

ARENA PHARMACEUTICALS INC

Form 10-Q

November 09, 2012

[Table of Contents](#)

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

Washington, D.C. 20549

**FORM 10-Q**

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

For the quarterly period ended September 30, 2012

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)

Edgar Filing: ARENA PHARMACEUTICALS INC - Form 10-Q

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

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

**6154 Nancy Ridge Drive, San Diego, CA**  
(Address of principal executive offices)

**92121**  
(Zip Code)

**858.453.7200**  
(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer  Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

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

The number of shares of common stock outstanding as of the close of business on November 1, 2012:

Class	Number of Shares Outstanding
Common Stock, \$0.0001 par value	217,292,992

**Table of Contents**

**ARENA PHARMACEUTICALS, INC.**

**INDEX**

	<u>PART I FINANCIAL INFORMATION</u>	
Item 1.	<u>Financial Statements</u>	1
	<u>Condensed Consolidated Balance Sheets As of September 30, 2012, and December 31, 2011</u>	1
	<u>Condensed Consolidated Statements of Operations and Comprehensive Loss Three and Nine Months Ended September 30, 2012, and 2011</u>	2
	<u>Condensed Consolidated Cash Flow Statements Nine Months Ended September 30, 2012, and 2011</u>	3
	<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	4
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	14
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	22
Item 4.	<u>Controls and Procedures</u>	22
	<u>PART II OTHER INFORMATION</u>	
Item 1.	<u>Legal Proceedings</u>	23
Item 1A.	<u>Risk Factors</u>	23
Item 5.	<u>Other Information</u>	44
Item 6.	<u>Exhibits</u>	45
	<u>Signatures</u>	46

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. BELVIQ® is a registered trademark of Arena Pharmaceuticals GmbH. Any other brand names or trademarks appearing in this Quarterly Report on Form 10-Q are the property of their respective holders.

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

	<b>September 30, 2012 (Unaudited)</b>	<b>December 31, 2011<sup>1</sup></b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 165,774	\$ 57,632
Accounts receivable	672	607
Inventory	2,808	0
Prepaid expenses and other current assets	4,439	2,021
<b>Total current assets</b>	<b>173,693</b>	<b>60,260</b>
Land, property and equipment, net	76,030	82,066
Acquired technology and other intangibles, net	10,515	11,032
Other non-current assets	3,922	3,771
<b>Total assets</b>	<b>\$ 264,160</b>	<b>\$ 157,129</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and other accrued liabilities	\$ 5,063	\$ 5,294
Accrued compensation	4,368	4,280
Current portion of deferred revenues	3,495	3,473
Current portion of derivative liabilities	4,100	0
Current portion of lease financing obligations	1,573	1,313
<b>Total current liabilities</b>	<b>18,599</b>	<b>14,360</b>
Deferred rent	95	225
Deferred revenues, less current portion	43,555	41,209
Derivative liabilities, less current portion	11,403	1,617
Lease financing obligations, less current portion	73,242	74,458
Note payable to Deerfield	0	14,698
Commitments and contingencies and subsequent events		
Stockholders' equity:		
Common stock	22	15
Additional paid-in capital	1,279,478	1,108,625
Treasury stock, at cost	0	(23,070)
Accumulated other comprehensive income	4,784	4,743
Accumulated deficit	(1,167,018)	(1,079,751)
<b>Total stockholders' equity</b>	<b>117,266</b>	<b>10,562</b>

Edgar Filing: ARENA PHARMACEUTICALS INC - Form 10-Q

Total liabilities and stockholders equity	\$	264,160	\$	157,129
---	----	---------	----	---------

<sup>1</sup> The balance sheet data at December 31, 2011, 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 and Comprehensive Loss****(In thousands, except per share data)****(Unaudited)**

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2012</b>	<b>2011</b>	<b>2012</b>	<b>2011</b>
<b>Revenues:</b>				
Manufacturing services	\$ 603	\$ 1,713	\$ 2,924	\$ 4,390
Collaborative agreements	882	1,746	22,727	6,253
Total revenues	1,485	3,459	25,651	10,643
<b>Operating Expenses:</b>				
Cost of manufacturing services	1,396	1,557	2,839	6,215
Research and development	11,619	14,978	40,165	45,616
General and administrative	7,392	6,029	18,963	18,996
Restructuring charges	0	0	0	3,467
Amortization of acquired technology and other intangibles	168	197	517	819
Total operating expenses	20,575	22,761	62,484	75,113
Loss from operations	(19,090)	(19,302)	(36,833)	(64,470)
<b>Interest and Other Income (Expense):</b>				
Interest income	41	20	81	102
Interest expense	(1,804)	(3,211)	(7,324)	(11,087)
Gain (Loss) from valuation of derivative liabilities	5,259	(233)	(13,886)	387
Loss on extinguishment of debt	0	0	(6,338)	(10,514)
Other	73	(10)	103	40
Total interest and other income (expense), net	3,569	(3,434)	(27,364)	(21,072)
Net loss	(15,521)	(22,736)	(64,197)	(85,542)
Deemed dividend related to beneficial conversion feature of convertible preferred stock	0	0	(2,824)	(2,260)
Net loss allocable to common stockholders	\$ (15,521)	\$ (22,736)	\$ (67,021)	\$ (87,802)
<b>Net loss per share allocable to common stockholders:</b>				
Basic	\$ (0.07)	\$ (0.16)	\$ (0.35)	\$ (0.64)
Diluted	\$ (0.07)	\$ (0.16)	\$ (0.35)	\$ (0.64)
<b>Shares used in calculating net loss per share allocable to common stockholders:</b>				
Basic	213,881	145,965	189,545	136,860
Diluted	213,881	145,965	189,545	136,860

Edgar Filing: ARENA PHARMACEUTICALS INC - Form 10-Q

<b>Comprehensive Loss:</b>				
Net loss	\$ (15,521)	\$ (22,736)	\$ (64,197)	\$ (85,542)
Foreign currency translation gain (loss)	588	(3,146)	41	1,551
Comprehensive loss	\$ (14,933)	\$ (25,882)	\$ (64,156)	\$ (83,991)

See accompanying notes to unaudited condensed consolidated financial statements.

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

	<b>Nine months ended September 30,</b>	
	<b>2012</b>	<b>2011</b>
<b>Operating Activities</b>		
Net loss	\$ (64,197)	\$ (85,542)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	7,060	7,694
Amortization of acquired technology and other intangibles	517	819
Share-based compensation	3,713	2,946
(Gain) Loss from valuation of derivative liabilities	13,886	(387)
Amortization of prepaid financing costs	258	384
Accretion of note payable to Deerfield	1,225	3,217
Accretion of note payable to Siegfried	0	332
Loss on extinguishment of debt	6,338	10,514
(Gain) Loss on disposal or sale of equipment	(1)	27
Changes in assets and liabilities:		
Accounts receivable	(438)	1,529
Inventory	(2,777)	0
Prepaid expenses and other assets	(2,502)	69
Accounts payable and accrued liabilities	(328)	(1,122)
Deferred revenues	2,368	(2,876)
Deferred rent	(130)	(139)
Net cash used in operating activities	(35,008)	(62,535)
<b>Investing Activities</b>		
Purchases of land, property and equipment	(1,035)	(347)
Proceeds from sale of equipment	1	10
Other non-current assets	(320)	22
Net cash used in investing activities	(1,354)	(315)
<b>Financing Activities</b>		
Principal payments on lease financing obligations	(956)	(723)
Principal payments on note payable to Deerfield	(22,261)	(37,739)
Payment on note payable to Siegfried	0	(7,346)
Proceeds from issuance of common stock	150,657	17,900
Proceeds from issuance of preferred stock	16,463	17,662
Net cash provided by (used in) financing activities	143,903	(10,246)
Effect of exchange rate changes on cash	601	310
Net increase (decrease) in cash and cash equivalents	108,142	(72,786)
Cash and cash equivalents at beginning of period	57,632	150,669
Cash and cash equivalents at end of period	\$ 165,774	\$ 77,883

**Supplemental Disclosure of Non-Cash Investing and Financing Information:**



Edgar Filing: ARENA PHARMACEUTICALS INC - Form 10-Q

Conversion of preferred stock into common stock	\$ 14,561	\$ 15,413
Retirement of treasury stock	\$ 23,070	\$ 0
Deemed dividend related to beneficial conversion feature of convertible preferred stock	\$ 2,824	\$ 2,260

See accompanying notes to unaudited condensed consolidated financial statements.

