacturing costs and other related expenses, and the development of our earlier-stage programs and technologies. Our most significant research and development costs are for clinical trials (including payments to contract research organizations, or CROs), preclinical study fees, salaries and personnel, research supplies, and facility and equipment costs. We expense research and development expenses to operations as they are incurred when these expenditures relate to our research and development efforts and have no alternative future uses. Other than external expenses for our clinical and preclinical programs, we generally do not track our research and development expenses by project; rather, we track such expenses by the type of cost incurred.

Research and development expenses decreased by \$25.4 million to \$22.1 million for the three months ended September 30, 2009, from \$47.5 million for the three months ended September 30, 2008. This was primarily due to decreases of (i) \$20.2 million in external clinical and preclinical study fees and expenses due to completing our BLOOM and BLOSSOM lorcaseerin trials in 2009, as well as completing our clinical trials of APD125 in 2008, and prioritizing our spending towards activities that support filing an NDA for lorcaseerin, (ii) \$2.6 million in salary and other personnel costs as a result of the workforce reduction we completed in June 2009 and (iii) \$1.6 million in research supplies primarily due to having less research personnel, as well as our cost-containment efforts. Although we expect to continue to incur substantial research and

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development expenses in 2009, primarily related to lorcaserin, we expect that our total research and development expenses in 2009 will be significantly lower than the 2008 level as we believe that most of the expenses from our BLOOM and BLOSSOM trials have been recognized. In addition, in light of our current financial condition, we do not plan to initiate in the near term any clinical trials of any other of our drug candidates, but are exploring the

**Table of Contents**

feasibility of initiating clinical trials of APD916 or APD811 next year. APD916 is being investigated for the treatment of narcolepsy and cataplexy, and potentially other indications, and APD811 is our lead drug candidate for the treatment of pulmonary arterial hypertension. Further, as a result of the workforce reduction, we expect that our research and development expenses, particularly salary, other personnel costs and research supplies, in the fourth quarter of 2009 will be significantly lower than in the first quarter of 2009. We also expect to incur substantial manufacturing costs for lorcaserin in 2010 and beyond, whether we decide to market and commercialize lorcaserin independently or with a partner.

Included in the \$7.7 million total external clinical and preclinical study fees and expenses noted in the table above for the three months ended September 30, 2009 was \$7.4 million related to our lorcaserin program and \$0.1 million related to each of our APD125 and APD811 programs. We previously studied APD125 for insomnia. Included in the \$27.9 million total external clinical and preclinical study fees and expenses noted in the table above for the three months ended September 30, 2008 was \$23.1 million related to our lorcaserin program, \$4.2 million related to our APD125 program and \$0.1 million related to each of our APD791 and APD916 programs. APD791 is our lead drug candidate for the treatment and prevention of arterial thrombosis.

**General and administrative expenses.** General and administrative expenses decreased by \$0.5 million to \$5.4 million for the three months ended September 30, 2009, from \$5.9 million for the three months ended September 30, 2008. This change was primarily comprised of (i) an increase of \$0.4 million in patent fees, (ii) a decrease of \$0.4 million in salary and other personnel costs as a result of the workforce reduction we completed in June 2009 and (iii) a decrease of \$0.3 million in lorcaserin market research expenses. We expect that our total general and administrative expenses in 2009 will be lower than the 2008 level as a result of the workforce reduction and other cost-containment measures. We also expect that, unless a partner pays for commercialization, marketing and business development expenses related to lorcaserin, our total general and administrative expenses will increase significantly beginning in 2010 primarily due to increases in such lorcaserin expenses.

**Amortization of acquired technology and other intangibles.** We recorded \$0.6 million for amortization of acquired technology and other intangibles in both of the three month periods ended September 30, 2009 and 2008. The workforce we acquired from Siegfried in January 2008 is being amortized over its estimated benefit of two years, for which we expect to record the remaining amortization expense of \$0.2 million in the fourth quarter of 2009. Our patented Melanophore technology, which we acquired in 2001 for \$15.4 million, is our primary screening technology and is being amortized over its estimated useful life of 10 years. We expect to record charges of \$0.4 million in the fourth quarter of 2009, \$1.5 million in 2010 and \$0.3 million in 2011 for amortization of this technology.

**Interest and other income (expense), net.** Interest and other expense, net, increased by \$5.8 million to \$7.6 million for the three months ended September 30, 2009, from \$1.8 million for the three months ended September 30, 2008. This increase in expense was primarily due to (i) a \$5.4 million increase in interest expense related to the Deerfield loan, (ii) a \$2.5 million non-cash loss on extinguishment of debt resulting from the \$10.0 million repayment on the Deerfield loan and (iii) a \$1.3 million decrease in interest income attributable to both lower interest rates and cash balances. This increase was partially offset by (i) a \$2.5 million non-cash gain from the revaluation of our derivative liabilities and (ii) a \$1.6 million write-down on our investment in TaiGen Biotechnology Co., Ltd., which we recorded in 2008. We expect our interest expense will continue to be substantial as a result of the Deerfield loan and payments on our lease financing obligations.

**Dividends on redeemable convertible preferred stock.** Because we redeemed all of the outstanding shares of our Series B Convertible Preferred Stock, or Series B Preferred, in November 2008, we recorded no dividends related to such stock in the three months ended September 30, 2009, compared to \$0.6 million in the three months ended September 30, 2008.

**NINE MONTHS ENDED SEPTEMBER 30, 2009 AND 2008**

**Revenues.** We recorded revenues of \$7.7 million during the nine months ended September 30, 2009, compared to \$7.1 million during the nine months ended September 30, 2008. Our revenues for the nine months ended September 30, 2009 included \$4.7 million under our manufacturing services agreement with Siegfried and \$3.0 million for patent activities and additional sponsored research from our collaborations with Ortho-McNeil-Janssen and Merck. Our revenues for the nine months ended September 30, 2008 included \$5.5 million under our manufacturing services agreement with Siegfried and \$1.6 million for patent activities from our collaborations with Ortho-McNeil-Janssen and Merck.

**Cost of manufacturing services.** Cost of manufacturing services decreased to \$4.7 million for the nine months ended September 30, 2009, compared to \$6.4 million for the nine months ended September 30, 2008. This decrease was primarily due to a decrease in manufacturing service activities.

**Research and development expenses.** Research and development expenses decreased \$62.0 million to \$89.0 million for the nine months ended September 30, 2009, from \$151.0 million for the nine months ended September 30, 2008. This was primarily due to decreases of (i) \$51.1 million in external clinical and preclinical study fees and expenses primarily due to completing our BLOOM and BLOSSOM trials, as well as



completing our clinical trials of APD125, (ii) \$4.6 million in research supplies due to having less

**Table of Contents**

research personnel, as well as our cost-containment efforts and (iii) \$4.0 million in salary and personnel costs. Included in the \$39.8 million of total external clinical and preclinical study fees and expenses for the nine months ended September 30, 2009 was \$38.4 million related to our lorcaserin program, \$0.6 million related to our APD811 program and \$0.4 million related to receipt of the complete data package from our Phase 2b clinical trial of APD125. Personnel-related employee separation costs resulting from the workforce reduction are reflected as a separate line item in our condensed consolidated statements of operations. Included in the \$90.9 million of total external clinical and preclinical study fees and expenses for the nine months ended September 30, 2008 was \$77.5 million related to our lorcaserin program, \$9.9 million related to our APD125 program, \$1.4 million related to our APD916 program and \$1.2 million related to our APD791 program.

**General and administrative expenses.** General and administrative expenses decreased \$3.2 million to \$18.7 million for the nine months ended September 30, 2009, from \$21.9 million for the nine months ended September 30, 2008. This was primarily due to decreases of (i) \$0.9 million in salary and personnel costs, (ii) \$0.6 million in legal fees, primarily patent fees, and (iii) \$0.6 million in non-cash share-based compensation expense.

**Restructuring charges.** We recorded a charge of \$3.3 million in the nine months ended September 30, 2009 in connection with the workforce reduction we completed in June 2009.

**Amortization of acquired technology and other intangibles.** We recorded \$1.7 million for amortization of acquired technology in each of the nine-month periods ended September 30, 2009 and 2008 related to our Melanophore screening technology and the workforce we acquired from Siegfried.

**Interest and other income (expense), net.** Interest and other expense, net, increased \$12.3 million to \$13.7 million for the nine months ended September 30, 2009, from \$1.4 million for the nine months ended September 30, 2008. This increase in expense was primarily due to (i) a \$6.2 million decrease in interest income, (ii) a \$5.4 million increase in interest expense related to the Deerfield loan, (iii) a \$2.5 million non-cash loss on extinguishment of debt and (iv) a \$1.4 million increase in interest expense related to our lease financing obligations. This increase was partially offset by a \$2.2 million non-cash warrant settlement with one of our Series B warrant holders and a \$1.6 million write-down on our investment in TaiGen Biotechnology Co., Ltd., both of which we recorded in 2008.

**Dividends on redeemable convertible preferred stock.** We recorded a dividend of \$1.6 million related to our previously outstanding Series B Preferred in the nine months ended September 30, 2008.

**LIQUIDITY AND CAPITAL RESOURCES***Short term*

Our sources of liquidity include our cash balances and short-term investments. As of September 30, 2009, we had \$143.5 million in cash and cash equivalents and short-term investments, which reflects net proceeds of \$95.6 million from the issuance of a note and related financial instruments to Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P., Deerfield Partners, L.P., Deerfield International Limited, Deerfield Special Situations Fund, L.P., and Deerfield Special Situations Fund International Limited, or collectively Deerfield, and net proceeds of \$49.7 million from a public offering of our common stock, both of which we received in July 2009. Upon the closing of such public offering, we were required to repay the first scheduled payment of \$10.0 million of the Deerfield loan. Other potential sources of near-term liquidity include (i) the partnering or out-licensing of our drug candidates, internal drug programs and technologies, (ii) equity, debt or other financing, (iii) the sale of facilities we own, and (iv) milestone payments from our collaborators. In addition, on or before June 17, 2011, Deerfield can make a one-time election to loan us up to an additional \$20.0 million under similar terms as the initial \$100.0 million loan. Although we will continue to be opportunistic in our efforts to obtain cash, we believe that our ability to obtain cash has been reduced based on ongoing uncertainties in the global economic market and our stock price. There is no guarantee that additional funding will be available or that, if available, such funding will be available on terms that we or our stockholders view as favorable.

