

ARENA PHARMACEUTICALS INC  
Form 10-Q  
May 11, 2009  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**  
**FORM 10-Q**

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended March 31, 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)

**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

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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

Smaller reporting company

(Do not check if a 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 May 6, 2009:

Class	Number of Shares Outstanding
Common Stock, \$0.0001 par value	80,030,641

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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>March 31, 2009 (Unaudited)</b>	<b>December 31, 2008 (Note)</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 62,458	\$ 73,329
Short-term investments, available-for-sale	7,799	36,800
Accounts receivable	1,795	1,823
Prepaid expenses and other current assets	3,898	5,031
<b>Total current assets</b>	<b>75,950</b>	<b>116,983</b>
Land, property and equipment, net	99,028	102,740
Acquired technology and other intangibles, net	14,885	16,262
Other non-current assets	5,648	5,346
<b>Total assets</b>	<b>\$ 195,511</b>	<b>\$ 241,331</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable, accrued compensation and other accrued liabilities	\$ 14,542	\$ 20,747
Accrued clinical and preclinical study fees	23,020	26,042
Warrant liability	1,753	
Current portion of lease financing obligations	525	410
<b>Total current liabilities</b>	<b>39,840</b>	<b>47,199</b>
Deferred rent	665	693
Deferred revenues	4,049	4,049
Note payable to Siegfried	8,091	8,567
Lease financing obligations, less current portion	77,340	62,657
Deferred income taxes	534	534
Commitments		
Stockholders' equity:		
Common stock	8	8
Additional paid-in capital	852,889	859,374
Stock subscription receivable	(900)	
Treasury stock, at cost	(23,070)	(23,070)
Accumulated other comprehensive income (loss)	(1,938)	256
Accumulated deficit	(761,997)	(718,936)
<b>Total stockholders' equity</b>	<b>64,992</b>	<b>117,632</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 195,511</b>	<b>\$ 241,331</b>

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Note: The balance sheet data at December 31, 2008 has been derived from audited financial statements at that date. It does not include, however, all of the information and notes required by US generally accepted accounting principles for complete financial statements.

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 March 31,</b>	
	<b>2009</b>	<b>2008</b>
<b>Revenues:</b>		
Manufacturing services	\$ 1,418	\$ 2,019
Collaborative agreements	1,240	590
Total revenues	2,658	2,609
<b>Operating Expenses:</b>		
Cost of manufacturing services	1,354	2,330
Research and development	42,620	47,368
General and administrative	7,642	8,861
Amortization of acquired technology and other intangibles	566	581
Total operating expenses	52,182	59,140
Loss from operations	(49,524)	(56,531)
<b>Interest and Other Income (Expense):</b>		
Interest income	170	3,433
Interest expense	(1,717)	(1,451)
Gain from valuation of warrant liability	365	
Other	92	84
Total interest and other income (expense), net	(1,090)	2,066
Net loss	(50,614)	(54,465)
Dividends on redeemable convertible preferred stock		(540)
Net loss allocable to common stockholders	\$ (50,614)	\$ (55,005)
Net loss per share allocable to common stockholders, basic and diluted	\$ (0.68)	\$ (0.75)
Shares used in calculating net loss per share allocable to common stockholders, basic and diluted	74,189	73,605

See accompanying notes to unaudited condensed consolidated financial statements.

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

	<b>Three months ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
<b>Operating Activities</b>		
Net loss	\$ (50,614)	\$ (54,465)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,829	2,840
Amortization of acquired technology and other intangibles	567	581
Share-based compensation	2,021	2,443
Gain from valuation of warrant liability	(365)	
Amortization of short-term investment premium	43	5
Amortization of prepaid financing costs	30	84
Accretion of note payable to Siegfried	59	57
Gain on disposal of equipment	(4)	(4)
Changes in assets and liabilities:		
Accounts receivable	(40)	(369)
Prepaid expenses and other current assets	702	246
Accounts payable and accrued liabilities	(6,872)	7,995
Deferred rent	(28)	(20)
Net cash used in operating activities	(51,672)	(40,607)
<b>Investing Activities</b>		
Purchases of short-term investments, available-for-sale		(30,982)
Proceeds from sales/maturities of short-term investments, available-for-sale	28,941	9,988
Purchase of drug product facility		(19,573)
Purchases of land, property and equipment	(2,275)	(4,479)
Proceeds from sale of equipment	6	4
Deposits, restricted cash and other non-current assets	83	(487)
Net cash provided by (used in) investing activities	26,755	(45,529)
<b>Financing Activities</b>		
Principal payments on lease financing obligations	(202)	(31)
Proceeds from lease financing	15,000	
Proceeds from issuance of common stock	266	527
Net cash provided by financing activities	15,064	496
Effect of exchange rate changes on cash	(1,018)	32
Net decrease in cash and cash equivalents	(10,871)	(85,608)
Cash and cash equivalents at beginning of period	73,329	386,989
Cash and cash equivalents at end of period	\$ 62,458	\$ 301,381

See accompanying notes to unaudited condensed consolidated financial statements.