**Table of Contents****Notes to Unaudited Condensed Consolidated Financial Statements****1. Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements of Arena Pharmaceuticals, Inc., which include our wholly owned subsidiaries, should be read in conjunction with the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2011, as filed with the Securities and Exchange Commission, or SEC, from which we derived our balance sheet as of December 31, 2011. 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 our 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.

In June 2011, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2011-05, Presentation of Comprehensive Income, which amends the presentation requirements for comprehensive income. Under ASU No. 2011-05, we have the option to present the components of net income and comprehensive income as one single continuous statement or in two separate but consecutive statements. ASU No. 2011-05 eliminates the option to present other comprehensive income in the statement of stockholders' equity, but it does not change the items that must be reported in comprehensive income. We adopted ASU No. 2011-05 in the three months ended March 31, 2012, by using a single-statement approach.

The preparation of financial statements in accordance with GAAP requires our management to make estimates and assumptions that affect amounts reported in the financial statements and notes thereto. The amounts reported could differ under different estimates and assumptions.

In June 2012, the US Food and Drug Administration, or FDA, approved our internally discovered drug, BELVIQ® (lorcaserin HCl), for chronic weight management in adults who are obese or are overweight with at least one weight related comorbid condition. BELVIQ (pronounced BEL-VEEK ) is the trade name for lorcaserin hydrochloride in the United States. While BELVIQ may in the future be marketed outside of the United States as BELVIQ or under a different trade name, we use BELVIQ in this report to refer to the finished drug product for lorcaserin hydrochloride or, depending on the context, lorcaserin hydrochloride or other solid state forms of lorcaserin.

**2. Fair Value Disclosures**

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

We use the following three-level valuation hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs to value our financial assets and liabilities:

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

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

Level 3 - Significant unobservable inputs based on our assumptions.

The following tables present our valuation hierarchy for our financial assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2012, and December 31, 2011, in thousands:

Fair Value Measurements at September 30, 2012			
Balance at September 30, 2012	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)

Edgar Filing: ARENA PHARMACEUTICALS INC - Form 10-Q

<i>Assets:</i>				
Money market funds and cash equivalents <sup>1</sup>	\$ 153,710	\$ 153,710	\$ 0	\$ 0
<i>Liabilities:</i>				
Warrants	\$ 15,503	\$ 0	\$ 0	\$ 15,503

<sup>1</sup> Included in cash and cash equivalents on our condensed consolidated balance sheet.

**Table of Contents**

	Fair Value Measurements at December 31, 2011			
	Balance at December 31, 2011	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 <sup>1</sup>	\$ 35,307	\$ 35,307	\$ 0	\$ 0
<i>Liabilities:</i>				
Warrants and other derivative instruments	\$ 1,617	\$ 0	\$ 0	\$ 1,617

<sup>1</sup> Included in cash and cash equivalents on our consolidated balance sheet.

The following table presents the activity for our derivative liabilities, which are classified as Level 3 in our valuation hierarchy, during the three and nine months ended September 30, 2012, in thousands:

	Three months ended September 30, 2012	Nine months ended September 30, 2012
Beginning balance	\$ 20,762	\$ 1,617
(Gain) Loss from valuation of derivative liabilities	(5,259)	13,886
Balance at September 30, 2012	\$ 15,503	\$ 15,503

**3. Inventory**

Upon receiving FDA approval of BELVIQ in June 2012, we began to capitalize inventory costs for BELVIQ, which were recorded as research and development expenses prior to such approval. All of our inventory relates to BELVIQ, and no inventory was recorded on our consolidated balance sheet as of December 31, 2011. Our inventory is stated at the lower of cost (using a first-in, first-out basis) or market, and consisted of the following as of September 30, 2012, in thousands:

	September 30, 2012
Raw materials	\$ 115
Work in process	1,279
Finished goods	1,414
Total inventory	\$ 2,808

**4. Accounts Payable and Other Accrued Liabilities**

Accounts payable and other accrued liabilities consisted of the following as of September 30, 2012, and December 31, 2011, in thousands:

	September 30, 2012	December 31, 2011
Accounts payable	\$ 2,195	\$ 2,363
Accrued expenses	1,725	1,046
Accrued clinical and preclinical study fees	310	430
Loss provision (see Note 5)	767	1,203
Other accrued liabilities	66	252

Total accounts payable and other accrued liabilities	\$	5,063	\$	5,294
--	----	-------	----	-------

**5. Agreements with Siegfried**

In January 2008, our wholly owned subsidiary, Arena Pharmaceuticals GmbH, or Arena GmbH, acquired from Siegfried Ltd (now Siegfried AG, and referred to herein collectively as Siegfried) certain drug product facility assets, including manufacturing facility production licenses, fixtures, equipment, other personal property and real estate assets in Zofingen, Switzerland, under an asset purchase agreement. These assets are being used to manufacture BELVIQ as well as certain drug products for Siegfried. In connection with this transaction, the parties also entered into a long-term supply agreement for the active pharmaceutical ingredient of BELVIQ, a manufacturing services agreement and a technical services agreement. The manufacturing services and technical services agreements have since been amended several times.

**Table of Contents**

Among other changes, under the amended manufacturing services agreement, in exchange for Arena GmbH providing reductions to previously agreed upon prices, and with a discount if the minimum requirements are met, for certain manufacturing services, Siegfried has agreed to order from Arena GmbH at least 80% of its requirements of certain drug products for the calendar year 2012 and at least 60% of its requirements of certain drug products for the calendar year 2013. If Siegfried does not order the agreed minimum amounts of its requirements, Siegfried is obligated to refund Arena GmbH the amounts it saved due to the price discounts.

At December 31, 2011, we recorded a \$1.2 million estimated contract loss provision related to the amount that the costs to manufacture drug product were expected to exceed the related revenues through December 31, 2012, under the amended manufacturing services agreement in place at that time. Our estimated contract loss provision of \$0.8 million at September 30, 2012, reflects the amount that the costs to manufacture drug product are expected to exceed the related revenues through December 31, 2013, under the further amended manufacturing services agreement. The loss provision is recorded in accounts payable and other accrued liabilities on our condensed consolidated balance sheet. See Note 4.

**6. Note Payable to Deerfield**

In July 2009, pursuant to a Facility Agreement we entered into in June 2009, or the Facility Agreement, with Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P., Deerfield Partners, L.P., Deerfield International Limited, Deerfield Special Situations Fund, L.P., and Deerfield Special Situations Fund International Limited, or collectively Deerfield, Deerfield provided us with a \$100.0 million secured loan. We received net proceeds of \$95.6 million from this loan and had the right, at any time, to prepay any or all of the outstanding principal at par. In connection with the funding of this loan, we issued Deerfield warrants to purchase an aggregate of 28,000,000 shares of our common stock, which were exercisable until June 17, 2013, at an exercise price of \$5.42 per share. As described below, the Deerfield loan has been repaid in full and none of Deerfield's former warrants remain outstanding.

As of the July 2009 funding of the loan, we separately valued the following four components under the Facility Agreement: (i) the formerly outstanding \$100.0 million loan was valued at \$47.9 million on a relative fair value basis and recorded as a liability on our condensed consolidated balance sheet, (ii) the formerly outstanding warrants to purchase 28,000,000 shares of our common stock, were valued at \$39.1 million on a relative fair value basis and recorded as additional paid-in capital on our condensed consolidated balance sheet, (iii) Deerfield's former right to loan us up to an additional \$20.0 million under the Facility Agreement was valued at \$9.5 million and classified as a liability on our condensed consolidated balance sheet and (iv) Deerfield's former ability to accelerate principal payments under the loan under certain circumstances was valued at \$0.5 million and classified as a liability on our condensed consolidated balance sheet.

As part of our various transactions with Deerfield subsequent to the funding of the loan, we amended the terms of the Facility Agreement, repaid portions of the loan and exchanged all of the original warrants for a lesser number of warrants at lower exercise prices. We exchanged certain of the warrants as part of equity financings with Deerfield in June 2010, March 2011 and January 2012. Other than the exercise period, the exercise price and certain provisions related to cashless exercise and early termination of the warrants, all of the warrants issued in exchange contained substantially the same terms as the original warrants. In May 2012, we repaid the remaining portion of our note payable to Deerfield.

In addition to our previous transactions with Deerfield that included warrant exchanges, in January 2012, we and Deerfield entered into a securities purchase agreement, an exchange agreement and a third amendment to the Facility Agreement.

Under the securities purchase agreement, Deerfield purchased 9,953,250 shares of our common stock for a purchase price of \$1.65775 per share and approximately 9,953 shares of our Series D Convertible Preferred Stock, or Series D Preferred, for a purchase price of \$1,657.75 per share. In February 2012, Deerfield converted all of the Series D Preferred into a total of 9,953,250 shares of common stock. The fair value of the common stock into which the Series D Preferred was convertible on the date of issuance of the Series D Preferred exceeded the proceeds allocated to the Series D Preferred on a relative fair value basis by \$2.8 million, resulting in a beneficial conversion feature that we recognized as a decrease to additional paid-in capital and a deemed dividend to the Series D Preferred stockholders in the three months ended March 31, 2012.