We are prioritizing our available cash towards funding activities that support completing our lorcaserin Phase 3 program and filing an NDA for lorcaserin, which we expect to file by the end of 2009. In connection with such prioritization, we are deferring the initiation of any new clinical trials for our other programs in the near term, deferring certain costs related to lorcaserin that are non-essential to the initial commercialization of lorcaserin and continuing our cost-containment efforts. In June 2009, we completed a workforce reduction of approximately 130 employees, which we expect will result in annual operating cost savings of approximately \$25.0 million. Along with this workforce reduction, we decreased the number of our research programs as well as our planned activities. We will continue to monitor and evaluate the level of our research, development and manufacturing expenditures, and may further adjust such expenditures based upon a variety of factors, such as our available cash, our ability to obtain additional cash and partner programs, the results and progress in our clinical and earlier-stage programs, the time and costs related to clinical trials and regulatory decisions, as well as the global economic environment.

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Although most of the external expenses for our two pivotal Phase 3 lorcaserin trials have been expensed, we expect that our research and development expenditures will continue to be substantial for the balance of 2009 and 2010 as we continue our lorcaserin program

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**Table of Contents**

and select earlier-stage research and development programs. In addition to costs related to our ongoing lorcaserin BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus) trial and filing an NDA for lorcaserin, we expect to incur substantial manufacturing costs and other pre-launch costs for lorcaserin in 2010 and beyond whether we decide to market and commercialize lorcaserin independently or with a partner.

*Long term*

We will need to obtain substantial amounts of cash to achieve our objectives of internally developing drugs, which will take many years and potentially several hundreds of millions of dollars to develop. If we decide to market and commercialize lorcaserin or any other drug candidate independently or with a partner, we may need to invest heavily in associated manufacturing, marketing and commercialization costs. Such costs will be substantial and some will need to be incurred prior to receiving marketing approval. We do not currently have adequate internal liquidity to meet these objectives in the long term. To do so, we will need to continue our partnering activities and look to other external sources of liquidity, including the public and private financial markets and strategic partners.

The length of time that our current cash and cash equivalents, short-term investments and any available borrowings will sustain our operations will be based on, among other things, our prioritization decisions regarding funding for our programs, our progress in our clinical and earlier-stage programs, the time and costs related to current and future clinical trials and regulatory decisions, our research, development, manufacturing and commercialization costs (including personnel costs), the progress in our collaborations, costs associated with intellectual property, our capital expenditures, and costs associated with securing any in-licensing opportunities. We do not know whether adequate funding will be available to us or, if available, that such funding will be available on acceptable terms. Any significant shortfall in funding will result in additional curtailment of our development and/or research activities, which, in turn, will affect our development pipeline and ability to obtain cash in the future.

In addition to the public and private financial markets, potential sources of liquidity in the long term are milestone and royalty payments from existing and future collaborators and revenues from sales of any drugs we own. Another potential source of liquidity is an additional loan of up to \$20.0 million from Deerfield if they elect in their sole discretion to make this additional loan.

At September 30, 2009, the principal balance outstanding on the Deerfield loan was \$90.0 million. The remaining principal repayments on the Deerfield loan are scheduled as follows: \$20.0 million in July 2011, \$30.0 million in July 2012, and \$40.0 million in June 2013. At any time we may prepay any or all of the outstanding principal at par, and we may be required to make the scheduled repayments earlier in connection with certain equity issuances. In addition, we are required to make mandatory prepayments of the loan under certain circumstances.

We evaluate from time to time potential acquisitions and in-licensing and other opportunities. Any such transaction may impact our liquidity as well as affect our expenses if, for example, our operating expenses increase as a result of such license or acquisition or we use our cash to finance the license or acquisition. In January 2008, we entered into strategic cooperation agreements with Siegfried that are primarily related to the manufacturing of lorcaserin, and which are expected to be necessary for our planned NDA submission to the FDA and for commercialization of lorcaserin after regulatory marketing approval. We paid CHF 21.8 million, or \$19.6 million, of the cash purchase price in January 2008, and are scheduled to pay the remaining cash portion of the purchase price of CHF 10.0 million in three equal installments in the third, fourth and fifth years after closing.

*Sources and Uses of Our Cash*

Net cash used in operating activities was \$129.6 million during the nine months ended September 30, 2009, and primarily was used to fund our net losses in the period, adjusted for non-cash items. Non-cash items included \$8.3 million in depreciation and amortization expense, \$5.4 million in share-based compensation expense, a \$2.5 million loss on extinguishment of debt resulting from the \$10.0 million repayment on the Deerfield loan, \$3.5 million in accretion of debt discount on the Deerfield loan, \$1.7 million in amortization expense related to acquired technology and other intangibles, as well as changes in operating assets and liabilities. Net cash used in operating activities was \$148.6 million during the nine months ended September 30, 2008, and primarily was used to fund our net losses in the period, adjusted for non-cash expenses. Non-cash expenses included \$8.7 million in depreciation and amortization expense, \$6.1 million in share-based compensation, \$2.2 million in warrant settlement charges related to a disagreement with one of our Series B warrant holders, \$1.7 million in amortization of acquired technology and other intangibles, as well as changes in operating assets and liabilities. We expect net cash used in operating activities in 2009 will decrease significantly from the 2008 level as we completed our BLOOM and BLOSSOM trials, prioritize our spending towards activities that support filing an NDA for lorcaserin and realize expected operating cost savings from the workforce reduction we completed in June 2009.

Net cash of \$12.3 million was provided by investing activities during the nine months ended September 30, 2009, and was primarily attributable to net proceeds of \$15.7 million from our short-term investments, which were partially offset by \$3.7 million used for equipment and

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improvements to our facilities. Net cash of \$73.1 million was used in investing activities during the nine months ended September 30, 2008, and was primarily the result of net purchases of short-term investments of \$34.3 million, \$19.6 million used for the purchase of our drug product manufacturing and packaging facility in Switzerland and \$19.2 million used for equipment and improvements to our facilities. We expect that our capital expenditures in 2009 will be substantially less than in 2008 due to our ongoing cost-containment efforts.

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**Table of Contents**

Net cash provided by financing activities was \$166.5 million during the nine months ended September 30, 2009, and was primarily attributable to net financing proceeds of \$96.9 million from the issuance of a note and related financial instruments to Deerfield, net proceeds of \$49.7 million from the sale of 12,500,000 shares of common stock at \$4.17 per share, \$15.0 million in reimbursements for improvements made to one of our leased facilities and net proceeds of \$14.7 million from the sale of a total of 5,745,591 shares of common stock under our equity financing commitment with Azimuth. Such proceeds were partially offset by the \$10.0 million of principal repayment on the Deerfield loan. Net cash provided by financing activities was \$2.2 million during the nine months ended September 30, 2008, and was primarily attributable to net proceeds of \$1.4 million received from option exercises and purchases under our employee stock purchase plan and \$1.0 million in reimbursements for improvements made to one of our facilities.

**CRITICAL ACCOUNTING POLICIES AND MANAGEMENT ESTIMATES**

The SEC defines critical accounting policies as those that are, in management's view, important to the portrayal of our financial condition and results of operations and demanding of management's judgment. Our discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with US generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosures. We base our estimates on historical experience and on various assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ significantly from those estimates.

Our critical accounting policies include:

**Clinical trial expenses.** We accrue clinical trial expenses based on work performed. In determining the amount to accrue, we rely on estimates of total costs incurred based on the enrollment of subjects, the completion of trials and other events. We follow this method because we believe reasonably dependable estimates of the costs applicable to various stages of a clinical trial can be made. However, the actual costs and timing of clinical trials are highly uncertain, subject to risks and may change depending on a number of factors. Differences between the actual clinical trial costs and the estimated clinical trial costs that we have accrued in any prior period are recorded in the subsequent period in which the actual costs become known. Historically, these differences have not been material and we have not had to make material adjustments in the amounts recorded in a subsequent period; however, material differences could occur in the future.

**Derivative liabilities.** We account for our warrants and other derivative financial instruments as either equity or liabilities based upon the characteristics and provisions of each instrument. Warrants classified as equity are recorded as additional paid-in capital on the consolidated balance sheet and no further adjustments to their valuation are made. Some of our warrants were determined to be ineligible for equity classification because of provisions that may result in an adjustment to their exercise price. Derivative financial instruments that are considered freestanding or embedded, and warrants classified as derivative liabilities, are recorded on the consolidated balance sheet at their fair value on the date of issuance and are revalued on each subsequent balance sheet date until such instruments are fully exercised or expire, with any changes in the fair value between reporting periods recorded as other income or expense. We estimate the fair value of these liabilities using option pricing models that are based on the individual characteristics of the instruments or warrants on the valuation date, as well as assumptions for expected volatility, expected life and risk-free interest rate. Changes in the assumptions can have a material impact on the resulting fair value.

**Revenue recognition.** Some of our agreements contain upfront technology access fees, research funding, milestone achievements and royalties. Revenue from a milestone achievement is recognized when earned, as evidenced by acknowledgment from our collaborator, provided that (i) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement, (ii) the milestone represents the culmination of an earnings process, (iii) the milestone payment is non-refundable and (iv) our performance obligations after the milestone achievement will continue to be funded by our collaborator at a level comparable to the level before the milestone achievement. If all of these criteria are not met, the milestone achievement is recognized over the remaining minimum period of our performance obligations under the agreement. We defer non-refundable upfront fees under our collaborations and recognize them over the period in which we have significant involvement or perform services, using various factors specific to each collaboration. Amounts we receive for research funding for a specified number of full-time researchers are recognized as revenue as the services are performed. Advance payments we receive in excess of amounts earned are classified as deferred revenues until earned.

We manufacture drug products under a manufacturing services agreement for a single customer, Siegfried. Upon Siegfried's acceptance of drug products manufactured by us, we recognize manufacturing services revenues at agreed upon prices for such drug products. We have also contracted with Siegfried for them to provide us with administrative and other services in exchange for a fee paid to Siegfried. We determined that we are receiving an identifiable benefit for these services from Siegfried, and are recording such fees in the operating expense section of our consolidated statements of operations.