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**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 to 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. There have been no significant changes from those included in the Company's annual report on Form 10-K for the year ended December 31, 2008 other than as described in Note 2.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. A going concern basis of accounting contemplates the recovery of the Company's assets and the satisfaction of its liabilities in the normal course of business.

To achieve its strategic goals, including filing a New Drug Application for lorcaserin, the Company will need to generate additional funds, which may be achieved through various activities, including raising additional funds through equity or debt financings or other strategic arrangements, selling assets or receiving milestone payments under its existing collaborations. However, the Company may not be successful in generating additional funds and there is no guarantee that funding will be available when needed or that, if available, such funding will be available on terms that the Company or its stockholders view as favorable.

On April 23, 2009, the Company committed to a reduction in its US workforce of approximately 31%, or a total of approximately 130 employees, which is expected to be substantially completed by June 22, 2009. The Company plans to continue to focus on the clinical development program for lorcaserin and select earlier-stage research and development programs. Even with such reductions and its cost-containment efforts, if the Company does not generate sufficient funding in 2009, the Company will eliminate or further postpone or scale back some or all of its research or development programs and may delay the timeline on the lorcaserin development program to meet its working capital requirements through March 31, 2010. If management does not make these adjustments in a timely manner, the Company's financial condition could be adversely impacted and its ability to operate as a going concern may be adversely affected.

**2. Adoption of New Accounting Standards**

On January 1, 2009, the Company adopted Emerging Issues Task Force, or EITF, Issue No. 07-5, Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock. EITF 07-5 provides a new two-step model to be applied in determining whether a financial instrument or an embedded feature in a financial instrument is indexed to an issuer's own stock, which would qualify as a scope exception under Paragraph 11(a) of Statement of Financial Accounting Standards, or SFAS, No. 133, Accounting for Derivative Instruments and Hedging Activities. Paragraph 11(a) of SFAS No. 133 specifies that a contract that would otherwise meet the definition of a derivative but is both (i) indexed to the company's own stock and (ii) classified in the stockholders' equity section of the balance sheet would not be considered a derivative financial instrument. The Company's adoption of EITF 07-5 resulted in the identification of warrants that were determined to be ineligible for equity classification because of certain provisions that may result in an adjustment to their exercise price. See Note 11 for the impact adoption of EITF Issue No. 07-5 had on the Company's condensed consolidated financial statements.

**3. Net Loss Per Share**

Basic and diluted net loss per share allocable to common stockholders are presented in conformity with SFAS No. 128, Earnings per Share, for all periods presented. In accordance with SFAS No. 128, basic and diluted net loss per share have been computed using the weighted-average number of shares of common stock outstanding during the period, less any shares subject to repurchase or forfeiture.



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The total number of shares of common stock outstanding excluded from the calculation of basic and diluted net loss per share because they were subject to repurchase or forfeiture was 25,000 and 31,312 for the three months ended March 31, 2009 and 2008, respectively. Had they been dilutive, such shares would have been included in the computation of diluted net loss per share allocable to common stockholders. In addition, 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.

**4. Comprehensive Income (Loss)**

In accordance with SFAS No. 130, Reporting Comprehensive Income, all components of comprehensive income (loss), including foreign currency translation gain and loss and unrealized gains and losses on investment securities, are reported 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.

	<b>Three months ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
Net loss	\$ (50,614)	\$ (54,465)
Foreign currency translation gain (loss)	(1,955)	3,198
Unrealized gain on available-for-sale securities and other investments	18	71
Comprehensive loss	\$ (52,551)	\$ (51,196)

**5. Share-based Activity****Share-based Compensation**

The Company recognized share-based compensation expense in accordance with SFAS No. 123R, Share-Based Payment, as follows, in thousands, except per share data:

	<b>Three months ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
Research and development	\$ 892	\$ 1,025
General and administrative	1,129	1,418
Total share-based compensation expense and impact on net loss allocable to common stockholders	\$ 2,021	\$ 2,443
Impact on net loss per share allocable to common stockholders, basic and diluted	\$ 0.03	\$ 0.04

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 under SFAS No. 123R. The table below sets forth the weighted-average assumptions and estimated fair value of stock options granted under the Company's 2006 Long-Term Incentive Plan, as amended, during the three months ended March 31, 2009 and 2008:

	<b>Three months ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
Risk-free interest rate	2.0%	2.5%