Under the exchange agreement, we issued Deerfield warrants to purchase 8,631,410 shares of our common stock at an exercise price of \$1.745 per share in exchange for the cancellation of outstanding warrants to purchase (i) 11,800,000 shares of our common stock at an exercise price of \$5.42 per share and (ii) 1,831,410 shares of our common stock at an exercise price of \$3.45 per share. We determined that the incremental value of these new warrants was \$4.5 million, which was recorded as a component of the stock issuance and warrant exchange in the stockholders' equity section of our condensed consolidated balance sheet. As of September 30,

2012, none of such warrants remain outstanding.

**Table of Contents**

Under the third amendment to the Facility Agreement, we prepaid \$5.0 million of the principal amount that was originally scheduled to be repaid to Deerfield in June 2013. After deducting such prepayment, net proceeds to us under this financing were \$27.9 million. In connection with the \$5.0 million prepayment, we retired a proportional share of the debt discount and issuance costs directly related to the repaid debt and recognized a non-cash loss on extinguishment of debt of \$1.7 million in the three months ended March 31, 2012.

In April and May 2012, Deerfield exercised certain of its warrants to purchase a total of 4,000,000 shares of our common stock, and elected to pay the exercise price by canceling \$6.7 million of the then outstanding principal balance on its loan. In May 2012, we prepaid the remaining outstanding principal balance and unpaid interest on the Deerfield loan, and the Facility Agreement was terminated. In connection with these transactions, we retired the related debt discount and issuance costs and recognized a non-cash loss on extinguishment of debt totaling \$4.7 million in the three months ended June 30, 2012.

From June to August 2012, we received net proceeds totaling \$32.5 million from the cash exercise of Deerfield's remaining warrants to purchase a total of 19,000,000 shares of our common stock.

The following table summarizes the principal repayments made on the Deerfield loan from its inception through the date it was repaid in full, in thousands:

	<b>Loan Principal</b>
Original loan principal	\$ 100,000
July 2009 repayment	(10,000)
August 2010 repayment	(30,000)
January 2011 repayment	(20,000)
March 2011 repayment	(17,739)
January 2012 repayment	(5,000)
April and May 2012 repayment from cancellation from warrant exercises	(6,720)
May 2012 repayment	(10,541)
<b>Outstanding principal balance at September 30, 2012</b>	<b>\$ 0</b>

As a result of the May 2012 payoff of the Deerfield loan, no related interest expense was recognized in the three months ended September 30, 2012. Total interest expense of \$1.9 million, including accretion of the debt discount attributable to the warrants and the other derivative financial instruments and amortization of capitalized issuance costs, was recognized in connection with this loan in the nine months ended September 30, 2012. Total interest expense of \$1.3 million and \$5.2 million was recognized in connection with this loan in the three and nine months ended September 30, 2011, respectively.

**7. Derivative Liabilities**

In June 2006 and August 2008, we issued seven-year warrants, which we refer to as the Series B Warrants, to purchase 829,856 and 1,106,344 shares of our common stock, respectively, at an exercise price of \$15.49 and \$7.71 per share, respectively. The Series B Warrants are related to our Series B Convertible Preferred Stock, which we redeemed in 2008 and is no longer outstanding. The warrants contain an anti-dilution provision and, as a result of certain subsequent equity issuances at prices below the adjustment price of \$6.72 defined in the warrants, as of September 30, 2012, the number of shares issuable upon exercise of the outstanding June 2006 and August 2008 Series B Warrants was increased to 1,467,405 and 1,965,418, respectively, and the exercise price was reduced to \$8.76 and \$4.34 per share, respectively. The Series B Warrants are classified as liabilities on our condensed consolidated balance sheets.

In accordance with relevant guidance, we have revalued these warrants on each subsequent balance sheet date, and will continue to do so until they are exercised or expire, with changes in the fair value between reporting periods recorded as other income or expense. The June 2006 and August 2008 Series B Warrants were valued at September 30, 2012, and 2011, using the Black-Scholes option pricing model and the following assumptions:

September 30, 2012

September 30, 2011



Edgar Filing: ARENA PHARMACEUTICALS INC - Form 10-Q

	<b>June 2006 Series B Warrants</b>	<b>August 2008 Series B Warrants</b>	<b>June 2006 Series B Warrants</b>	<b>August 2008 Series B Warrants</b>
Risk-free interest rate	0.2%	0.3%	0.3%	0.7%
Dividend yield	0%	0%	0%	0%
Expected volatility	105%	91%	99%	99%
Expected life (years)	0.75	2.88	1.75	3.87

**Table of Contents**

We separately valued Deerfield's right to require us to accelerate payments under the loan at \$0.5 million as of the July 2009 issuance date (see Note 6). The value of this acceleration right was classified as a liability on our condensed consolidated balance sheet, with changes in the fair value between reporting periods recorded as other income or expense, until it was terminated in connection with the full repayment of the Deerfield loan in the three months ended June 30, 2012.

Our derivative liabilities consisted of the following as of September 30, 2012, and December 31, 2011, in thousands:

	September 30, 2012	December 31, 2011
Series B Warrants - current portion	\$ 4,100	\$ 0
Total current derivative liabilities	4,100	0
Series B Warrants - less current portion	11,403	1,562
Deerfield acceleration right	0	55
Total long-term derivative liabilities	11,403	1,617
Total derivative liabilities	\$ 15,503	\$ 1,617

The change in the fair value of our derivative liabilities is recorded in the interest and other income (expense) section of our condensed consolidated statements of operations and comprehensive loss. We recognized the following gain (loss) in the three and nine months ended September 30, 2012, and 2011, in thousands:

	Three months ended September 30, 2012		Nine months ended September 30, 2011	
Series B Warrants	\$ 5,259	\$ (234)	\$ (13,941)	\$ 30
Deerfield acceleration right	0	1	55	357
Total gain (loss) from valuation of derivative liabilities	\$ 5,259	\$ (233)	\$ (13,886)	\$ 387

**8. Marketing and Supply Agreement with Eisai Inc.**

In May 2012, Arena GmbH and Eisai Inc., or Eisai, entered into the Amended and Restated Marketing and Supply Agreement, or Eisai Agreement, which amended and restated the original marketing and supply agreement the parties entered into in July 2010. This amendment expanded Eisai's exclusive rights to commercialize BELVIQ to include, in addition to the United States and its territories and possessions, most of North and South America, including Canada, Mexico and Brazil, subject to applicable regulatory approval in the additional territories.

We received from Eisai upfront payments of \$50.0 million when we entered into the original agreement and \$5.0 million when we entered into the amended agreement. We recorded both upfront payments as deferred revenues and are recognizing them as revenue ratably over 16.0 years and 13.2 years, respectively, which are the periods in which we expect to have significant involvement. At September 30, 2012, our condensed consolidated balance sheet included \$3.5 million and \$43.6 million for the current and non-current portion, respectively, of the total deferred revenues attributable to such upfront payments.

In addition to the upfront payments, we received a \$20.0 million non-refundable milestone payment that we earned for the inclusion in the FDA-approved prescribing information of the efficacy and safety data from the Phase 3 BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus) clinical trial in patients with type 2 diabetes. We recognized this \$20.0 million milestone payment as revenue when the FDA approved BELVIQ on June 27, 2012. We are also entitled to receive from Eisai up to \$119.5 million of additional non-refundable milestone payments, consisting of \$65.0 million upon the DEA's final scheduling designation for BELVIQ and other milestone payments totaling \$54.5 million based on achievement of regulatory filings and approvals. Under the milestone method of

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

revenue recognition, we will recognize revenue for the amount payable to us for achieving each substantive milestone payment, if any, in the period the milestone is achieved.