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## **Table of Contents**

**Share-based compensation.** We recognize compensation expense for all share-based awards based on the grant-date fair value, using the Black-Scholes option pricing model. The determination of the grant-date fair value of share-based awards using the Black-Scholes option pricing model is based on the exercise price of the award and the fair market value of our stock price on the date of grant, as well as assumptions for expected volatility, expected life of options granted and risk-free interest rate. Changes in the assumptions can have a material impact on the compensation expense we recognize. Expected volatility is based on a combination of 75% historical volatility of our common stock and 25% market-based implied volatilities from traded options on our common stock, with historical volatility being more heavily weighted due to the low volume of traded options on our common stock. The expected life of options granted is determined based on historical experience of similar awards, giving consideration to the contractual terms of the share-based awards, vesting schedules and post-vesting cancellations. The risk-free interest rates are based on the US Treasury yield curve, with a remaining term approximately equal to the expected term used in the option pricing model.

As compensation expense recognized is based on awards ultimately expected to vest, it is reduced for estimated forfeitures. We estimate forfeitures at the time of grant and revise such estimates, if necessary, in subsequent periods if actual forfeitures differ from those estimates. If actual forfeitures vary from estimates, we recognize the difference in compensation expense in the period the actual forfeitures occur or when options vest.

**Accounting for lease financing obligations.** We account for our sale and leaseback transactions using the financing method because our options to repurchase these properties in the future is considered continued involvement requiring such method. Under the financing method, the book value of the properties and related accumulated depreciation remain on our balance sheet and no sale is recognized. Instead, the sales price of the properties is recorded as a financing obligation, and a portion of each lease payment is recorded as interest expense. We estimated the borrowing rate that we use to impute interest expense on our lease payments.

*The above listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by GAAP. See our audited consolidated financial statements and notes thereto included in our 2008 Annual Report, which contain additional accounting policies and other disclosures required by GAAP.*

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

There have been no material changes from the information we included in this section of our annual report on Form 10-K for the year ended December 31, 2008.

### **Item 4. Controls and Procedures.**

Based on an evaluation carried out as of the end of the period covered by this quarterly report, under the supervision and with the participation of our management, including our Chief Executive Officer and Vice President, Finance and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, our Chief Executive Officer and Vice President, Finance and Chief Financial Officer have concluded that, as of the end of such period, our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934) were effective. There was no change in our internal control over financial reporting that occurred during the quarter covered by this quarterly report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **Item 1A. Risk Factors.** **RISK FACTORS**

*Investment in our stock involves a high degree of risk. You should consider carefully the risks described below, together with other information in this quarterly report on Form 10-Q and our other public filings, before making investment decisions regarding our stock. If any of the following events actually occur, our business, operating results, prospects or financial condition could be materially and adversely affected. This could cause the trading price of our common stock to decline and you may lose all or part of your investment. Moreover, the risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, operating results, prospects or financial condition.*



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*The risk factors set forth below with an asterisk (\*) before the title are new risk factors or risk factors containing substantive changes, including any material changes, from the risk factors previously disclosed in Item 1A to Part I of our annual report on Form 10-K for the year ended December 31, 2008, as filed with the Securities and Exchange Commission.*

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## **Table of Contents**

### ***Risks Relating to Our Business***

**\*We will need additional funds to conduct our planned research and development efforts, we may not be able to obtain such funds and may never become profitable.**

We have accumulated a large deficit since inception that has primarily resulted from the significant research and development expenditures we have made in seeking to identify and validate new drug targets and develop compounds that could become marketed drugs. We expect that our losses will continue to be substantial for at least the short term and that our operating expenses will also continue to be substantial, even if we or our collaborators are successful in advancing our compounds or partnered compounds.

We do not have any commercially available drugs, and we have substantially less money than we need to develop our compounds into marketed drugs. It takes many years and potentially hundreds of millions of dollars to successfully develop a preclinical or early clinical compound into a marketed drug, and our efforts may not result in any marketed drugs.

We will need additional funds or a partner to bring our most advanced drug candidate, lorcaserin, to market, if ever, and we may not be able to secure adequate funding or find an acceptable partner at all or on terms you or we believe are favorable. We also believe that due to global economic challenges, and as our cash balances decline, it may be difficult for us to obtain additional financing or enter into strategic relationships on terms acceptable to us, if at all. If additional funding is not available, we will have to eliminate or further postpone or scale back some or all of our research or development programs or delay the development of one or more of such programs, including our lorcaserin program.

**The current global economic environment poses severe challenges to our business strategy, which relies on access to capital from the markets and our collaborators, and creates other financial risks for us.**

The global economy, including credit markets and the financial services industry, has been experiencing a period of substantial turmoil and uncertainty. These conditions have generally made equity and debt financing more difficult to obtain, and may negatively impact our ability to complete financing transactions. The duration and severity of these conditions is uncertain, as is the extent to which they may adversely affect our business and the business of current and prospective collaborators and vendors. If the global economy does not improve or worsens, we may be unable to secure additional funding to sustain our operations or to find suitable partners to advance our internal programs, even if we receive positive results from our research and development or business development efforts.

We maintain a portfolio of investments in marketable debt securities which are recorded at fair value. Although we have established investment guidelines relative to diversification and maturity with the objectives of maintaining safety of principal and liquidity, credit rating agencies may reduce the credit quality of our individual holdings which could adversely affect their value. Lower credit quality and other market events, such as changes in interest rates and further deterioration in the credit markets, may have an adverse effect on the fair value of our investment holdings and cash position.

**We are focusing our activities and resources on the development of lorcaserin and depend on its success.**

We are focusing our near-term research and development activities and resources on lorcaserin, and we believe a significant portion of the value of our company relates to our ability to develop this drug candidate. The development of lorcaserin is subject to many risks, including the risks discussed in other risk factors. If the results of clinical trials and preclinical studies of lorcaserin, the regulatory decisions affecting lorcaserin, the anticipated or actual timing and plan for commercializing lorcaserin, or, ultimately, the market acceptance of lorcaserin do not meet our, your, analysts' or others' expectations, the market price of our common stock could decline significantly.

**\*Our stock price could decline significantly based on the results and timing of clinical trials and preclinical studies of, and decisions affecting, our most advanced drug candidates.**

The results and timing of clinical trials and preclinical studies can affect our stock price. Preclinical studies include experiments performed in test tubes, in animals, or in cells or tissues from humans or animals. These studies include all drug studies except those conducted in human subjects, and may occur before or after initiation of clinical trials for a particular compound. Results of clinical trials and preclinical studies of lorcaserin or our other drug candidates may not be viewed favorably by us or third parties, including investors, analysts, potential collaborators, the academic and medical communities, and regulators. The same may be true of how we design the development programs of our most advanced drug candidates and regulatory decisions (including by us or regulatory authorities) affecting those development programs. Biotechnology company stock prices have declined significantly when such results and decisions were unfavorable or perceived negatively or when a drug candidate did not otherwise meet expectations.

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We have drug programs that are currently in clinical trials. In addition to successfully completing clinical trials, to conduct long-term clinical trials and gain regulatory approval to commercialize drug candidates, regulatory authorities require that all drug candidates complete short- and long-term preclinical toxicity and carcinogenicity studies. These preclinical, animal studies are required to help

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**Table of Contents**

us and regulatory authorities assess the potential risk that drug candidates may be toxic or cause cancer in humans. The results of clinical trials and preclinical studies are uncertain and subject to different interpretations, and the design of these trials and studies (which may change significantly and be more expensive than anticipated depending on results and regulatory decisions) may also be viewed negatively by us, regulatory authorities or other third parties and adversely impact the development and opportunities for regulatory approval and commercialization of our and our partnered drug candidates. We may not be successful in advancing our programs on our projected timetable, if at all. Failure to initiate or delays in the development programs for any of our drug candidates, or unfavorable results or decisions or negative perceptions regarding any of such programs, could cause our stock price to decline significantly. This is particularly the case with respect to lorcaserin.

**\*We have significant indebtedness and debt service obligations as a result of our \$100 million secured loan, which may adversely affect our cash flow, cash position and stock price.**

We substantially increased our total debt and debt service obligations when we received a \$100.0 million loan from Deerfield on July 6, 2009. This loan matures on June 17, 2013, and the outstanding principal accrues interest at a rate of 7.75% per annum on the stated principal balance, payable quarterly in arrears. The schedule of our required principal repayments is as follows: \$10.0 million in July 2010, \$20.0 million in July 2011, \$30.0 million in July 2012, and \$40 million at maturity. We may be required to make the scheduled repayments earlier in connection with certain equity issuances. For example, we were required to make the first scheduled repayment of \$10.0 million in connection with the closing of our July 2009 public offering. In addition, we are required to make mandatory prepayments of the loan upon certain changes of control and in the event we issue equity securities (other than certain exempted issuances) at a price of less than \$2.00 per share.

On or before June 17, 2011, the lenders may elect to provide us with an additional loan in a principal amount of up to \$20.0 million under similar terms as the \$100.0 million loan, with the additional loan also maturing on June 17, 2013.

In the future, if we are unable to generate cash from operations sufficient to meet these debt obligations, we will need to obtain additional funds from other sources, which may include one or more financings. However, we may be unable to obtain sufficient additional funds when we need them, on favorable terms or at all. The sale of equity or convertible debt securities in the future may be dilutive to our stockholders, and debt-financing arrangements may require us to enter into covenants that would restrict certain business activities or our ability to incur further indebtedness, and may contain other terms that are not favorable to our stockholders or us.

Also, if we are unable to generate cash from operations or obtain additional funds from other sources sufficient to meet these debt obligations, or we need to use existing cash to fund these debt obligations, we may have to delay or curtail some or all of our research, development and commercialization programs or sell or license some or all of our assets. Our indebtedness could have significant additional negative consequences, including, without limitation:

increasing our vulnerability to general adverse economic conditions;

limiting our ability to obtain additional funds; and

placing us at a possible competitive disadvantage to less leveraged competitors and competitors that have better access to capital resources.