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Dividend yield	0%	0%
Expected volatility	86%	57%
Expected life (years)	5.72	5.50
Weighted-average estimated fair value of stock options granted	\$ 2.88	\$ 3.70

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The table below sets forth the weighted-average assumptions and estimated fair value of the options to purchase stock granted under the Company's 2001 Arena Employee Stock Purchase Plan, as amended, for multiple offering periods during the three months ended March 31, 2009 and 2008:

	<b>Three months ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
Risk-free interest rate	0.1% - 5.1%	2.7% - 5.3%
Dividend yield	0%	0%
Expected volatility	53% - 72%	53% - 69%
Expected life (years)	0.25 - 2.0	0.25 - 2.0
Weighted-average estimated fair value of options granted under Employee Stock Purchase Plan	\$ 1.85 - \$4.70	\$ 2.85 - \$5.46

Expected volatility for awards granted after the adoption of SFAS No. 123R 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 granted under SFAS No. 123R 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.

SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures of unvested options were estimated to be 6.4% and 5.1% for the three months ended March 31, 2009 and 2008, respectively, based on historical experience. 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.

Tax benefits recognized and related to share-based compensation and related cash flow impacts were not material during the three months ended March 31, 2009 and 2008 because the Company is in a net operating loss position.

**Share-based Award Activity**

The following table summarizes the Company's stock option activity during the three months ended March 31, 2009:

	<b>Options</b>	<b>Weighted-Average Exercise Price</b>
Outstanding at January 1, 2009	6,556,630	\$ 9.74
Granted	1,231,269	4.03
Exercised	(60,000)	0.60
Forfeited/cancelled/expired	(41,224)	9.52
Outstanding at March 31, 2009	7,686,675	\$ 8.90

The following table summarizes activity with respect to the Company's performance-based restricted stock unit awards during the three months ended March 31, 2009:

	<b>Performance Units</b>	<b>Weighted-Average Grant-Date Fair Value</b>
Outstanding at January 1, 2009	1,950,100	\$ 12.30
Granted		

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Vested			
Forfeited/cancelled	(19,950)		10.97
Outstanding at March 31, 2009	1,930,150	\$	12.32

### 6. Fair Value Disclosures

On January 1, 2008, the Company adopted SFAS No. 157, which defines fair value, establishes a framework for measuring fair value in accordance with GAAP and expands disclosures about fair value measurements. SFAS No. 157 defines fair value as the exchange price that would be received to sell an asset or paid to transfer a liability, based upon an exit price, in an orderly transaction between market participants at the measurement date.

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SFAS No. 157 establishes a three-level valuation hierarchy of valuation techniques that is based on observable and unobservable inputs.

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.

In accordance with SFAS No. 157, the following table presents the Company's valuation hierarchy for its financial assets and liabilities measured at fair value on a recurring basis as of March 31, 2009, in thousands:

	Fair Value Measurements at March 31, 2009			
	Balance at March 31, 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 and cash equivalents (1)	\$ 46,338	\$ 46,338	\$	\$
US government, agency and government-sponsored enterprise obligations (2)	5,285		5,285	
Corporate debt instruments (2)	2,514		2,514	
<i>Liabilities:</i>				
Warrants	\$ 1,753	\$	\$	\$ 1,753

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

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

The following table presents the activity for the Company's outstanding warrants during the three months ended March 31, 2009, in thousands:

	Significant Unobservable Inputs (Level 3)
Balance at January 1, 2009 after reclassification from additional paid-in capital upon adoption of EITF Issue No. 07-5	\$ 2,118
Unrealized gain from valuation of warrant liability	(365)
Balance at March 31, 2009	\$ 1,753

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

In accordance with SFAS No. 115, Accounting for Certain Debt and Equity Securities, short-term investments are classified as available-for-sale. The Company defines short-term investments as income-yielding securities that can be readily converted to cash. 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.





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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 will be tested for impairment annually in accordance with SFAS No. 142, Goodwill and Other Intangible Assets. 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. As of March 31, 2009 and using the exchange rate in effect on March 31, 2009, the Company expects to record expense of \$0.6 million in the remainder 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 March 31, 2009, the Company expects to record expense of \$1.2 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 March 31, 2009, in thousands:

	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Net</b>
<i>Amortizable intangible assets:</i>			
Acquired technology from Bunsen Rush	\$ 15,378	\$ (12,424)	\$ 2,954
Acquired workforce from Siegfried	1,474	(921)	553
	\$ 16,852	\$ (13,345)	3,507
<i>Indefinite-lived intangible assets:</i>			
Acquired licensed production facility from Siegfried			11,378
<b>Total identifiable intangible assets, net</b>			<b>\$ 14,885</b>

**9. 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:

<b>Source of Revenue</b>	<b>Three months ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
Manufacturing services agreement with Siegfried	53.3%	77.4%

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Collaboration with Ortho-McNeil-Janssen Pharmaceuticals, Inc.	46.3%	22.2%
Collaboration with Merck & Co., Inc.	0.4%	0.4%

### 10. Commitments

On March 23, 2009, the Company entered into an equity financing commitment of up to \$50.0 million with Azimuth Opportunity Ltd., or Azimuth. During the 18-month term of the equity financing commitment, the Company may sell newly issued registered shares of its common stock to Azimuth at a pre-negotiated discount to the market price. The Company will determine, at its sole discretion, the timing and amount of any sales of its stock, subject to certain conditions. In no event may the Company sell more than 14,838,891 shares of its common stock to Azimuth.