We will sell BELVIQ to Eisai for marketing and distribution in the United States and, subject to applicable regulatory approval, in the additional territories for a purchase price starting at 31.5% and 30.75%, respectively, of Eisai's aggregate annual net sales (which are the gross invoiced sales less certain deductions described in the Eisai Agreement, including for certain taxes, credits, allowances, discounts, rebates, chargebacks and other items) in all of such territories on an aggregate basis. The purchase price will increase on a tiered basis in the United States and in the additional territories to as high as 36.5% and 35.75%, respectively, on the portion of Eisai's annual net sales exceeding \$750.0 million, subject to reduction (for sales in a particular country) in the event of generic competition in the applicable country. The Eisai Agreement includes payments by Eisai if annual minimum sales requirements in the additional territories are not met during the first ten years after initial commercial sale in Canada, Mexico or Brazil. In addition, we are eligible to receive up to an aggregate of \$1.19 billion in one-time purchase price adjustments and other payments based on Eisai's annual net

**Table of Contents**

sales of BELVIQ in all of the territories under our agreement on an aggregate basis, with the first and last amounts payable with annual net sales of \$250.0 million and \$2.5 billion, respectively. Of these payments, Eisai will pay us a total of \$330.0 million for annual net sales of up to \$1.0 billion. We are also eligible to receive up to an additional \$185.0 million in one-time purchase price adjustment payments based on Eisai's annual net sales of BELVIQ in the non-US territories under our agreement, with the first and last amounts payable upon first achievement of annual net sales of \$100.0 million and \$1.0 billion, respectively, in such territories.

With respect to the post-marketing studies we and Eisai committed to conduct as part of the FDA approval of BELVIQ, Eisai will bear 90% and we will bear 10% of the expenses for the cardiovascular outcomes trial, and Eisai and we will share equally the costs of certain pediatric studies. Eisai is responsible for regulatory activities related to the BELVIQ New Drug Application, or NDA, and for the regulatory activities for obtaining regulatory approval in any country in the additional territories. If the regulatory authority for a country in the additional territories requires development work before or following approval of BELVIQ in such country, Eisai will bear 90% and we will bear 10% of the expenses for such work, with the exception of the expenses for stability testing, which will be shared equally by the parties.

Arena GmbH has agreed to indemnify Eisai for certain losses resulting from product liability claims, except to the extent caused by Eisai's negligence, willful misconduct, violation of law or breach of the Eisai Agreement or related agreements. We have limited product liability insurance, and are unable to predict the maximum potential amount of any future payment for product liability.

**9. Warrants**

All of Deerfield's formerly outstanding warrants to purchase 23,000,000 shares of our common stock were exercised at various dates in 2012. See Note 6.

The following table summarizes our outstanding warrants as of September 30, 2012:

	<b>Balance Sheet Classification</b>	<b>Number of Warrants</b>	<b>Exercise Price</b>	<b>Expiration Date</b>
August 2008 Series B Warrants	Liability	1,965,418	\$ 4.34	August 14, 2015
June 2006 Series B Warrants	Liability	1,467,405	\$ 8.76	June 30, 2013
<b>Total number of warrants outstanding</b>		<b>3,432,823</b>		

**10. Stockholders' Equity****Issuances of Common Stock**

In January 2012, we issued Deerfield 9,953,250 shares of our common stock and approximately 9,953 shares of our Series D Preferred, and exchanged certain of Deerfield's warrants to purchase shares of our common stock. After deducting our \$5.0 million prepayment of loan principal, net proceeds to us from this financing were \$27.9 million. In February 2012, Deerfield converted all of the Series D Preferred into a total of 9,953,250 shares of our common stock. See Note 6.

In March 2012, we issued 14,414,370 shares of our common stock under an equity line of credit agreement with Azimuth Opportunity, L.P., resulting in net proceeds to us of \$24.7 million.

In May 2012, we received net proceeds of \$65.7 million in a public offering of 12,650,000 shares of our common stock at \$5.50 per share, including 1,650,000 shares sold pursuant to the full exercise of an over-allotment option.

In addition to the above, in the nine months ended September 30, 2012, we issued a total of 23,000,000 shares of our common stock with respect to the exercise of all of Deerfield's formerly outstanding warrants, resulting in net proceeds to us of \$32.5 million, which proceeds do not include \$6.7 million from the exercise of warrants that was used to cancel a portion of the then outstanding principal on the Deerfield loan (see Note 6). We also issued a total of 928,323 shares of our common stock pursuant to stock option exercises and a total of 244,230 shares of our common stock under our employee stock purchase plan, resulting in net proceeds to us of \$4.2 million and \$0.3 million, respectively.

**Authorized Shares**

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

On June 15, 2012, our stockholders approved an amendment to our Fifth Amended and Restated Certificate of Incorporation, as amended, to increase the total number of authorized shares from 250,000,000 to 375,000,000 and the number of authorized shares of common stock from 242,500,000 to 367,500,000.

---

## **Table of Contents**

### ***Equity Compensation Plans***

On June 15, 2012, our stockholders approved our 2012 Long-Term Incentive Plan, or 2012 LTIP. Upon such approval, our 2009 Long-Term Incentive Plan, or 2009 LTIP, was terminated. Our 2006 Long-Term Incentive Plan, as amended, Amended and Restated 1998 Equity Compensation Plan, Amended and Restated 2000 Equity Compensation Plan, and 2002 Equity Compensation Plan (or together with the 2009 LTIP, the Prior Plans ) were previously terminated. However, notwithstanding such termination of the Prior Plans, all outstanding awards under the Prior Plans will continue to be governed by the terms of the applicable Prior Plan in effect at the time of grant and the agreements evidencing those awards. The number of shares of common stock authorized for issuance under the 2012 LTIP may be increased by the number of shares subject to any stock awards under the Prior Plans that are forfeited, expire or otherwise terminate without the issuance of such shares and would otherwise be returned to the share reserve under the Prior Plans but for their termination and as otherwise provided in the 2012 LTIP.

The 2012 LTIP provides for the grant of a total of 18,000,000 shares of our common stock, as (i) decreased for grants made under the Prior Plans between December 31, 2011, and the approval of the 2012 LTIP and (ii) increased by the number of shares subject to any stock awards under the Prior Plans that, between December 31, 2011, and the approval of the 2012 LTIP, are forfeited, expire or settled for cash and as otherwise provided in the 2012 LTIP. When approved by our stockholders, there were 15,384,713 shares of common stock available for issuance under the 2012 LTIP. As of September 30, 2012, there were 15,375,926 shares of common stock available for issuance under the 2012 LTIP.

Shares may be granted under the 2012 LTIP as incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and performance awards. Subject to certain limited exceptions, (i) stock options and stock appreciation rights granted under the 2012 LTIP reduce the available number of shares by one share for every share issued while awards other than stock options and stock appreciation rights granted under the 2012 LTIP reduce the available number of shares by 1.2 shares for every share issued. In addition, shares that are released from awards granted under the Prior Plans or the 2012 LTIP because the awards expire, are forfeited or are settled for cash will increase the number of shares available under the 2012 LTIP by one share for each share released from a stock option or stock appreciation right and by 1.2 shares for each share released from a restricted stock award or restricted stock unit award.

Stock options granted under the 2012 LTIP generally vest 25% a year for four years and are exercisable for up to 10 years from the date of grant. The recipient of a restricted stock award has all rights of a stockholder at the date of grant, subject to certain restrictions on transferability and a risk of forfeiture. The minimum performance period under a performance award is 12 months. Neither the exercise price of an option nor the grant price of a stock appreciation right may be less than 100% of the fair market value of the common stock on the date such option is granted, except in specified situations. The 2012 LTIP prohibits option and stock appreciation right repricings (other than to reflect stock splits, spin-offs or certain other corporate events) unless stockholder approval is obtained.

### ***Employee Stock Purchase Plan***

On June 15, 2012, our stockholders approved our 2009 Employee Stock Purchase Plan, as amended, or 2009 ESPP, which (i) increased the shares of our common stock authorized and available for future issuance under the plan to a total of 1,500,000 as of June 15, 2012, (ii) modified the plan's automatic transfer to a lower price offering period to be based on the enrollment date of a new offering period instead of the exercise date of the immediately preceding offering period, (iii) eliminated references to our former 2001 Employee Stock Purchase Plan, as amended, and (iv) changed the termination date of the plan to the date our Board of Directors determines to terminate the plan. As of September 30, 2012, a total of 1,331,897 shares of common stock were available for issuance under the 2009 ESPP.

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

### ***Treasury Stock***

On May 14, 2012, we retired all of the 3,000,000 shares we formerly held as treasury shares, and restored them to the status of authorized but unissued common stock. Such retirement resulted in a \$23.1 million increase to our accumulated deficit in the three months ended June 30, 2012, and no treasury stock remains outstanding.