If an event of default occurs under our loan documents, including in certain circumstances the warrants issued in connection with the loan transaction, the lenders may declare the outstanding principal balance and accrued but unpaid interest owed to them immediately due and payable, which would have a material adverse affect on our financial position. We may not have sufficient cash to satisfy this obligation. Also, if a default occurs under our \$100.0 million loan, and we are unable to repay the lenders, the lenders could seek to enforce their rights under their security interests in substantially all of our assets. If this were to happen, we may lose some or all of our assets in order to satisfy our debt, which could cause our business to fail.

**\*If we do not partner one or more unpartnered programs or raise additional funds, we may have to further curtail our activities.**

In light of our financial resources, we decreased the number of our US employees in June 2009 by approximately 31% in a workforce reduction. We also are focusing our near-term research and development efforts on our lorcaserin Phase 3 program and select earlier-stage preclinical and

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research programs. While we believe this strategy will conserve resources, our ability to advance our drug candidate pipeline outside of lorcaserin will be limited. Without additional capital or funding from partners, we will need to significantly curtail some of our planned activities and expenditures. Any such further reductions may adversely impact our lorcaserin development and commercialization timeline or narrow or slow the development of our pipeline, which we believe would reduce our opportunities for success. Our decision to limit near-term development of drug candidates other than lorcaserin will likely extend the time it will take us to reach the market in these other therapeutic areas and may allow competing products to reach the market before our drug candidates.

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**Table of Contents**

**\*Our development of lorcaserin may be adversely impacted by cardiovascular side effects previously associated with fenfluramine and dexfenfluramine.**

We have developed lorcaserin to more selectively stimulate the serotonin 2C receptor because we believe this may avoid the cardiovascular side effects associated with fenfluramine and dexfenfluramine (often used in combination with phentermine, the combination of which was commonly referred to as fen-phen). These two drugs were serotonin-releasing agents and non-selective serotonin receptor agonists, and were withdrawn from the market in 1997 after reported incidences of heart valve disease and pulmonary hypertension associated with their usage. We may not be correct in our belief that selectively stimulating the serotonin 2C receptor will avoid these undesired side effects or lorcaserin's selectivity profile may not be adequate to avoid these side effects. Moreover, the potential relationship between the activity of lorcaserin and the activity of fenfluramine and dexfenfluramine may result in increased US Food and Drug Administration, or FDA, regulatory scrutiny of the safety of lorcaserin and may raise potential adverse publicity in the marketplace, which could affect clinical enrollment or sales if lorcaserin is approved for commercialization. We have completed two large pivotal lorcaserin trials of one and two years' duration, both of which showed no apparent effects on heart valves or pulmonary artery pressures, but these results will need to be reviewed by the FDA.

**\*The development programs for our drug candidates are expensive, time consuming, uncertain and susceptible to change, interruption, delay or termination.**

Drug development programs are very expensive, time consuming and difficult to design and implement. Our drug candidates are in various stages of research and development and are prone to the risks of failure inherent in drug development. Clinical trials and preclinical studies are needed to demonstrate that drug candidates are safe and effective to the satisfaction of the FDA and similar non-US regulatory authorities. These trials are expensive and uncertain processes that take years to complete. Failure can occur at any stage of the process, and successful early clinical or preclinical trials do not ensure that later trials or studies will be successful. In addition, the commencement or completion of our planned clinical trials could be substantially delayed or prevented by several factors, including:

limited number of, and competition for, suitable patients required for enrollment in our clinical trials;

limited number of, and competition for, suitable sites to conduct our clinical trials;

delay or failure to obtain FDA approval or agreement to commence a clinical trial;

delay or failure to obtain sufficient supplies of our drug candidates for our clinical trials;

delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or investigators; and

delay or failure to obtain institutional review board, or IRB, approval to conduct a clinical trial at a prospective site.

Even if the results of our development programs are favorable, the development programs of our most advanced drug candidates, including those being developed by our collaborators, may take significantly longer than expected to complete. In addition, the FDA, other regulatory authorities, our collaborators, or we may suspend, delay or terminate our development programs at any time for various reasons, including:

lack of effectiveness of any drug candidate during clinical trials;

side effects experienced by study participants or other safety issues;

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slower than expected rates of patient recruitment and enrollment or lower than expected patient retention rates;

delays or inability to manufacture or obtain sufficient quantities of materials for use in clinical trials;

inadequacy of or changes in our manufacturing process or compound formulation;

delays in obtaining regulatory approvals to commence a study, or clinical holds, or delays requiring suspension or termination of a study by a regulatory authority, such as the FDA, after a study is commenced;

changes in applicable regulatory policies and regulations;

delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;

## Table of Contents

uncertainty regarding proper dosing;

unfavorable results from ongoing clinical trials and preclinical studies;

failure of our clinical research organizations to comply with all regulatory and contractual requirements or otherwise perform their services in a timely or acceptable manner;

scheduling conflicts with participating clinicians and clinical institutions;

failure to design appropriate clinical trial protocols;

insufficient data to support regulatory approval;

termination of clinical trials by one or more clinical trial sites;

inability or unwillingness of medical investigators to follow our clinical protocols;

difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data; or

lack of sufficient funding to continue clinical trials and preclinical studies.

There is typically a high rate of attrition from the failure of drug candidates proceeding through clinical trials, and many companies have experienced significant setbacks in advanced development programs even after promising results in earlier studies or trials. For example, because our drug candidate for insomnia, APD125, did not meet the primary or secondary endpoints of a Phase 2b clinical trial, we are not planning any further clinical development of APD125. We have experienced setbacks in other development programs and may experience additional setbacks in the future. If we or our collaborators abandon or are delayed in our development efforts related to lorcasein or any other drug candidate, we may not be able to generate sufficient revenues to continue our operations at the current level or become profitable, our reputation in the industry and in the investment community would likely be significantly damaged, additional funding may not be available to us or may not be available on terms you or we believe are favorable, and our stock price would likely decrease significantly.

**\*Our drug candidates are subject to extensive regulation, and we may not receive required regulatory approvals, or timely approvals, for any of our drug candidates.**

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, marketing and distribution, and other possible activities relating to our drug candidates are, and any resulting drugs will be, subject to extensive regulation by the FDA and other regulatory agencies in the United States. Neither our collaborators nor we are permitted to market our drug candidates in the United States until we receive regulatory approval from the FDA. Neither our collaborators nor we have received marketing approval for any of our drug candidates. Specific preclinical data, chemistry, manufacturing and controls data, a proposed clinical trial protocol and other information must be submitted to the FDA as part of an investigational new drug, or IND, application, and clinical trials may commence only after the IND application becomes effective. To market a new drug in the United States, we must submit to the FDA and obtain FDA approval of a New Drug Application, or NDA. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls to demonstrate the safety and effectiveness of the drug candidate.

Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. As part of the Prescription Drug User Fee Act, or PDUFA, the FDA has a goal to review and act on a percentage of all submissions in a given time frame. The general review goal for a drug application is 10 months for a standard application and six months for priority review. The FDA has missed a portion of their PDUFA goals, and it is unknown



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whether the review of an NDA filing for lorcaserin, or for any of our other drug candidates, will be completed within the FDA review goals or will be delayed. Moreover, the duration of the FDA's review may depend on the number and type of other NDAs that are filed with the FDA around the same time period. For example, we believe that at least two companies are planning to file an NDA for a drug candidate for weight management at around the time we expect the FDA will review our NDA for lorcaserin, which may impact the review of our NDA. Furthermore, any drug that acts on the central nervous system, or CNS, such as lorcaserin, has the potential to be scheduled as a controlled substance by the Drug Enforcement Administration of the US Department of Justice, or DEA. DEA scheduling is an independent process that can delay drug launch beyond an NDA approval date.

**Table of Contents**

In addition, failure to comply with FDA and other applicable regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions, including:

Form 483 notices and Warning Letters;

civil and criminal penalties;

injunctions;

withdrawal of approved products;

product seizure or detention;

product recalls;

total or partial suspension of production;

imposition of restrictions on operations, including costly new manufacturing requirements; and

refusal to approve pending NDAs or supplements to approved NDAs.

Regulatory approval of an NDA or NDA supplement is not guaranteed. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to target and the regulations applicable to any particular drug candidate. The FDA can delay, limit or deny approval of a drug candidate for many reasons, including:

a drug candidate may not be deemed adequately safe and effective;

FDA officials may not find the data from preclinical studies and clinical trials sufficient;

the FDA may not approve the manufacturing processes or facilities;

the FDA may change its approval policies or adopt new regulations; or

the FDA may not accept our NDA submission (which is expected to be electronic) due to, among other reasons, the formatting of the submission.

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We do not expect any drugs resulting from our research and development efforts to be commercially available until at least late 2010. We have not previously filed NDAs with the FDA, either by paper or electronically. This lack of corporate experience may impede our ability to successfully complete these trials and obtain FDA approval in a timely manner, if at all, for our drug candidates for which development and commercialization is our responsibility. Even if we believe that data collected from our preclinical studies and clinical trials of our drug candidates are promising and that our information and procedures regarding chemistry, manufacturing and controls are sufficient, our data may not be sufficient to support approval by the FDA or any other United States or foreign regulatory authority. In addition, we believe that the regulatory review of NDAs for drug candidates intended for widespread use by a large proportion of the general population is becoming increasingly focused on safety. In this regard, it is possible that some of our drug candidates, including lorcaserin, will be subject to increased scrutiny to show adequate safety than would drug candidates for more acute or life-threatening diseases such as cancer. Even if approved, drug candidates may not be approved for all indications requested and such approval may be subject to limitations on the indicated uses for which the drug may be marketed. Our business and reputation may be harmed by any failure or significant delay in receiving regulatory approval for the sale of any drugs resulting from our drug candidates. As a result, we cannot predict when or whether regulatory approval will be obtained for any drug we develop.

To market any drugs outside of the United States, we and our collaborators must comply with numerous and varying regulatory requirements of other countries. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects associated with regulatory approval in the United States, including the risk that our drug candidates may not be approved for all indications requested and that such approval may be subject to limitations on the indicated uses for which the drug may be marketed.