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Upon adoption of EITF Issue No. 07-5, and as a result of provisions in the agreements for the Company's outstanding warrants that may result in an adjustment to their exercise price, on January 1, 2009, the Company recorded a \$9.7 million adjustment to equity, a \$2.1 million current liability for the fair value of the warrants on January 1, 2009 and a \$7.6 million adjustment to the opening accumulated deficit balance as a cumulative effect of a change in accounting principle. The Company revalued the warrants at March 31, 2009, and will continue to revalue the warrants on each subsequent balance sheet date until they are fully exercised, with any changes in the fair value between reporting periods recorded as other income or expense. For the three months ended March 31, 2009, the Company recorded a gain of \$0.4 million in the interest and other income (expense) section of the accompanying condensed consolidated statements of operations.

**12. Subsequent Events***Equity Financing*

On April 14, 2009, the Company received aggregate proceeds of \$14.6 million (which is net of \$0.4 million in estimated costs) from the sale of a total of 5,745,591 shares of common stock under its equity financing commitment with Azimuth. The Company recorded a stock subscription receivable of \$0.9 million for stock subscriptions prior to March 31, 2009 for which payment was received on April 14, 2009. Under the Company's outstanding warrants, subsequent equity sales at an effective net price below \$6.72 result in an adjustment to the number of common shares issuable under the warrants and the per share exercise price. Upon the issuance of shares to Azimuth under the equity financing commitment, the number of warrants outstanding increased from 1,106,344 to 1,160,532 and from 829,056 to 869,721 while the per share exercise price decreased from \$7.71 to \$7.35 and from \$15.49 to \$14.78, respectively.

*Restructuring Plan*

On April 23, 2009, the Company committed to a reduction in its US workforce of approximately 31%, or a total of approximately 130 employees, which is expected to be substantially completed by June 22, 2009. The Company plans to continue to focus on the clinical development program for lorcaserin and select earlier-stage research and development projects. As a result of this workforce reduction, the Company expects to incur cash charges, primarily in the second quarter of 2009, of approximately \$3.0 million in connection with one-time employee termination costs, including severance and other benefits.

**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.

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**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 that target known and orphan G protein-coupled receptors, or GPCRs, which includes compounds being evaluated independently and with partners, including Merck & Co., Inc., or Merck, and Ortho-McNeil-Janssen Pharmaceuticals, Inc., or Ortho-McNeil-Janssen. We incorporated on April 14, 1997 in the state of Delaware and commenced operations in July 1997.

Our recent developments include:

Abstract accepted for presentation of data from BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management), the first of two pivotal trials evaluating the safety and efficacy of lorcaserin for weight management, at the 69<sup>th</sup> Scientific Sessions of the American Diabetes Association scheduled for June 5-9, 2009 in New Orleans, Louisiana.

Announced positive top-line results from BLOOM. Lorcaserin was highly efficacious, achieving statistical significance ( $p < 0.0001$  vs. placebo) on all three co-primary efficacy endpoints ( $\geq 5\%$  categorical, absolute, and  $\geq 10\%$  categorical weight loss). The BLOOM results also satisfy the efficacy benchmark in the most recent US Food and Drug Administration, or FDA, draft guidance for the development of drugs for weight management. Treatment with lorcaserin was generally very well tolerated. Lorcaserin treatment for up to two years was not associated with evidence of heart valve damage; rates for the development of echocardiographic FDA-defined valvulopathy were similar to placebo throughout the study. We are on track to report results from the second pivotal trial, BLOSSOM (Behavioral modification and LORcaserin Second Study for Obesity Management), by the end of September 2009.

Committed to a reduction in our US workforce of approximately 31%, or a total of approximately 130 employees, which is expected to be substantially completed by June 22, 2009. As a result of this workforce reduction, we expect to incur cash charges, primarily in the second quarter of 2009, of approximately \$3.0 million in connection with one-time employee termination costs, including severance and other benefits. This workforce reduction is expected to result in annual operating cost savings of approximately \$25.0 million.