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

We recognized share-based compensation expense as follows, in thousands:

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Research and development	\$ 509	\$ 471	\$ 1,215	\$ 1,510
General and administrative	843	321	2,498	1,342
Restructuring charges	0	0	0	94
Total share-based compensation expense	\$ 1,352	\$ 792	\$ 3,713	\$ 2,946

**Share-based Award Activity**

The following table summarizes our stock option activity during the nine months ended September 30, 2012:

	Options	Weighted- Average Exercise Price
Outstanding at January 1, 2012	10,309,972	\$ 5.63
Granted	5,158,400	2.41
Exercised	(928,323)	4.58
Forfeited/cancelled/expired	(1,128,826)	8.23
Outstanding at September 30, 2012	13,411,223	\$ 4.25

We granted 1,690,500 and 371,800 performance-based restricted stock unit awards in February 2007 and March 2008, respectively. The awards provided employees until February 26, 2012, to achieve four specific drug development and strategic performance goals. As none of these performance goals was achieved by February 26, 2012, all of the 1,171,250 then outstanding awards expired on such date without any vesting. No compensation expense was recognized related to these awards.

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

Financial instruments, which potentially subject us to concentrations of credit risk, consist primarily of cash, cash equivalents and short-term investments. We limit our exposure to credit loss by holding our cash primarily in US dollars or placing our cash and investments in US government, agency and government-sponsored enterprise obligations and in corporate debt instruments that are rated investment grade, in accordance with an investment policy approved by our Board of Directors.

Eisai is our only customer for sales of BELVIQ in the United States and, subject to applicable regulatory approval, the additional territories under the Eisai Agreement. We manufacture drug products for Siegfried under a manufacturing services agreement, and all of our manufacturing services revenues are attributable to Siegfried.

Percentages of our total revenues are as follows for the periods presented:

Source of Revenue	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Eisai Agreement	58.2%	50.1%	88.3%	53.2%

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

Manufacturing services agreement with Siegfried	40.6%	49.5%	11.4%	41.2%
Former collaboration with Ortho-McNeil-Janssen Pharmaceuticals, Inc.	0.0%	0.0%	0.0%	5.2%
Other	1.2%	0.4%	0.3%	0.4%
<b>Total percentage of revenues</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>



**Table of Contents****12. Net Loss Per Share**

We calculate basic and diluted net loss per share allocable to common stockholders using the weighted-average number of shares of common stock outstanding during the period, less any shares subject to repurchase or forfeiture. There were no shares of our common stock subject to repurchase or forfeiture for the three and nine months ended September 30, 2012, or 2011.

Since we are in a net loss position, we have excluded outstanding warrants and stock options, as well as unvested restricted stock in our deferred compensation plan, from our calculation of diluted net loss per share, and our diluted net loss per share is the same as our basic net loss per share. The table below presents the potentially dilutive securities that would have been included in our calculation of diluted net loss per share allocable to common stockholders if they were not antidilutive for the periods presented.

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Warrants	1,054,138	0	400,296	0
Stock options	6,228,215	0	3,538,554	0
Unvested restricted stock	79,169	79,169	79,169	79,169
Total	7,361,522	79,169	4,018,019	79,169

**13. Lease Obligation**

In May 2007, pursuant to an agreement that was originally with BioMed Realty, L.P., a Maryland limited partnership, or BioMed, and later assigned by BioMed to one of its subsidiaries, BMR-6114-6154 Nancy Ridge Drive LLC, a Delaware limited liability company, or BMR, we sold to BMR three of our US properties and our right, title and interest in the option to purchase a fourth US property, which we were leasing from another lessor. In connection with this transaction, we also (i) entered into agreements with BMR to lease back the properties under 20-year leases, and (ii) agreed that, upon the exercise of the option on the fourth property, we would continue to lease such property, but with BMR for a term that is concurrent with the leases for the other three properties.

In April 2012, BMR exercised its option and purchased the fourth property. As a result of the purchase, we are obligated to lease this property through May 2027, which resulted in an operating lease obligation of \$14.2 million over the term of this lease. In addition, subject to certain restrictions, we have the option to repurchase this property, as well as the other three properties, on the 10th, 15th or 20th anniversary of the May 2007 execution date of the leases, and earlier if the leases are terminated under certain circumstances.

**14. Legal Proceedings**

Beginning on September 20, 2010, a number of complaints were filed in the US District Court for the Southern District of California against us and certain of our current and former employees and directors on behalf of certain purchasers of our common stock. The complaints have been brought as purported stockholder class actions, and, in general, include allegations that we and certain of our current and former employees and directors violated federal securities laws by making materially false and misleading statements regarding our BELVIQ program, thereby artificially inflating the price of our common stock. The plaintiffs are seeking unspecified monetary damages and other relief. On November 19, 2010, eight prospective lead plaintiffs filed motions to consolidate, appoint a lead plaintiff, and appoint lead counsel. The Court took the motions to consolidate under submission on January 14, 2011. On August 8, 2011, the Court consolidated the actions and appointed a lead plaintiff and lead counsel. On November 1, 2011, the lead plaintiff filed a consolidated amended complaint. On December 30, 2011, we filed a motion to dismiss the consolidated amended complaint. The motion to dismiss has been fully briefed and the Court took the motion to dismiss under submission on April 13, 2012. In addition to the class actions, a complaint involving similar legal and factual issues has been brought by at least one individual stockholder and is pending in federal court. On December 30, 2011, we filed a motion to dismiss the stockholder's complaint. The motion to dismiss has been fully briefed and the Court took the motion to dismiss under submission on April 13, 2012. We intend to defend against the claims advanced and to seek dismissal of these complaints. Due to the early stage of these proceedings, we are not able to predict or reasonably estimate the ultimate outcome or possible losses relating to these claims.

On September 24, 2010, a stockholder derivative complaint was filed in the Superior Court of California for the County of San Diego against certain of our current and former employees and directors, and other stockholder derivative complaints were subsequently filed in state court. On October 19, 2010, the Superior Court ordered that the pending state derivative actions be consolidated. The Superior Court also ordered that later

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

filed, related state derivative actions be consolidated as well. We refer to the consolidated state derivative actions as the State Derivative Action. In November 2010, plaintiffs in the State Derivative Action filed a consolidated stockholder derivative complaint. We filed a demurrer to the consolidated stockholder derivative complaint on February 15, 2011. On October 6, 2010, a stockholder derivative complaint was filed in the US District Court for the Southern District of California. Thereafter, a number of other stockholder derivative complaints were also filed in federal court. On March 3, 2011, the federal court ordered that the pending federal derivative actions be consolidated. The federal court also ordered that later filed, related federal derivative actions

## **Table of Contents**

be consolidated as well. We refer to the consolidated federal derivative actions as the Federal Derivative Action. We refer to the State Derivative Action and the Federal Derivative Action collectively as the Derivative Actions. The Derivative Actions allege breaches of fiduciary duties by the defendants and other violations of law. In general, the Derivative Actions allege that certain of our current and former employees and directors caused or allowed for the dissemination of materially false and misleading statements regarding our BELVIQ program, thereby artificially inflating the price of our common stock. On September 9, 2011, we and lead counsel for the plaintiffs in the Derivative Actions entered into a stipulation of settlement to resolve the Derivative Actions. The current and former employees and directors named as individual defendants in the Derivative Actions have also entered into the stipulation of settlement. On October 19, 2011, the Superior Court of California entered an order preliminarily approving the proposed settlement. On December 16, 2011, the Superior Court of California issued its final order and judgment approving the settlement and dismissing the State Derivative Action with prejudice. On December 29, 2011, the US District Court issued an order dismissing the Federal Derivative Action with prejudice. In accordance with the terms of the settlement, and in exchange for a release of all claims by the plaintiffs, among others, we agreed to adopt certain corporate governance measures and cause our insurers to pay the plaintiffs' attorneys a total of \$1.1 million. The time for appeals of the settlement of the Derivative Actions has lapsed without any appeal.

### **15. Subsequent Events**

We have evaluated subsequent events after the balance sheet date of September 30, 2012, and up to the date we filed this report.

#### ***BELVIQ Product Supply***

In October 2012, Arena GmbH delivered to Eisai BELVIQ product supply pursuant to an initial order under the Eisai Agreement. Eisai will pay us \$11.6 million for such product supply, which will be recorded as deferred revenues until earned.

#### ***Collaboration with Ildong Pharmaceutical Co., Ltd.***

In November 2012, Arena GmbH entered into a Marketing and Supply Agreement, or Ildong Agreement, with Ildong Pharmaceutical Co., Ltd., or Ildong, for BELVIQ. Under the Ildong Agreement, Arena GmbH granted Ildong exclusive rights to commercialize BELVIQ in South Korea for weight loss or weight management in obese and overweight patients, subject to regulatory approval of BELVIQ by the Korea Food and Drug Administration, or KFDA.