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## **Table of Contents**

**\*The results of preclinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidates may not have favorable results in later studies or trials.**

Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate's side effects at various doses and schedules. To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our drug candidates, except lorcaserin. Favorable results in our early studies or trials may not be repeated in later studies or trials, including continuing preclinical studies and large-scale clinical trials, and our drug candidates in later-stage trials may fail to show desired safety and efficacy despite having progressed through earlier-stage trials. Unfavorable results from ongoing preclinical studies or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials, or abandonment of a clinical program. Preclinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated, or a clinical program to be abandoned. In addition, we may report top-line data from time to time, which is based on a preliminary analysis of key efficacy and safety data, and is subject to change following a more comprehensive review of the data related to the applicable clinical trial.

**Many of our research and development programs are in early stages of development, and may not result in the commencement of clinical trials.**

Many of our research and development programs are in the discovery or preclinical stage of development. The process of discovering compounds with therapeutic potential is expensive, time consuming and unpredictable. Similarly, the process of conducting preclinical studies of compounds that we discover requires the commitment of a substantial amount of our technical and financial resources and personnel. We may not discover additional compounds with therapeutic potential, and any of the compounds for which we are conducting preclinical studies may not result in the commencement of clinical trials. We cannot be certain that results sufficiently favorable to justify commencement of Phase 1 clinical trials will be obtained in these preclinical investigations. Even if such favorable preclinical results are obtained, our financial resources may not allow us to commence Phase 1 clinical trials. If we are unable to identify and develop new drug candidates, we may not be able to maintain a clinical development pipeline or generate revenues.

**\*Our revenues, for at least the short term, depend upon the actions of our collaborators and our ability to enter into new collaborations.**

We expect that, for at least the short term, our ability to generate significant revenues will depend upon the success of our existing collaborations and our ability to enter into new collaborations. Future revenues from our collaborations with Merck and Ortho-McNeil-Janssen will depend on, in addition to patent reimbursements, milestone and royalty payments, if any. Thus, we will receive little additional revenues from our existing collaborators if our own or our collaborators' research, development or, ultimately, marketing efforts are unsuccessful.

Typically, our collaborators (and not us) control the development of partnered compounds into drugs after we have met early preclinical scientific milestones. In addition, we may not have complete access to information about the results and status of our collaborators' clinical trials and regulatory programs and strategies. We are not entitled to the more significant milestone payments under our agreements until our collaborators have advanced compounds in clinical testing. Our partners may not devote adequate resources to the development of our compounds and may not develop or implement a successful clinical or regulatory strategy. We cannot guarantee that any development, approval or sales milestones in our existing or future collaborations will be achieved in the future, or that we will receive any payments for the achievement of any milestones. In addition, our existing collaborations, including our collaborations with Merck and Ortho-McNeil-Janssen, may be terminated early in certain circumstances, in which case we may not receive future milestone or royalty payments or patent reimbursements.

Moreover, our ability to enter into new collaborations depends on the outcomes of our preclinical and clinical testing. We do not control these outcomes. In addition, even if our testing is successful, pharmaceutical companies may not partner with us on terms that we believe are acceptable until we have advanced our drug candidates into the clinic and, possibly, through later-stage clinical trials, if at all.

**\*We may participate in new partnerships and other strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.**

From time to time we consider strategic transactions, such as out-licensing or in-licensing of compounds or technologies, acquisitions of companies and asset purchases. Additional potential transactions we may consider include a variety of different business arrangements, including strategic partnerships, joint ventures, spin-offs, restructurings, divestitures, business combinations and investments. In addition, another entity may pursue us as an acquisition target. Any such transactions may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges, require additional expertise or disrupt our management or

business, which could harm our operations and financial results.

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## **Table of Contents**

As part of an effort to enter into significant transactions, we conduct business, legal and financial due diligence with the goal of identifying and evaluating material risks involved in the transaction. Despite our efforts, we ultimately may be unsuccessful in ascertaining or evaluating all such risks and, as a result, might not realize the intended advantages of the transaction. If we fail to realize the expected benefits from any transaction we may consummate, whether as a result of unidentified risks, integration difficulties, regulatory setbacks or other events, our business, results of operations and financial condition could be adversely affected.

**Drug discovery and development is intensely competitive in the therapeutic areas on which we focus. If our competitors develop treatments that are approved faster, marketed better, less expensive or demonstrated to be more effective or safer than our drug candidates, our commercial opportunities will be reduced or eliminated.**

We focus our efforts on GPCRs. Because GPCRs are an important target class for drug discovery efforts, we believe that many pharmaceutical and biotechnology companies and other organizations have internal drug discovery programs focused on GPCRs.

Many of the drugs that our collaborators or we are attempting to discover and develop would compete with existing therapies. In addition, many companies are pursuing the development of new drugs that target the same diseases and conditions that we target. Many of our competitors, particularly large pharmaceutical companies, have substantially greater research, development and marketing capabilities and greater financial, scientific and human resources than we do. Companies that complete clinical trials, obtain required regulatory agency approvals and commence commercial sale of their drugs before we do for the same indication may achieve a significant competitive advantage, including certain patent and FDA marketing exclusivity rights. In addition, our competitors may develop drugs with fewer side effects, more desirable characteristics (such as route of administration or frequency of dosing) or better efficacy than our drug candidates or drugs, if any, for the same indication. Our competitors may also market generic or other drugs that compete with our drugs at a lower price than our drugs, which may negatively impact our drug sales, if any. Any results from our research and development efforts, or from our joint efforts with our existing or any future collaborators, may not compete successfully with existing or newly discovered products or therapies.

**Collaborative relationships may lead to disputes and delays in drug development and commercialization.**

We have had conflicts with collaborators and may in the future have conflicts with our prospective, current or past collaborators, such as conflicts concerning the interpretation of preclinical or clinical data, the achievement of milestones, or the ownership of intellectual property. Our collaborators may stop supporting our drug candidates if they develop or obtain rights to competing drug candidates or drugs. If any conflicts arise with Ortho-McNeil-Janssen, Merck or any other prospective, current or past collaborator, such collaborator may act in a manner that is adverse to our interests. Any such disagreement could result in one or more of the following, each of which could delay, or lead to termination of, development or commercialization of our partnered drug candidates, and in turn prevent us from generating revenues:

unwillingness on the part of a collaborator to pay us research funding, milestone payments or royalties that we believe are due to us under a collaboration;

uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations;

unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities;

slowing or cessation of a collaborator's development or commercialization efforts with respect to our drug candidates; or

litigation or arbitration.

**Setbacks and consolidation in the pharmaceutical and biotechnology industries, and our or our collaborators' inability to obtain third-party coverage and adequate reimbursement, could make partnering more difficult and diminish our revenues.**

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Setbacks in the pharmaceutical and biotechnology industries, such as those caused by safety concerns relating to high-profile drugs like Avandia, Vioxx and Celebrex, or drug candidates, as well as competition from generic drugs, litigation, and industry consolidation, may have an adverse effect on us. For example, pharmaceutical companies may be less willing to enter into new collaborations or continue existing collaborations if they are integrating a new operation as a result of a merger or acquisition or if their therapeutic areas of focus change following a merger. Moreover, our and our collaborators' ability to commercialize any of our drugs that may be approved will depend in part on government regulation and the availability of coverage and adequate reimbursement from third-party payers, including private health insurers and government payers, such as the Medicaid and Medicare programs, increases in government-run, single-payer health insurance plans and compulsory licenses of drugs. Government and third-party payers are increasingly attempting to contain healthcare costs by limiting coverage and reimbursement levels for new drugs. Given the continuing discussion regarding the cost of healthcare, managed care, universal healthcare coverage and other healthcare

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**Table of Contents**

issues, we cannot predict with certainty what additional healthcare initiatives, if any, will be implemented or the effect any future legislation or regulation will have on our business. These efforts may limit our commercial opportunities by reducing the amount a potential collaborator is willing to pay to license our programs or drug candidates in the future due to a reduction in the potential revenues from drug sales. Moreover, legislation and regulations affecting the pricing of pharmaceuticals may change before regulatory agencies approve our drug candidates for marketing. Adoption of such legislation and regulations could further limit pricing approvals for, and reimbursement of, drugs. A government or third-party payer decision not to approve pricing for, or provide adequate coverage and reimbursements of, our drugs, if any, could limit market acceptance of such drugs.

**We rely on third parties to conduct our clinical trials and many of our preclinical studies. If those parties do not successfully carry out their contractual duties or meet expected deadlines, our drug candidates may not advance in a timely manner or at all.**

In the course of our discovery, preclinical testing and clinical trials, we rely on third parties, including laboratories, investigators, clinical research organizations and manufacturers, to perform critical services for us. For example, we rely on third parties to conduct our clinical trials and many of our preclinical studies. Clinical research organizations are responsible for many aspects of the trials, including finding and enrolling subjects for testing and administering the trials. Although we rely on these third parties to conduct our clinical trials, we are responsible for ensuring that each of our clinical trials is conducted in accordance with its investigational plan and protocol. Moreover, the FDA and foreign regulatory authorities require us to comply with regulations and standards, commonly referred to as good clinical practices, or GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. Our reliance on third parties does not relieve us of these responsibilities and requirements. These third parties may not be available when we need them or, if they are available, may not comply with all regulatory and contractual requirements or may not otherwise perform their services in a timely or acceptable manner, and we may need to enter into new arrangements with alternative third parties and our clinical trials may be extended, delayed or terminated. These independent third parties may also have relationships with other commercial entities, some of which may compete with us. In addition, if such third parties fail to perform their obligations in compliance with our clinical trial protocols or GCPs, our clinical trials may not meet regulatory requirements or may need to be repeated. As a result of our dependence on third parties, we may face delays or failures outside of our direct control. These risks also apply to the development activities of our collaborators, and we do not control our collaborators' research and development, clinical trials or regulatory activities. We do not expect any drugs resulting from our collaborators' research and development efforts to be commercially available for many years, if ever.

**\*We rely on third-party manufacturers and we or such third parties may encounter failures or difficulties that could delay the clinical development or regulatory approval of our drug candidates, or their ultimate commercial production if approved.**

We and third parties manufacture our drug candidates. We do not have manufacturing facilities that can produce sufficient quantities of drug candidates for large-scale clinical trials. Accordingly, we must either develop such facilities, which will require substantial additional funds, or rely, at least to some extent, on third-party manufacturers for the production of drug candidates. Furthermore, should we obtain FDA approval for any of our drug candidates, we expect to rely, at least to some extent, on third-party manufacturers for commercial production. Our dependence on others for the manufacture of our drug candidates may adversely affect our ability to develop and deliver such drug candidates on a timely and competitive basis.