Received aggregate net proceeds of \$14.6 million under a \$50.0 million equity financing commitment entered into in March 2009 with Azimuth Opportunity Ltd., or Azimuth. During the 18-month term of the equity financing commitment, we may sell newly issued registered shares of our common stock to Azimuth at a pre-negotiated discount to the market price.

Received net proceeds of \$14.6 million as reimbursement for improvements made to one of our facilities.

Announced the completion of a positive randomized, double-blind, placebo-controlled Phase 1 program and the initiation of a Phase 2 clinical trial of a second generation oral niacin receptor agonist intended for the treatment of atherosclerosis in our partnership with Merck.

**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**

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Source of revenue	Three months ended	
	March 31,	
	2009	2008
Manufacturing services agreement	\$ 1.4	\$ 2.0
Collaborative agreements	1.3	0.6
Total revenues	\$ 2.7	\$ 2.6

**Table of Contents****Research and development expenses**

Type of expense	Three months ended March 31,	
	2009	2008
External clinical and preclinical study fees and expenses	\$ 23.3	\$ 27.0
Salary and other personnel costs (excluding non-cash share-based compensation)	10.9	10.6
Facility and equipment costs	4.0	3.9
Research supplies	2.2	3.2
Non-cash share-based compensation	0.9	1.0
Other	1.3	1.7
<b>Total research and development expenses</b>	<b>\$ 42.6</b>	<b>\$ 47.4</b>

**General and administrative expenses**

Type of expense	Three months ended March 31,	
	2009	2008
Salary and other personnel costs (excluding non-cash share-based compensation)	\$ 2.6	\$ 2.6
Legal, accounting and other professional fees	2.4	3.0
Non-cash share-based compensation	1.1	1.4
Facility and equipment costs	1.0	0.9
Other	0.5	1.0
<b>Total general and administrative expenses</b>	<b>\$ 7.6</b>	<b>\$ 8.9</b>

**THREE MONTHS ENDED MARCH 31, 2009 AND 2008**

**Revenues.** We recorded revenues of \$2.7 million during the three months ended March 31, 2009, compared to \$2.6 million during the three months ended March 31, 2008. Our revenues for the three months ended March 31, 2009 included \$1.4 million under our manufacturing services agreement with Siegfried Ltd, or Siegfried, a decrease of \$0.6 million from the \$2.0 million of manufacturing services revenues recorded in the three months ended March 31, 2008. Our revenues for the three months ended March 31, 2009 also included \$1.3 million for patent activities from our collaborations with Ortho-McNeil-Janssen and Merck, compared to \$0.6 million of such revenues recorded in the three months ended March 31, 2008.

Absent any new collaborations or achievement of a milestone in one of our existing collaborations, we expect our 2009 revenues will consist 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 5.4 million in the remaining three quarters of 2009 and CHF 6.6 million in 2010. Using the exchange rate in effect on March 31, 2009, this would translate to approximately \$4.7 million and \$5.7 million in manufacturing services revenues for the balance of 2009 and in 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 over the next several years 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

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of manufacturing services of \$1.4 million and \$2.3 million were recorded for the three months ended March 31, 2009 and 2008, respectively.

**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 costs 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.

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Research and development expenses decreased by \$4.8 million to \$42.6 million for the three months ended March 31, 2009, from \$47.4 million for the three months ended March 31, 2008. The decrease was primarily due to decreases of (i) \$3.7 million in external clinical and preclinical study fees and expenses due to the completion of our clinical studies of APD125 and APD791 and our preclinical studies of APD916 as we prioritized our spending towards the completion of our BLOOM trial for lorcaserin and activities that support filing a New Drug Application, or NDA, for lorcaserin, and (ii) \$1.0 million in research supplies due to our cost-containment efforts. Although we expect to continue to incur substantial research and development expenses in 2009, primarily related to lorcaserin, we expect our research and development expenses will be significantly lower than the 2008 level as we expect that the majority of expenses from our Phase 3 lorcaserin BLOOM and BLOSSOM trials will be recognized in the first half of 2009. In addition, we do not plan to initiate any further clinical trials of any other of our drug candidates until our financial condition improves. Further, as a result of our recently announced workforce reduction of approximately 130 employees that is expected to be substantially completed in June 2009, we expect our research and development expenses, particularly salary, other personnel costs and research supplies, in the second half of 2009 will be less than in the first half of 2009. Unless we can obtain substantial funds through equity or debt financings, partnerships or sales of assets, we may have to further reduce our research and development activities.

Included in the \$23.3 million total external clinical and preclinical study fees and expenses noted in the table above for the three months ended March 31, 2009 was \$22.7 million related to our lorcaserin program and \$0.3 million related to receipt of the complete data package from our Phase 2b clinical trial of APD125. Included in the \$27.0 million total external clinical and preclinical study fees and expenses noted in the table above for the three months ended March 31, 2008 was \$23.3 million related to our lorcaserin program, \$1.8 million related to our APD125 program and \$0.9 million related to our APD791 program.