Arena GmbH will receive from Ildong an upfront payment of \$5.0 million, and an additional \$3.0 million upon the approval of BELVIQ by the KFDA. Ildong is responsible for the regulatory approval and, ultimately, commercialization of BELVIQ in South Korea for weight loss or weight management in obese and overweight patients, including related development and other costs and expenses. Arena GmbH will manufacture BELVIQ at its facility in Switzerland, and sell BELVIQ to Ildong for a purchase price starting at 35% of Ildong's annual net sales. The purchase price will increase on a tiered basis up to 45% on the portion of annual net sales exceeding \$15.0 million. If certain annual net sales amounts are not met, Arena GmbH can convert Ildong's right to commercialize BELVIQ in South Korea to be non-exclusive.

Ildong has agreed not to (i) commercialize any pharmaceutical product containing BELVIQ (other than BELVIQ purchased from Arena GmbH), (ii) develop or commercialize any pharmaceutical product containing BELVIQ outside of South Korea, or (iii) conduct activities outside of the Ildong Agreement related to the approval or commercialization of any other pharmaceutical product for weight loss, weight management or obesity in South Korea. Arena GmbH has agreed not to commercialize in South Korea any pharmaceutical product containing BELVIQ intended for end use in weight loss or weight management in obese and overweight patients.

Unless terminated earlier, the Ildong Agreement will continue in effect until the later of the expiration of all issued patents relating to BELVIQ in South Korea and 12 years after the first commercial sale of BELVIQ in South Korea. Either party has the right to terminate the Ildong Agreement early in certain circumstances, including (i) if the other party is in material breach, (ii) for certain commercialization concerns, and (iii) for certain intellectual property concerns. Ildong also has the right to terminate the Ildong Agreement early in certain circumstances, including if Arena GmbH notifies Ildong that Ildong's right to commercialize BELVIQ in South Korea will become non-exclusive.

Ildong will indemnify Arena GmbH for certain losses resulting from third-party claims, including for (i) Ildong's negligence, willful misconduct or violation of law, (ii) Ildong's breach of the Ildong Agreement or related agreements, (iii) certain uses or misuses of BELVIQ (including any product liability claim and other claims relating to sales or development of BELVIQ in South Korea), (iv) certain governmental investigations of Ildong, and (v) infringement relating to Ildong's use of trademarks related to BELVIQ. Arena GmbH will indemnify Ildong for certain losses resulting from third-party claims, including for (i) Arena GmbH's negligence, willful misconduct or violation of law, and (ii) Arena GmbH's breach of the Ildong Agreement or related agreements.



---

## **Table of Contents**

### **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, 2011, or 2011 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 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.

BELVIQ® is the trade name for lorcaserin hydrochloride in the United States. While BELVIQ (lorcaserin HCl) may in the future be marketed outside of the United States as BELVIQ or under a different trade name, we use BELVIQ in this Quarterly Report to refer to the finished drug product for lorcaserin hydrochloride or, depending on the context, lorcaserin hydrochloride or other solid state forms of lorcaserin.

## **OVERVIEW AND RECENT DEVELOPMENTS**

We are a biopharmaceutical company focused on discovering, developing and commercializing novel drugs that selectively target G protein-coupled receptors. Our most advanced program is for our internally discovered drug, BELVIQ (pronounced BEL-VEEK), which was approved by the US Food and Drug Administration, or FDA, on June 27, 2012, for chronic weight management in adults who are obese or are overweight with at least one weight related comorbid condition. BELVIQ will be marketed in the United States by Eisai Inc., or Eisai, under the Amended and Restated Marketing and Supply Agreement, or Eisai Agreement, with our wholly owned subsidiary, Arena Pharmaceuticals GmbH, or Arena GmbH.

Under the Eisai Agreement, we provided Eisai with the marketing and distribution rights for BELVIQ in most of North and South America, including Canada, Mexico and Brazil. Eisai will launch BELVIQ in the United States following the scheduling designation by the US Drug Enforcement Administration, or DEA. In addition, under the Marketing and Supply Agreement, or Ildong Agreement, between Arena GmbH and Ildong Pharmaceutical Co., Ltd., or Ildong, we provided Ildong with the marketing and distribution rights for BELVIQ in South Korea for weight loss or weight management in obese and overweight patients, subject to regulatory approval of BELVIQ by the Korea Food and Drug Administration, or KFDA. We continue to own rights to market and distribute BELVIQ outside of these territories.

We have filed marketing authorization applications, or MAAs, for the regulatory approval of BELVIQ in the European Union and Switzerland, and the applications are currently under review. We also intend to seek regulatory approval of BELVIQ in additional territories.

Our prioritized earlier-stage programs include APD811 (an orally available agonist of the prostacyclin receptor intended for the treatment of pulmonary arterial hypertension), APD334 (an orally available agonist of the S1P1 receptor intended for the treatment of a number of conditions related to autoimmune diseases) and APD371 (an orally available agonist of the cannabinoid receptor 2 intended for the treatment of pain), all of which we internally discovered. In October 2012, we initiated a Phase 1 multiple-dose clinical trial of APD811. We expect to advance APD334 into a Phase 1 clinical trial in 2013, and are continuing our efforts to discover and advance other drug candidates.

Our recent and third quarter 2012 developments include:

Established the Ildong Agreement, under which Arena GmbH granted Ildong exclusive rights to market and distribute BELVIQ in South Korea for weight loss or weight management in obese and overweight patients, subject to regulatory approval of BELVIQ by

the KFDA.

**Table of Contents**

Submitted our response to the European Medicines Agency's Committee for Medicinal Products for Human Use's 120-day assessment report and list of questions regarding the MAA for the marketing of BELVIQ in the European Union.

Initiated dosing in a Phase 1 multiple-dose clinical trial of APD811. This randomized, double-blind and placebo-controlled dose titration trial is evaluating the safety, tolerability, pharmacokinetics and optimal titration schedule of multiple-ascending doses of APD811. We previously evaluated single-ascending doses of APD811 in the initial Phase 1 clinical trial.

We refer you to our previously filed SEC reports for a more complete discussion of certain of these and related developments.

Developing marketed drugs is a long, uncertain and expensive process, and our ability to achieve our goals, including commercializing BELVIQ in the United States, obtaining regulatory approval of, and commercializing, BELVIQ in additional territories, conducting required and potentially other post-marketing studies of BELVIQ, and advancing our drug candidates, depends on numerous factors, many of which we do not control. We will continue to seek to balance the high costs of research, development and manufacturing against the need to sustain our operations long enough to commercialize the results of our efforts and attain profitability.

We will use substantial cash to achieve our goals. To date, we have not generated any revenues from the sale of any of our drug candidates, and BELVIQ will not be commercially available until the DEA provides the final scheduling designation. We expect to continue to incur substantial losses, and do not expect to generate consistent positive operating cash flows, for at least the short term. Accordingly, we will need to receive additional funds under the Eisai Agreement or Ildong Agreement, under future collaborative agreements for BELVIQ or one or more of our drug candidates or programs, or by raising additional funds through equity, debt or other financing transactions.

**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 dollar values in the following tables are in millions.

**Revenues**

Source of revenue	Three months ended		Nine months ended	
	September 30, 2012	September 30, 2011	September 30, 2012	September 30, 2011
Amortization of upfront payments from Eisai	\$ 0.9	\$ 1.0	\$ 2.7	\$ 2.9
Manufacturing services agreement	0.6	1.7	2.9	4.4
Milestone payments from Eisai	0.0	0.0	20.0	0.0
Other payments from Eisai	0.0	0.8	0.0	2.8
Other collaborative agreements	0.0	0.0	0.1	0.5
Total revenues	\$ 1.5	\$ 3.5	\$ 25.7	\$ 10.6

**Research and development expenses**

Type of expense	Three months ended		Nine months ended	
	September 30, 2012	September 30, 2011	September 30, 2012	September 30, 2011
Salary and other personnel costs (excluding non-cash share-based compensation)	\$ 6.3	\$ 6.4	\$ 17.2	\$ 19.4
Facility and equipment costs	2.9	2.9	8.5	9.2
Research supplies	0.8	1.1	2.3	2.8
External clinical and preclinical study fees and expenses, including external manufacturing costs	0.6	1.7	5.3	5.4
Non-cash share-based compensation	0.5	0.5	1.2	1.5
Internal research and development manufacturing costs related to Swiss facility	0.0	1.8	4.0	5.5
Other	0.5	0.6	1.7	1.8

Edgar Filing: ARENA PHARMACEUTICALS INC - Form 10-Q

Total research and development expenses	\$ 11.6	\$ 15.0	\$ 40.2	\$ 45.6
---	---------	---------	---------	---------



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

Type of expense	Three months ended		Nine months ended	
	September 30, 2012	September 30, 2011	September 30, 2012	September 30, 2011
Salary and other personnel costs (excluding non-cash share-based compensation)	\$ 2.9	\$ 2.5	\$ 7.1	\$ 6.9
Legal, accounting and other professional fees	1.7	1.6	4.7	6.1
Facility and equipment costs	1.4	1.1	3.4	3.2
Non-cash share-based compensation	0.8	0.3	2.4	1.4
Other	0.6	0.5	1.4	1.4
Total general and administrative expenses	\$ 7.4	\$ 6.0	\$ 19.0	\$ 19.0

**THREE MONTHS ENDED SEPTEMBER 30, 2012, AND 2011**

**Revenues.** Total revenues decreased by \$2.0 million to \$1.5 million for the three months ended September 30, 2012, from \$3.5 million for the three months ended September 30, 2011. This was primarily due to decreases of (i) \$1.1 million under our manufacturing services agreement with Siegfried Ltd (now Siegfried AG, and referred to herein collectively as Siegfried), and (ii) \$0.8 million for reimbursements we received from Eisai related to additional BELVIQ development work for the three months ended September 30, 2011.