Any performance failure on the part of us or a third-party manufacturer could delay clinical development, regulatory approval or, ultimately, sales of our drug candidates. We or third-party manufacturers may encounter difficulties involving production yields, regulatory compliance, lot release, quality control and quality assurance, as well as shortages of qualified personnel. Approval of our drug candidates could be delayed, limited or denied if the FDA does not approve our or a third-party manufacturer's processes or facilities. Moreover, the ability to adequately and timely manufacture and supply drug candidates is dependent on the uninterrupted and efficient operation of the manufacturing facilities, which is impacted by many manufacturing variables including:

availability or contamination of raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier;

capacity of our facilities or those of our contract manufacturers;

facility contamination by microorganisms or viruses or cross contamination;



compliance with regulatory requirements, including Form 483 notices and Warning Letters;

changes in forecasts of future demand;

timing and actual number of production runs;

production success rates and bulk drug yields; and

timing and outcome of product quality testing.

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## **Table of Contents**

In addition, we or our third-party manufacturers may encounter delays and problems in manufacturing our drug candidates or drugs for a variety of reasons, including accidents during operation, failure of equipment, delays in receiving materials, natural or other disasters, political or governmental changes, or other factors inherent in operating complex manufacturing facilities. Supply chain management is complex. Commercially available starting materials, reagents and excipients may become scarce or more expensive to procure, and we may not be able to obtain favorable terms in agreements with subcontractors. We or our third-party manufacturers may not be able to operate our respective manufacturing facilities in a cost-effective manner or in a time frame that is consistent with our expected future manufacturing needs. If we or our third-party manufacturers cease or interrupt production or if our third-party manufacturers and other service providers fail to supply materials, products or services to us for any reason, such interruption could delay progress on our programs, or interrupt the commercial supply, with the potential for additional costs and lost revenues. If this were to occur, we may also need to seek alternative means to fulfill our manufacturing needs.

We may not be able to enter into agreements for the manufacture of our drug candidates with manufacturers whose facilities and procedures comply with applicable law. Manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the DEA and corresponding state and foreign authorities to ensure strict compliance with current Good Manufacturing Practices, or cGMPs, and other applicable government regulations and corresponding foreign standards. We do not have control over a third-party manufacturer's compliance with these regulations and standards. In addition, our Swiss subsidiary, Arena Pharmaceuticals GmbH, or Arena GmbH, has contracted with Siegfried to provide safety, health and environmental services and assess compliance, train personnel and oversee Arena GmbH's compliance with the applicable safety, health and environmental regulations. We are, therefore, relying at least in part on Siegfried's judgment, experience and expertise. If we or one of our manufacturers fail to maintain compliance, we or they could be subject to civil or criminal penalties, the production of our drug candidates could be interrupted or suspended, or our product could be recalled or withdrawn, resulting in delays, additional costs and potentially lost revenues.

**\*Our efforts will be seriously jeopardized if we are unable to retain and attract key employees.**

Our success depends on the continued contributions of our principal management, development and scientific personnel, and the ability to hire and retain key personnel, particularly in the area of clinical development. We face competition for such personnel. The loss of services of any principal member of our management or scientific staff or other key personnel, particularly Jack Lief, our Chairman, President and Chief Executive Officer, and Dominic P. Behan, Ph.D., our Senior Vice President and Chief Scientific Officer, could adversely impact our operations and ability to raise additional capital. To our knowledge, neither Mr. Lief nor Dr. Behan plans to leave, retire or otherwise disassociate with us in the near future.

**We may incur substantial liabilities from any product liability claims if our insurance coverage for those claims is inadequate.**

We develop, test and manufacture drugs that are used by humans. We face an inherent risk of product liability exposure related to the testing of our drug candidates in clinical trials, and will face an even greater risk if we sell our own drugs commercially. An individual may bring a liability claim against us if one of our drug candidates or drugs causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against a product liability claim, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

decreased demand for our drug;

injury to our reputation;

withdrawal of clinical trial subjects;

costs of related litigation;

substantial monetary awards to subjects or other claimants;

loss of revenues; and

the inability to commercialize our drug candidates.

We have limited product liability insurance that covers our clinical trials. We intend to expand our insurance coverage to include the sale of drugs if marketing approval is obtained for any of our drug candidates. However, insurance coverage is increasingly expensive. We may not be able to obtain or maintain insurance coverage at a reasonable cost, and we may not have insurance coverage that will be adequate to satisfy any liability that may arise.

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## **Table of Contents**

Damages awarded in a product liability action could be substantial and could have a negative impact on our financial condition. Whether or not we were ultimately successful in product liability litigation, such litigation would consume substantial amounts of our financial and managerial resources, and might result in adverse publicity, all of which would impair our business.

### **Even if any of our drug candidates receives regulatory approval, our drug candidates will still be subject to extensive post-marketing regulation.**

If we or our collaborators receive regulatory approval for our drug candidates in the United States or other jurisdictions, we will also be subject to ongoing obligations and continued regulatory review from the FDA and other applicable regulatory agencies, such as continued adverse event reporting requirements. We may also be subject to additional FDA post-marketing obligations, all of which may result in significant expense and limit our ability to commercialize such drugs in the United States or other jurisdictions.

If any of our drug candidates receive US regulatory approval or approval in other jurisdictions, the FDA or other regulatory agencies may still impose significant restrictions on the indicated uses for which such drugs may be marketed or impose ongoing requirements for potentially costly post-approval studies. If the FDA or other regulatory agencies approve any of our drug candidates, the labeling, packaging, adverse event reporting, storage, advertising and promotion for the drug will be subject to extensive regulatory requirements. We and the manufacturers of our products are also required to comply with cGMP regulations, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory agencies must approve these manufacturing facilities before they can be used to manufacture our products, and these facilities are subject to ongoing regulatory inspections. In addition, regulatory agencies subject a drug, its manufacturer and the manufacturer's facilities to continual review and inspections. The subsequent discovery of previously unknown problems with a drug, including adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured, may result in restrictions on the marketing of that drug, up to and including withdrawal of the drug from the market. In the United States, the DEA and comparable state-level agencies also heavily regulate the manufacturing, holding, processing, security, recordkeeping and distribution of drugs that are considered controlled substances. If any of our drug candidates are scheduled by the DEA as controlled substances (due to abuse potential), we will become subject to the DEA's regulations. The DEA periodically inspects facilities for compliance with its rules and regulations. If our manufacturing facilities or those of our suppliers fail to comply with applicable regulatory requirements, it could result in regulatory action and additional costs to us. Failure to comply with applicable FDA and other regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions, including:

issuance of Form 483 notices or Warning Letters by the FDA or other regulatory agencies;

imposition of fines and other civil penalties;

criminal prosecutions;

injunctions, suspensions or revocations of regulatory approvals;

suspension of any ongoing clinical trials;

total or partial suspension of manufacturing;

delays in commercialization;

refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our collaborators;

refusals to permit drugs to be imported into or exported from the United States;

restrictions on operations, including costly new manufacturing requirements; and

product recalls or seizures.

The FDA's and other regulatory agencies' policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our drug candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we might not be permitted to market our drugs and our business could suffer.

## **Table of Contents**

**Even if we receive regulatory approval to commercialize our drug candidates, our ability to generate revenues from any resulting products will be subject to a variety of risks, many of which are out of our control.**

Even if our drug candidates obtain regulatory approval, resulting products may not gain market acceptance among physicians, patients, healthcare payers or the medical community. We believe that the degree of market acceptance and our ability to generate revenues from such products will depend on a number of factors, including:

timing of market introduction of competitive drugs;

efficacy and safety of our drug candidates;

prevalence and severity of any side effects;

potential or perceived advantages or disadvantages over alternative treatments;

strength of sales, marketing and distribution support;

price of our future products, both in absolute terms and relative to alternative treatments;

the effect of current and future healthcare laws on our drug candidates;

availability of coverage and reimbursement from government and other third-party payers; and

product labeling or product insert requirements of the FDA or other regulatory authorities.

If our approved drugs, if any, fail to achieve market acceptance, we may not be able to generate significant revenue to achieve or sustain profitability.

In addition, lorcaserin is being assessed for drug abuse potential. If lorcaserin is approved for marketing, regulatory authorities may determine that lorcaserin will be a scheduled drug if it is found to have abuse potential or for other reasons. If lorcaserin were scheduled as a controlled substance by the DEA, we would expect it would be a schedule IV or V drug, which we believe would have little or no impact on our ability to commercialize lorcaserin. However, if lorcaserin were scheduled in a more tightly controlled category, such scheduling could negatively impact the ability to prescribe lorcaserin, a patient's willingness to use it and other aspects of our ability to commercialize it.

**\*We may not be able to effectively integrate or manage our international operations and such difficulty could adversely affect our stock price, business operations, financial condition and results of operations.**

In January 2008, we purchased from Siegfried certain drug product facility assets, including a licensed production facility, fixtures, equipment, other personal property and real estate assets and acquired employees in Zofingen, Switzerland. There are significant risks associated with the establishment of foreign operations, including, but not limited to, compliance with local laws and regulations, the protection of our intellectual property, the ability to integrate our corporate culture with local customs and cultures, the distraction to our management and foreign currency exchange rates and the impact of shifts in the United States and local economies on those rates. We also manufacture drug products for Siegfried and, therefore, are subject to liability for non-performance, product recalls and other claims against manufacturers.

**We use biological materials, hazardous materials, chemicals and radioactive compounds.**

Our research and development and manufacturing activities involve the use of potentially harmful biological materials as well as materials, chemicals and various radioactive compounds that could be hazardous to human health and safety or the environment. These materials and various wastes resulting from their use are stored at our facility pending ultimate use and disposal. We cannot completely eliminate the risk of contamination, which could cause:

interruption of our research and development or manufacturing efforts;

injury to our employees and others;

environmental damage resulting in costly clean up; and

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## **Table of Contents**

liabilities under domestic or foreign federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products.