**General and administrative expenses.** General and administrative expenses decreased by \$1.3 million to \$7.6 million for the three months ended March 31, 2009, from \$8.9 million for the three months ended March 31, 2008. This decrease was primarily due to decreases of (i) \$0.8 million in patent costs and (ii) \$0.2 million in consulting services. We expect that our total general and administrative expenses in 2009 will be less than in 2008 as a result of our recent 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 due primarily to increases in such expenses. However, if we are unable to obtain adequate funds, we may have to further reduce our general and administrative expenditures.

**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 March 31, 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 additional amortization expense of \$0.6 million in the remainder 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 \$1.2 million in the remainder of 2009, \$1.5 million in 2010 and \$0.3 million in 2011 for amortization of the Melanophore technology.

**Interest and other income (expense), net.** Interest and other income, net, decreased by \$3.2 million to an expense of \$1.1 million for the three months ended March 31, 2009, from income of \$2.1 million for the three months ended March 31, 2008. This change was due primarily to (i) a \$3.3 million decrease in interest income attributable to both significantly lower cash balances and interest rates, (ii) a \$0.4 million non-cash gain from the revaluation of our warrant liability and (iii) a \$0.3 million increase in interest expense and financing costs, which included lease payments on our lease financing obligations accounted for in accordance with SFAS No. 66, Accounting for Sales of Real Estate and SFAS No. 98 Accounting for Leases. Due to declining cash balances and low interest rates, we expect our interest income will continue to decrease in 2009.

**Dividends on redeemable convertible preferred stock.** Because we redeemed all of the outstanding shares of our Series B Convertible Preferred Stock in November 2008, we recorded no dividend expense related to such stock in the three months ended March 31, 2009, compared to \$0.5 million in the three months ended March 31, 2008.



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**LIQUIDITY AND CAPITAL RESOURCES**

*Short term*

Our sources of liquidity include our cash balances and short-term investments. As of March 31, 2009, we had \$70.3 million in cash and cash equivalents and short-term investments. On April 14, 2009, we received aggregate net proceeds of \$14.6 million from the sale of a total of 5,745,591 shares of common stock under our equity financing commitment with Azimuth. Other potential sources of near-term liquidity include (i) equity, debt or other financing, (ii) the partnering or out-licensing of our drug candidates, internal drug programs and technologies, (iii) the sale of facilities that we own, and (iv) milestone payments from our collaborators. 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 our stock price, the global economic market and our financial condition. 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, which we expect to file by the end of 2009, assuming positive data from BLOSSOM, the second of our pivotal Phase 3 trials. In connection with such prioritization, we are deferring the initiation of any new clinical trials for our other programs, deferring certain costs related to lorcaserin that are non-essential to the initial commercialization of lorcaserin and continuing our cost-containment efforts. As a result of our recently announced workforce reduction of approximately 130 employees, we expect (i) annual operating cost savings of approximately \$25.0 million, and (ii) to incur cash charges, primarily in the second quarter of 2009, of approximately \$3.0 million in connection with one-time employee termination costs, including severance and other benefits. Along with this workforce reduction, we decreased the number of our research programs as well as our current and planned activities. Even with the workforce reduction, deferring of expenses and other cost-containment efforts, we may not have sufficient cash to meet all of our objectives over the next 12 months which, in addition to our primary focus of lorcaserin, include continuing to improve and develop our manufacturing capabilities for lorcaserin, including our manufacturing facilities in Switzerland, and maintaining select research capabilities. If we do not generate sufficient funding in the short-term, we would need to eliminate or further postpone or scale back some or all of our research programs and further reduce our expenses, and may need to delay the timeline on the lorcaserin development program to meet our short-term working capital requirements. 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.

Although we expect that the majority of the external expenses for our Phase 3 lorcaserin program will be expensed by mid-2009, we expect that our research and development expenditures will continue to be substantial as we continue our lorcaserin program and select earlier-stage research and development programs. In addition to clinical trial costs for lorcaserin, we expect that we will continue to incur increasing manufacturing costs and other pre-launch costs for lorcaserin.

*Long term*

We will need to obtain substantial amounts of cash to achieve our objectives of internally developing drugs, which 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.

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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.