We expect our 2012 revenues will primarily consist of (i) the \$20.0 million milestone payment from Eisai that we earned in connection with the FDA approval of BELVIQ, (ii) amortization of (a) the \$50.0 million non-refundable, upfront payment we received in July 2010 in connection with entering into the original marketing and supply agreement with Eisai, (b) the \$5.0 million non-refundable, upfront payment we received in May 2012 in connection with entering into the amended and restated marketing and supply agreement with Eisai, and (c) the \$5.0 million non-refundable, upfront payment we will receive from Ildong in connection with entering into the Ildong Agreement in November 2012, and (iii) manufacturing services revenue from Siegfried. We expect our 2012 revenues from manufacturing services will be lower than in 2011, due to both decreased units of drug product expected to be manufactured and lower agreed upon prices. Upon the DEA's final scheduling designation for BELVIQ, we will also recognize milestone payments from Eisai totaling \$65.0 million.

Revenues for milestones that may be achieved in the future are difficult to predict, and our revenues will likely vary significantly from quarter to quarter and year to year. We expect that any significant revenues in the short term will depend on when Eisai begins marketing BELVIQ in the United States, as well as whether and when we (i) receive regulatory approval of, and commercialize, BELVIQ outside of the United States, (ii) enter into any additional agreements to commercialize BELVIQ and (iii) enter into any agreements to collaborate on or license any of our drug candidates or intellectual property. Our short-term revenues will also include amounts we earn under our amended manufacturing services agreement with Siegfried.

**Cost of manufacturing services.** Cost of manufacturing services is comprised of direct costs associated with manufacturing drug products for Siegfried under our amended manufacturing services agreement, including related salaries, other personnel costs and machinery depreciation costs. We recognized cost of manufacturing services of \$1.4 million and \$1.6 million for the three months ended September 30, 2012, and 2011, respectively. The amount recognized for the three months ended September 30, 2012, included a \$0.7 million charge for the increase in the previously estimated contract loss provision for services expected to be rendered through the extended agreement period, which now ends on December 31, 2013, under the amended manufacturing services agreement. The amount recognized for the three months ended September 30, 2011, included a \$0.2 million reduction for the decrease in the contract loss provision estimated at that time.

**Research and development expenses.** Research and development expenses, which account for the majority of our expenses, consist primarily of salaries and other personnel costs, clinical trial costs (including payments to contract research organizations, or CROs), preclinical study fees, manufacturing costs for non-commercial products, costs for the development of our earlier-stage programs and technologies, research supply costs and facility and equipment costs. We expense research and development costs as they are incurred when these expenditures have no alternative future uses. We generally do not track our earlier-stage, internal research and development expenses by project; rather, we track such expenses by the type of cost incurred.

Research and development expenses decreased by \$3.4 million to \$11.6 million for the three months ended September 30, 2012, from \$15.0 million for the three months ended September 30, 2011. This was primarily due to decreases of (i) \$1.8 million in internal research and development manufacturing costs related to our Swiss manufacturing facility and (ii) \$1.1 million in external clinical and preclinical study fees

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

and expenses. Prior to the FDA approval of BELVIQ, we recorded BELVIQ manufacturing costs as research and development expenses. However, once the FDA approved BELVIQ, we began to capitalize our BELVIQ manufacturing costs, which we expect to be significant, as inventory, and will subsequently record such costs as cost of goods sold as the related inventory is sold. We expect to continue to incur substantial research and development expenses in 2012, which we expect will be slightly lower than the 2011 level.

---

**Table of Contents**

Of the \$0.6 million total external clinical and preclinical study fees and expenses noted in the table above for the three months ended September 30, 2012, \$0.4 million related to our BELVIQ program and \$0.1 million related to our APD811 program. Included in the \$1.7 million total external clinical and preclinical study fees and expenses noted in the table above for the three months ended September 30, 2011, was \$1.3 million related to our BELVIQ program and \$0.3 million related to our APD811 program.

**General and administrative expenses.** General and administrative expenses increased by \$1.4 million to \$7.4 million for the three months ended September 30, 2012, from \$6.0 million for the three months ended September 30, 2011. This was primarily due to increases of (i) \$0.5 million in non-cash share-based compensation and (ii) \$0.4 million in salary and personnel costs. We expect that our 2012 general and administrative expenses will be slightly higher than the 2011 level.

**Amortization of acquired technology and other intangibles.** We recognized \$0.2 million for amortization of acquired technology and other intangibles for each of the three-month periods ended September 30, 2012, and 2011. This amortization expense relates to the manufacturing facility production licenses we acquired in January 2008, which are being amortized over their estimated useful life of 20 years. Using the exchange rate in effect on September 30, 2012, we expect to record amortization expense of \$0.7 million per year through 2027 for the manufacturing facility production licenses.

**Interest and other income (expense), net.** Net interest and other income (expense) increased to income of \$3.6 million for the three months ended September 30, 2012, from an expense of \$3.4 million for the three months ended September 30, 2011. This \$7.0 million increase was primarily due to (i) a \$5.3 million non-cash gain from revaluation of our derivative liabilities and (ii) a \$1.4 million decrease in interest expense due to our payoff of the Deerfield loan in May 2012. We did not pay any interest to Deerfield in the three months ended September 30, 2012, compared to the \$0.4 million we paid Deerfield for the three months ended September 30, 2011. Although our total interest expense will decrease due to the payoff of the Deerfield loan, we expect that it will continue to be substantial due to payments on our lease financing obligations.

**NINE MONTHS ENDED SEPTEMBER 30, 2012, AND 2011**

**Revenues.** Total revenues increased by \$15.1 million to \$25.7 million during the nine months ended September 30, 2012, from \$10.6 million during the nine months ended September 30, 2011. This increase was primarily due to the \$20.0 million non-refundable milestone payment that we earned in connection with the FDA approval of BELVIQ, which was partially offset by (i) a \$2.8 million decrease for reimbursements related to additional BELVIQ development work that we received from Eisai and (ii) a \$1.5 million decrease in manufacturing services revenue under our manufacturing services agreement with Siegfried.

**Cost of manufacturing services.** We recognized cost of manufacturing services of \$2.8 million and \$6.2 million for the nine months ended September 30, 2012, and 2011, respectively. The decrease between periods was primarily driven by our contract loss provisions for these services, which are the result of the services being provided at sales prices that are less than our costs, and the reduced volume of manufacturing services performed. Specific to the contract loss provision, the amount recognized for the nine months ended September 30, 2011, included a \$1.7 million charge for the increase in the contract loss provision estimated during such period and a reduction of \$0.8 million to reflect the loss incurred on the services rendered.

**Research and development expenses.** Research and development expenses decreased \$5.4 million to \$40.2 million for the nine months ended September 30, 2012, from \$45.6 million for the nine months ended September 30, 2011. This was primarily due to decreases of (i) \$2.2 million in salary and personnel costs as a result of our 2011 workforce reduction, (ii) \$1.5 million in internal research and development manufacturing costs related to our Swiss manufacturing facility and (iii) \$0.7 million in facility and equipment costs, primarily depreciation expense. Included in the \$5.3 million of total external clinical and preclinical study fees and expenses for the nine months ended September 30, 2012, was \$4.1 million related to our BELVIQ program, \$0.9 million related to our APD371 program and \$0.1 million related to our APD811 program. Included in the \$5.4 million of total external clinical and preclinical study fees and expenses for the nine months ended September 30, 2011, was \$2.5 million related to our BELVIQ program, \$1.7 million related to our APD811 program and \$0.7 million related to our APD334 program.