In such an event, we may be held liable for any resulting damages, and any such liability could exceed our resources. Although we carry insurance in amounts and type that we consider commercially reasonable, we cannot be certain that the coverage or coverage limits of our insurance policies will be adequate and we do not have insurance coverage for losses relating to an interruption of our research and development efforts caused by contamination.

### **Our operations might be interrupted by the occurrence of a natural disaster or other catastrophic event.**

Our US operations, including laboratories, offices and a chemical development facility, are located in the same business park in San Diego. We also have a drug product facility that is located in Zofingen, Switzerland. We depend on our facilities and on our collaborators, contractors and vendors for the continued operation of our business. Natural disasters or other catastrophic events, including terrorist attacks, interruptions in the supply of natural resources, political and governmental changes, wildfires and other fires, explosions, actions of animal rights activists, earthquakes and wars could disrupt our operations or those of our collaborators, contractors and vendors. Even though we believe we carry commercially reasonable business interruption and liability insurance, and our contractors may carry liability insurance that protect us in certain events, we might suffer losses as a result of business interruptions that exceed the coverage available under our and our contractors' insurance policies or for which we or our contractors do not have coverage. For example, we are not insured against a terrorist attack. Any natural disaster or catastrophic event could have a significant negative impact on our operations and financial results. Moreover, any such event could delay our research and development programs.

### **There may be sales of our stock by our executive officers and directors, and these sales could adversely affect our stock price.**

Sales of our stock by our executive officers and directors, or the perception that such sales may occur, could adversely affect the market price of our stock. Some of our executive officers have adopted trading plans under SEC Rule 10b5-1 to dispose of a portion of their stock. Any of our executive officers or directors may adopt such trading plans in the future.

### **Currency fluctuations may negatively affect our financial condition.**

We primarily spend and generate cash in US dollars, and present our consolidated financial statements in US dollars. However, a portion of our expected and potential payments and receipts under our agreements are in foreign currencies, including Swiss francs. For example, payments and receipts under our asset purchase agreement, manufacturing services agreement and long-term API manufacturing agreement with Siegfried are required to be paid in Swiss francs. A fluctuation of the exchange rates of foreign currencies versus the US dollar may, thus, adversely affect our financial results, including cash balances, expenses and revenues. We may enter into hedging transactions to try to reduce our foreign currency exposure in the future, but there is no assurance that such transactions will occur or be successful.

### **Laws, rules and regulations relating to public companies may be costly and impact our ability to attract and retain directors and executive officers.**

Laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted by the SEC and by the NASDAQ Global Market, as well as the laws and regulations of foreign governments, may result in increased costs to us, particularly as we continue to develop the required capabilities in the United States and abroad to commercialize our products. These laws, rules and regulations could make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on our board committees or as executive officers. We cannot estimate accurately the amount or timing of additional costs we may incur to respond to these laws, rules and regulations.

### ***Risks Relating to Our Intellectual Property***

**\*Our success is dependent on intellectual property rights held by us and third parties and our interest in these rights is complex and uncertain.**

Our success will depend on our own and on our collaborators' abilities to obtain, secure and defend patents. In particular, the patents directed to our most advanced drug candidates and other compounds discovered using our technologies or that are otherwise part of our collaborations are important to commercializing drugs. We have numerous US and foreign patent applications pending for our technologies. There is no assurance that any of our patent applications will issue, or that any of the patents will be enforceable or will cover a drug or other commercially significant



technology or method, or that the patents will be held to be valid for their expected terms.

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## **Table of Contents**

The procedures for obtaining a patent in the United States and in most foreign countries are complex. These procedures require an analysis of the scientific technology related to the invention and many sophisticated legal issues. Obtaining patent rights outside the United States often requires the translation of highly technical documents and an improper translation may lead to the loss of, or otherwise jeopardize, the patent protection of our inventions. Ensuring adequate quality of translators and foreign patent attorneys is often very challenging. Consequently, the process for having our pending patent applications issue as patents will be difficult, complex and time consuming. Our patent position is very uncertain and we do not know when, or if, we will obtain additional patents for our technologies, or if the scope of the patents obtained will be sufficient to protect our drugs, or be considered sufficient by parties reviewing our patent positions pursuant to a potential licensing or financing transaction.

In addition, other entities may challenge the validity or enforceability of our patents and patent applications in litigation or administrative proceedings. Even the issuance of a patent is not conclusive as to its validity or enforceability. We cannot make assurances as to how much protection, if any, will be given to our patents if we attempt to enforce them or they are challenged. It is possible that a competitor or a generic pharmaceutical provider may successfully challenge our patents and those challenges may result in reduction or elimination of our patents coverage.

We also rely on confidentiality agreements and trade secrets to protect our technologies. However, such information is difficult to protect. We require our employees to contractually agree not to improperly use our confidential information or disclose it to others, but we may be unable to determine if our employees have conformed or will conform to their legal obligations under these agreements. We also enter into confidentiality agreements with prospective collaborators, collaborators, service providers and consultants, but we may not be able to adequately protect our trade secrets or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of this information. Many of our employees and consultants were, and many of them may currently be, parties to confidentiality agreements with other pharmaceutical and biotechnology companies, and the use of our technologies could violate these agreements. In addition, third parties may independently discover our trade secrets or proprietary information.

Some of our academic institution licensors, research collaborators and scientific advisors have rights to publish data and information to which we have rights. We generally seek to prevent our partners from disclosing scientific discoveries before we have the opportunity to file patent applications on such discoveries. In some of our collaborations, we do not have control over our partners' ability to disclose their own discoveries under the collaboration and in some of our academic collaborations we are limited to relatively short periods to review a proposed publication and file a patent application. If we cannot maintain the confidentiality of our technologies and other confidential information in connection with our collaborations, our ability to receive patent protection or protect our proprietary information will be impaired.

The US Congress is considering changes to federal patent laws on several issues including, but not limited to: (i) the information can be used to determine whether an invention is not new and, therefore, not patentable, (ii) the limits on the independent administrative rulemaking authority of the US Patent and Trademark Office, (iii) the duties of patent applicants to disclose information that relates to their applications, (iv) whether, under what circumstances, and how many times a third party can challenge an issued US patent before the US Patent and Trademark Office, (v) whether and under what circumstances patent applicants can lose their ability to enforce their patents in the United States based on their failure to disclose certain information relating to their inventions, and (vi) how damages for patent infringement may be reduced based by a number of factors, including the similarity of a patented invention to preexisting technologies.

We believe that the United States is by far the largest single market for pharmaceuticals in the world. Because of the critical nature of patent rights to the pharmaceutical industry, changes in US patent laws could have a profound effect on our future profits. Several of the patent law changes that are being considered could significantly weaken patent protections in the United States in general. They may also have a disproportionately large negative impact on the biotechnology and pharmaceutical industries in particular, as well as tilt the balance of market control and distribution of profits between the manufacturers of patented pharmaceutical products and the manufacturers of generic pharmaceutical products towards the generics manufacturers. At present there is considerable uncertainty as to which patent laws will be changed and exactly how changes to the patent laws will ultimately be enforced by the courts.

### **A dispute regarding the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be costly and result in delays or termination of our future research, development, manufacturing and sales activities.**

Our commercial success also depends upon our ability to develop and manufacture our drug candidates and market and sell drugs, if any, and conduct our research and development activities without infringing or misappropriating the proprietary rights of others. There are many patents and patent applications filed, and that may be filed, by others relating to drug discovery and development programs that could be determined to be similar, identical or superior to ours or our licensors or collaborators. We may be exposed to future litigation by others based on claims that our drug candidates, technologies or activities infringe the intellectual property rights of others. Numerous US and foreign issued patents and pending patent applications owned by others exist in the area of GPCRs, including some which purport to allow the patent holder to control the use of all drugs that modulate a particular drug target or GPCR, regardless of whether the infringing drug bears any structural resemblance to a chemical compound known to the patent holder at the



## Table of Contents

time of patent filing. Numerous US and foreign issued patents and pending patent applications owned by others also exist in the therapeutic areas in, and for the therapeutic targets for, which we are developing drugs. There are also numerous issued patents and patent applications to chemical compounds or synthetic processes that may be necessary or useful to use in our research, development, manufacturing or commercialization activities. These could materially affect our ability to develop our drug candidates or manufacture, import or sell drugs, and our activities, or those of our licensors or collaborators, could be determined to infringe these patents. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our drug candidates or technologies may infringe. There also may be existing patents, of which we are not aware, that our drug candidates or technologies may infringe. Further, there may be issued patents or pending patent applications in fields relevant to our business, of which we are or may become aware, that we believe (i) are invalid or we do not infringe; (ii) relate to immaterial portions of our overall drug discovery, development, manufacturing and commercialization efforts; or (iii) in the case of pending patent applications, the resulting patent would not be granted or, if granted, would not likely be enforced in a manner that would materially impact such efforts. We cannot assure you that others holding any of these patents or patent applications will not assert infringement claims against us for damages or seek to enjoin our activities. We also cannot assure you that, in the event of litigation, we will be able to successfully assert any belief we may have as to non-infringement, invalidity or immateriality, or that any infringement claims will be resolved in our favor.

In addition, others may infringe or misappropriate our proprietary rights, and we may have to institute costly legal action to protect our intellectual property rights. We may not be able to afford the costs of enforcing or defending our intellectual property rights against others.

Other organizations, companies and individuals are seeking proprietary positions on genomics information that overlap with the government-sponsored project to sequence the human genome. Our activities, or those of our licensors or collaborators, could be affected by conflicting positions that may exist between any overlapping genomics information made available publicly as a result of the government-sponsored project and genomics information that other organizations, companies or individuals consider to be proprietary. There could also be significant litigation and other administrative proceedings in our industry that affect us regarding patent and other intellectual property rights. Any legal action or administrative action against us, or our collaborators, claiming damages or seeking to enjoin commercial activities relating to our drug discovery, development, manufacturing and commercialization activities could:

require us, or our collaborators, to obtain a license to continue to use, manufacture or market the affected drugs, methods or processes, which may not be available on commercially reasonable terms, if at all;

prevent us from importing, making, using, selling or offering to sell the subject matter claimed in patents held by others and subject us to potential liability for damages;

consume a substantial portion of our managerial, scientific and financial resources; or

be costly, regardless of the outcome.