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 lorcasein, and which are expected to be necessary for our planned NDA submission to the FDA and for commercialization of lorcasein after regulatory marketing approval. We paid CHF 21.8 million, or \$19.6 million, of the cash purchase price in January 2008, and will 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 \$51.7 million during the three months ended March 31, 2009, and primarily was used to fund our net losses in the period, adjusted for non-cash items. Non-cash items included \$2.8 million in depreciation and amortization expense, \$2.0 million in share-based compensation expense, \$0.6 million in amortization expense related to acquired technology and other intangibles, \$0.4 million gain from the revaluation of our warrant liability, as well as changes in operating assets and liabilities. Net cash used in operating activities was \$40.6 million during the three months ended March 31, 2008, and primarily was used to fund our net losses in the period, adjusted for non-cash expenses. Non-cash expenses included \$2.8 million in depreciation and amortization expense, \$2.4 million in share-based compensation, \$0.6 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 from the 2008 level as we complete our Phase 3 lorcasein BLOOM and BLOSSOM trials, prioritize our spending towards activities that support filing an NDA for lorcasein and realize expected operating cost savings from our recent workforce reduction.

Net cash of \$26.8 million was provided by investing activities during the three months ended March 31, 2009, primarily proceeds of \$28.9 million from our short-term investments. These proceeds were partially offset by \$2.3 million used for equipment and improvements to our facilities. Net cash used in investing activities was \$45.5 million during the three months ended March 31, 2008, and was primarily the result of net purchases of short-term investments of \$21.0 million, \$19.6 million used for the purchase of our drug product manufacturing and packaging facility in Switzerland and \$4.5 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.

Net cash provided by financing activities was \$15.1 million during the three months ended March 31, 2009, and was primarily attributable to \$15.0 million in reimbursements for improvements made to one of our facilities. Net cash provided by financing activities was \$0.5 million during the three months ended March 31, 2008, and was primarily attributable to proceeds of \$0.5 million received from option exercises and purchases under our employee stock purchase plan.

## **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



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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.

**Revenue recognition.** Our revenue recognition policies are in accordance with the SEC Staff Accounting Bulletin, or SAB, No. 101, Revenue Recognition in Financial Statements, as amended by No. 104, Revenue Recognition, and Emerging Issues Task Force, or EITF, 00-21, Revenue Arrangements with Multiple Deliverables, which provide guidance on revenue recognition in financial statements. 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.

**Share-based compensation.** On January 1, 2006, we adopted SFAS No. 123R using the modified-prospective transition method. Compensation expense recognized subsequent to adoption includes: (i) compensation expense for all share-based awards granted prior to, but unvested as of, January 1, 2006, based on the grant-date fair value, estimated in accordance with the original provision of SFAS No. 123 using the Black-Scholes option pricing model, and (ii) compensation expense for all share-based awards granted subsequent to January 1, 2006, based on the grant-date fair value, estimated in accordance with the provisions of SFAS No. 123R 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 our stock price on the date of grant, as well as assumptions for expected volatility, the expected life of options granted and the risk-free interest rate. Changes in the assumptions can have a material impact on the compensation expense we recognize. Expected volatility for awards granted after adoption of SFAS No. 123R 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 under SFAS No. 123R 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. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. If actual forfeitures vary from estimates, we will recognize the difference in compensation expense in the period the actual forfeitures occur or when options vest.

**Accounting for lease financing obligations.** We have accounted for our sale and leaseback transactions in accordance with SFAS Nos. 66 and 98. Our option to repurchase these properties in the future is considered continued involvement under SFAS No. 66 and, therefore, we have applied the financing method under SFAS No. 98. 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.

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*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.*

*The risk factors set forth below with an asterisk (\*) before the title are 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.*

#### ***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 next several years 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 are depleted, it may be difficult for us to obtain additional financing or enter into strategic

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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 lorcasein program.

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**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.

**\*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 current financial resources, we decided to focus our near-term research and development efforts on our lorcaserin Phase 3 program and select earlier-stage preclinical and research programs. We also decreased the number of our US employees by approximately 31% in a workforce reduction expected to be substantially completed by June 22, 2009. 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 current and 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.

**\*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.**

We announce results of clinical trials and preclinical studies from time to time. For example, we announced the results from our Phase 3 BLOOM pivotal trial for lorcaserin in March 2009 and expect to announce the results of our Phase 3 BLOSSOM pivotal trial for lorcaserin by the end of September 2009.

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 community, 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 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.

### **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.

### **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. We will need to complete additional clinical trials and preclinical studies before we can demonstrate that our 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.





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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;

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;

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 lorcaserin 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

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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 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 the treatment of obesity 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 United States Department of Justice, or DEA. DEA scheduling is an independent process that can delay drug launch beyond an NDA approval date.

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.

We do not expect any drugs resulting from our research and development efforts to be commercially available until at least late 2010. Our most advanced drug candidates, including lorcaserin, have not completed all preclinical studies and the large, pivotal Phase 3 clinical trials for efficacy and safety that are required for FDA approval. Also, 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

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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.