Furthermore, because of the substantial amount of pre-trial document and witness discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the trading price of our common stock.

We have been contacted from time to time by third parties regarding their intellectual property rights, sometimes asserting that we may need a license to use their technologies. If we fail to obtain any required licenses or make any necessary changes to our technologies, we may be unable to develop or commercialize some or all of our drug candidates.

### **We cannot protect our intellectual property rights throughout the world.**

Filing, prosecuting, defending and enforcing patents on all of our drug discovery technologies and all of our potential drug candidates throughout the world would be prohibitively expensive. Competitors may use our technologies to develop their own drugs in jurisdictions where we have not obtained patent protection. These drugs may compete with our drugs, if any, and may not be covered by any of our patent claims or

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other intellectual property rights. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to work the invention in that country or the third party has patented improvements). In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Compulsory licensing of life-saving drugs is also becoming increasingly popular in developing countries either through direct legislation or international initiatives. Such compulsory licenses could be extended to include some of our drug candidates, which could limit our potential revenue opportunities. Moreover, the legal

## **Table of Contents**

systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patents and other intellectual property protection, particularly those relating to biotechnology and/or pharmaceuticals, which makes it difficult for us to stop the infringement of our patents. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

### ***Risks Relating to Our Securities***

**\*Our stock price will likely be volatile, and your investment in our stock could decline in value.**

Our stock price has fluctuated historically. From January 1, 2007 to October 31, 2009, the market price of our stock was as low as \$2.26 per share and as high as \$14.78 per share.

Very few drug candidates being tested will ultimately receive FDA approval, and biotechnology or biopharmaceutical companies may experience a significant drop in stock price based on a clinical trial result or regulatory action. Our stock price may fluctuate significantly depending on a variety of factors, including:

the success or failure of our clinical-stage development programs or other results or decisions affecting the development of our drug candidates;

the timing of the discovery of drug leads and the development of our drug candidates;

the modification or termination of an existing collaboration or the entrance into, or failure to enter into, a new collaboration;

the timing and receipt by us of milestone and royalty payments or failing to achieve and receive the same;

changes in our research and development budget or the research and development budgets of our existing or potential collaborators;

the introduction, development or withdrawal of drug candidates or drugs by others that target the same diseases and conditions that we or our collaborators target or the introduction of new drug discovery techniques;

regulatory actions;

expenses related to, and the results of, litigation and other proceedings relating to intellectual property rights or other matters;

financing strategy or decisions;

developments in intellectual property rights or related announcements;

capital market conditions; and

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accounting changes.

We are not able to control many of these factors. If our financial or scientific results in a particular period do not meet stockholders' or analysts' expectations, our stock price may decline and such decline could be significant.

**\*There are a substantial number of shares of our common stock eligible for future sale in the public market, and the sale of these shares could cause the market price of our common stock to fall.**

There were 92,717,635 shares of our common stock outstanding as of October 31, 2009. We also had outstanding as of October 31, 2009 a seven-year warrant issued in June 2006 to purchase 916,213 shares of our common stock at an exercise price of \$14.03 per share and a seven-year warrant issued in August 2008 to purchase 1,222,050 shares of our common stock at an exercise price of \$6.98 per share. Such warrants were adjusted as a result of certain equity sales following their issuance, to decrease the exercise price and increase the number of shares issuable upon exercise of the warrants. Certain future equity issuances below the pre-defined warrant adjustment price may result in additional adjustments to any such warrants then outstanding.

On July 6, 2009, in connection with our receipt of a \$100.0 million loan, we issued warrants to purchase 28,000,000 shares of our common stock at an exercise price of \$5.42 per share. In addition, in certain circumstances we may be obligated to issue additional warrants to purchase up to 5,600,000 shares of common stock at an exercise price of \$5.42 per share. All of these warrants are exercisable until June 17, 2013. We have agreed to register for resale all of the shares underlying these warrants.

## **Table of Contents**

In addition to our outstanding warrants, as of October 31, 2009, there were (i) options to purchase 7,249,186 shares of our common stock outstanding under our equity incentive plans at a weighted-average exercise price of \$8.95, (ii) 1,717,850 performance-based restricted stock unit awards outstanding under our 2006 Long-Term Incentive Plan, as amended, (iii) 6,548,619 additional shares of common stock remaining issuable under our 2009 Long-Term Incentive Plan, (iv) 1,319,256 shares of common stock remaining issuable under our 2009 Employee Stock Purchase Plan, and (v) 101,669 shares of common stock remaining issuable under our Deferred Compensation Plan.

The shares described above, when issued, will be available for immediate resale in the public market. The market price of our common stock could decline as a result of such resales due to the increased number of shares available for sale in the market.

### **\*Any future equity or debt issuances by us may have dilutive or adverse effects on our existing stockholders.**

We have financed our operations, and we expect to continue to finance our operations, primarily by issuing and selling our common stock or securities convertible into or exercisable for shares of our common stock. In light of our need for additional financing, we may issue additional shares of common stock or convertible securities that could dilute your ownership in our company and may include terms that give new investors rights that are superior to yours. Moreover, any issuances by us of equity securities may be at or below the prevailing market price of our common stock and in any event may have a dilutive impact on your ownership interest, which could cause the market price of our common stock to decline. In addition, we may also raise additional funds through the incurrence of debt, and the holders of any debt we may issue would have rights superior to your rights in the event we are not successful and are forced to seek the protection of bankruptcy laws. For example, in July 2009 we issued debt to Deerfield that is secured by assets of the Company.

### **The holders of our stock and other securities may take actions that are contrary to your interests, including selling their stock.**

A small number of our stockholders hold a significant amount of our outstanding stock. These stockholders may support competing transactions and have interests that are different from yours. Sales of a large number of shares of our stock by these large stockholders or other stockholders within a short period of time could adversely affect our stock price.

We previously had disagreements with the holders of the warrants we issued in connection with our Series B Convertible Preferred Stock financing regarding whether their original warrants entitled them to receive exchange warrants following the exercise of such warrants in full. We entered into agreements to settle such disagreements. We may be involved with other disagreements with the holders of our stock, warrants or other securities in the future. Such disagreements may lead to litigation which may be expensive and consume management's time, or involve settlements, the terms of which may not be favorable to us.

### **Our rights agreement and certain provisions in our charter documents and Delaware law could delay or prevent a change in management or a takeover attempt that you may consider to be in your best interest.**

We have adopted certain anti-takeover provisions, including a stockholders' rights agreement, dated as of October 30, 2002, between us and Computershare Trust Company, Inc., as Rights Agent, as amended. The rights agreement will cause substantial dilution to any person who attempts to acquire us in a manner or on terms not approved by our board of directors.

The rights agreement, as well as other provisions in our certificate of incorporation and bylaws and under Delaware law, could delay or prevent the removal of directors and other management and could make more difficult a merger, tender offer or proxy contest involving us that you may consider to be in your best interest. For example, these provisions:

allow our board of directors to issue preferred stock without stockholder approval;

limit who can call a special meeting of stockholders;

eliminate stockholder action by written consent; and



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establish advance notice requirements for nomination for election to the board of directors or for proposing matters to be acted upon at stockholders meetings.

**Table of Contents**

**Item 6. Exhibits.**

<b>EXHIBIT NO.</b>	<b>DESCRIPTION</b>
3.1	Fifth Amended and Restated Certificate of Incorporation of Arena (incorporated by reference to Exhibit 3.1 to Arena's quarterly report on Form 10-Q for the quarter ended June 30, 2002, filed with the Securities and Exchange Commission on August 14, 2002, Commission File No. 000-31161)
3.2	Certificate of Amendment of the Fifth Amended and Restated Certificate of Incorporation of Arena (incorporated by reference to Exhibit 4.2 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 28, 2006, Commission File No. 333-135398)
3.3	Certificate of Amendment No. 2 of the Fifth Amended and Restated Certificate of Incorporation of Arena, as amended (incorporated by reference to Exhibit 4.3 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 30, 2009, Commission File No. 333-160329)
3.4	Amended and Restated Bylaws of Arena (incorporated by reference to Exhibit 3.1 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on October 4, 2007, Commission File No. 000-31161)
3.5	Certificate of Designations of Series A Junior Participating Preferred Stock of Arena, dated November 4, 2002 (incorporated by reference to Exhibit 3.3 to Arena's quarterly report on Form 10-Q for the quarter ended September 30, 2002, filed with the Securities and Exchange Commission on November 14, 2002, Commission File No. 000-31161)
4.1	Rights Agreement, dated October 30, 2002, between Arena and Computershare Trust Company, Inc. (incorporated by reference to Exhibit 4.1 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on November 1, 2002, Commission File No. 000-31161)
4.2	Amendment No. 1, dated December 24, 2003, to Rights Agreement, dated October 30, 2002, between Arena and Computershare Trust Company, Inc. (incorporated by reference to Exhibit 4.1 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on December 30, 2003, Commission File No. 000-31161)
4.3	Amendment No. 2, dated November 16, 2006, to Rights Agreement, dated October 30, 2002, between Arena and Computershare Trust Company, Inc. (incorporated by reference to Exhibit 4.3 to Amendment No. 2 to Arena's registration statement on Form 8-A filed with the Securities and Exchange Commission on November 16, 2006, Commission File No. 000-31161)
4.4	Form of common stock certificate (incorporated by reference to Exhibit 4.2 to Arena's registration statement on Form S-1, as amended, filed with the Securities and Exchange Commission on July 19, 2000, Commission File No. 333-35944)
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(B) promulgated under the Securities Exchange Act of 1934

**Table of Contents**

**SIGNATURES**

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

Date: November 9, 2009

ARENA PHARMACEUTICALS, INC.

By: */s/ JACK LIEF*  
**Jack Lief**  
**President and Chief Executive Officer (principal executive officer authorized to sign on behalf of the registrant)**

By: */s/ ROBERT E. HOFFMAN*  
**Robert E. Hoffman, CPA**  
**Vice President, Finance and Chief Financial Officer (principal financial and chief accounting officer authorized to sign on behalf of the registrant)**

**Table of Contents**

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