**\*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. In the case of lorcaserin, results in one pivotal trial (BLOOM) may not be confirmed in another pivotal trial (BLOSSOM). 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.

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**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 next few years, 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.

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

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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.**

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 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.



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**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, 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;

facility capacity of our facilities or those of our contract manufacturers;

facility contamination by microorganisms or viruses;

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.

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 difficult. 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

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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 President, Chief Executive Officer and Chairman, 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.

## Edgar Filing: ARENA PHARMACEUTICALS INC - Form 10-Q

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.

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.

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**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 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.

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**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 will also be manufacturing drug products for Siegfried for at least the next several years and, therefore, be 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

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.



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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.

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### ***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 United States 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.

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 Patent and Trademark Office has over the last few years tried to enact and/or has proposed changes in the rules governing (i) the duties of patent applicants to disclose information that relates to their applications, (ii) the ability of patent applicants to file unlimited numbers of patent applications and patent claims that concern closely related inventions and/or different aspects of the same invention, and (iii) the manner in which the US Patent and Trademark Office will decide whether to require patent applicants to separate closely related inventions into separate patent applications. Some of these rule changes are being challenged in the courts. It is unclear which of these rule changes, if any, will be allowed by the courts and which of them will continue to be pursued. In addition, 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.



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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 rules and laws could have a profound effect on our future profits. Several of the patent rule and 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 rules and laws will be changed and whether changes to the patent rules will ultimately be enforced or struck down 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 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;

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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 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 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 April 30, 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;

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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;

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the introduction or withdrawal of 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

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 74,284,300 shares of our common stock outstanding as of March 31, 2009. We also had outstanding as of March 31, 2009 a seven-year warrant we issued in June 2006 to purchase 829,856 shares of our common stock at an exercise price of \$15.49 per share and a seven-year warrant we issued in August 2008 to purchase 1,106,344 shares of our common stock at an exercise price of \$7.71 per share. As a result of our issuance of common stock in April 2009 at a price below a pre-defined adjustment price, such warrants were adjusted as follows as of April 13, 2009: the June 2006 warrant is for 869,721 shares of our common stock at an exercise price of \$14.78 per share and the August 2008 warrant is for 1,160,532 shares of our common stock at an exercise price of \$7.35 per share. Additional equity sales below the pre-defined adjustment price may result in additional adjustments to our outstanding warrants. In addition, as of March 31, 2009, there were (i) options to purchase 7,686,675 shares of our common stock outstanding under our equity incentive plans at a weighted-average exercise price of \$8.90, (ii) 1,930,150 performance-based restricted stock unit awards outstanding under our 2006 Long-Term Incentive Plan, as amended, or LTIP, (iii) 55,010 additional shares of common stock remaining issuable under our LTIP, (iv) 2,655 shares of common stock remaining issuable under our 2001 Employee Stock Purchase Plan, as amended, and (v) 107,919 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.

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

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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.



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**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

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

**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	Amended and Restated Bylaws of Arena (incorporated by reference to Exhibit 3.1 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on October 4, 2007, Commission File No. 000-31161)
3.4	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)
3.5	Certificate of Designations of Series B-1 Convertible Preferred Stock and Series B-2 Convertible Preferred Stock of Arena, dated December 24, 2003 (incorporated by reference to Exhibit 3.1 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on December 30, 2003, 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 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 report on Form 8-K filed with the Securities and Exchange Commission on December 30, 2003, Commission File No. 000-31161)

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- 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 certificates (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. 333-3594)

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10.1*	2009 Annual Incentive Plan for Arena's executive officers (incorporated by reference to Exhibit 10.1 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on January 29, 2009, Commission File No. 000-31161)
10.2	Common Stock Purchase Agreement between Arena and Azimuth Opportunity Ltd., dated March 23, 2009 (incorporated by reference to Exhibit 10.1 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on March 23, 2009, Commission File No. 000-31161)
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

\* Management contract or compensatory plan or arrangement.

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**SIGNATURES**

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

Date: May 11, 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)

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**EXHIBIT INDEX**

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3.5	Certificate of Designations of Series B-1 Convertible Preferred Stock and Series B-2 Convertible Preferred Stock of Arena, dated December 24, 2003 (incorporated by reference to Exhibit 3.1 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on December 30, 2003, 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 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 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 certificates (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. 333-3594)
10.1*	2009 Annual Incentive Plan for Arena's executive officers (incorporated by reference to Exhibit 10.1 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on January 29, 2009, Commission File No. 000-31161)
10.2	Common Stock Purchase Agreement between Arena and Azimuth Opportunity Ltd., dated March 23, 2009 (incorporated by reference to Exhibit 10.1 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on March 23, 2009, Commission File No. 000-31161)
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

\* Management contract or compensatory plan or arrangement.