**General and administrative expenses.** We recognized general and administrative expenses of \$19.0 million for each of the nine-month periods ended September 30, 2012, and 2011. Comparing these periods, a \$1.4 million decrease in legal fees in 2012 was partially offset by a \$1.0 million increase in non-cash share-based compensation.

**Restructuring charges.** We recognized no restructuring charges for the nine months ended September 30, 2012, compared to \$3.5 million for the nine months ended September 30, 2011, in connection with one-time employee termination costs, including severance and other benefits related to our 2011 workforce reduction.



---

## **Table of Contents**

**Amortization of acquired technology and other intangibles.** We recognized \$0.5 million for amortization of acquired technology and other intangibles for the nine months ended September 30, 2012, compared to \$0.8 million for the nine months ended September 30, 2011. This decrease was primarily due to reaching the end of the 10-year estimated useful life of the Melanophore screening technology in the three months ended March 31, 2011.

**Interest and other expense, net.** Total interest and other expense, net, increased by \$6.3 million to \$27.4 million for the nine months ended September 30, 2012, from \$21.1 million for the nine months ended September 30, 2011, primarily due to a \$13.9 million non-cash loss from revaluation of our derivative liabilities, primarily resulting from the increase in our stock price in 2012, which is an input into our Black-Scholes option pricing model. This increased expense was partially offset by (i) a \$4.2 million decrease in the non-cash loss on extinguishment of debt and (ii) a \$3.8 million decrease in interest expense primarily related to the lower outstanding balance on our Deerfield loan prior to its payoff in May 2012. The interest expense recognized for the nine months ended September 30, 2012, included \$0.6 million we paid Deerfield, compared to \$1.9 million we paid Deerfield for the nine months ended September 30, 2011.

**Deemed dividend related to beneficial conversion feature of convertible preferred stock.** We recorded a deemed dividend of \$2.8 million in the nine months ended September 30, 2012, upon the issuance of our formerly outstanding Series D Convertible Preferred Stock and, in the nine months ended September 30, 2011, we recorded a deemed dividend of \$2.3 million upon the issuance of our formerly outstanding Series C Convertible Preferred Stock. The fair value of the common stock into which both series of preferred stock was convertible on the respective dates of issuance of the preferred stock exceeded the allocated proceeds on a relative fair value basis, resulting in the beneficial conversion feature.

## **LIQUIDITY AND CAPITAL RESOURCES**

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. Notwithstanding the FDA approval of BELVIQ and related payments received and expected from collaborators, we expect that we will continue to incur losses, and that our operating expenses will continue to be substantial, for at least the short term, as a result of manufacturing and commercializing BELVIQ, conducting required and potentially other post-marketing studies of BELVIQ, seeking regulatory approval of BELVIQ outside of the United States and advancing other of our current and future compounds and drug candidates.

### *Short term*

As of September 30, 2012, we had \$165.8 million in cash and cash equivalents. We believe our cash and cash equivalents will be sufficient to fund our operations for at least the next 12 months. Other potential sources of liquidity in the short term include (i) payments from Eisai upon achievement of milestones and sale of BELVIQ, (ii) entering into new collaborative, licensing or commercial agreements for BELVIQ in additional territories or for one or more of our drug candidates or programs or our patent portfolios, (iii) equity, debt or other financing and (iv) the sale or lease of facilities or other assets we own.

To date, we have obtained cash and funded our operations primarily through equity financings, the issuance of debt and related financial instruments, payments from collaborators and sale leaseback transactions. We will continue to evaluate various funding alternatives on an ongoing basis. There is no guarantee that additional funding will be available or that, if available, such funding will be adequate or available on terms that we or our stockholders view as favorable.

As part of the FDA's approval of BELVIQ in June 2012, we and Eisai committed to evaluate the effect of long-term treatment with BELVIQ on the incidence of major adverse cardiovascular events in overweight and obese subjects with cardiovascular disease or multiple cardiovascular risk factors, as well as to conduct post-marketing studies to assess the safety and efficacy of BELVIQ for weight management in obese pediatric patients. With respect to such studies, which we expect will take several years to complete, Eisai will bear 90% and we will bear 10% of the expenses for the cardiovascular outcomes trial, and Eisai and we will share equally the costs of certain pediatric studies. In addition, in the event that we conduct any non-FDA required development work relating to BELVIQ, we would expect to incur additional expenses, which may be significant depending on whether, and to what extent, a collaborator shares the expenses.

Eisai is responsible for regulatory activities related to the BELVIQ New Drug Application, or NDA, and for the regulatory activities for obtaining marketing approval in any country in the additional territories under the Eisai Agreement. If the regulatory authority for a country in the additional territories requires development work before or following approval of BELVIQ in such country, Eisai will bear 90% and we will bear 10% of the expenses for such work, with the exception of the expenses for stability testing, which will be shared equally by the parties.

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

In connection with the FDA approval of BELVIQ, we received a \$20.0 million non-refundable milestone payment from Eisai. In addition, we will receive milestone payments from Eisai totaling \$65.0 million in connection with the DEA's scheduling designation for BELVIQ. Following the DEA scheduling of BELVIQ, we expect Eisai to launch BELVIQ in the United States, and we will receive payments based on Eisai's net sales of BELVIQ.

---

**Table of Contents**

In connection with entering into the Ildong Agreement in November 2012, we will receive a non-refundable, upfront payment of \$5.0 million. Ildong is responsible for the regulatory approval and, ultimately, marketing and distribution of BELVIQ in South Korea, including related development and other costs and expenses.

In January 2008, Arena GmbH acquired from Siegfried certain drug product manufacturing assets under an asset purchase agreement, and, in connection with such purchase, also entered into a manufacturing services agreement and a technical services agreement with Siegfried. Under the agreements, as amended, Siegfried agreed (i) to order at least 80% of its requirements of certain drug products from Arena GmbH for the calendar year 2012 in exchange for a discount on the price of the packaged drug products, (ii) to order at least 60% of its requirements of certain drug products from Arena GmbH for the calendar year 2013 in exchange for a discount on the price of such drug products, and (iii) to reduce its fees for providing Arena GmbH with certain technical and business services. Without applying the additional discount on the prices of such drug products, the agreed upon prices are still generally below Arena GmbH's cost, and were reduced from the prices in prior years. Accordingly, we expect the cash we receive from Siegfried in 2012 and 2013 will be lower than in previous years due to (i) decreases in prices and units manufactured, and (ii) the additional discounts on orders placed in 2012 and 2013. If Siegfried does not order the agreed minimum amounts of its requirements, Siegfried is obligated to refund Arena GmbH the amounts it saved due to the price discounts.

We expect that our 2012 operating expenses will be substantial, but slightly lower than in 2011, as we continue to fund BELVIQ-related activities, and, at the same time, selectively advance certain of our research and development programs.

*Long term*

We will need substantial cash to achieve our objectives of discovering, developing and commercializing drugs, and this process typically takes many years and potentially several hundreds of millions of dollars for an individual drug. We may not have adequate available cash, or assets that could be readily turned into cash, to meet these objectives in the long term. We will need to obtain significant funds under our Eisai Agreement or Ildong Agreement, under new collaborative, licensing or other commercial agreements for BELVIQ or one or more of our drug candidates and programs or patent portfolios, or from other potential sources of liquidity, which may include the public and private financial markets.

We expect to continue to incur substantial costs for BELVIQ, including costs related to manufacturing and required and potentially other post-marketing studies. As described above under *short term*, we will be responsible for a portion of the costs for development work required by regulatory agencies. In addition, in the event that we conduct any non-FDA required development work relating to BELVIQ, we would expect to incur additional expenses, which may be significant depending on whether, and to what extent, a collaborator shares the expenses.

Following the DEA scheduling of BELVIQ, we expect Eisai to launch BELVIQ in the United States. Subject to applicable regulatory approval, we also expect Eisai to commercialize BELVIQ in additional territories in North and South America.

We will manufacture BELVIQ at our facility in Switzerland, and sell BELVIQ to Eisai for marketing and distribution in the United States and, subject to applicable regulatory approval, in the additional territories under the Eisai Agreement for a purchase price starting at 31.5% and 30.75%, respectively, of Eisai's aggregate annual net sales (which are the gross invoiced sales less certain deductions described in the Eisai Agreement, including for certain taxes, credits, allowances, discounts, rebates, chargebacks and other items) in all of such territories on an aggregate basis. The purchase price will increase on a tiered basis in the United States and in the additional territories to as high as 36.5% and 35.75%, respectively, on the portion of Eisai's annual net sales exceeding \$750.0 million, subject to reduction (for sales in a particular country) in the event of generic competition in the applicable country. The Eisai Agreement includes payments by Eisai if annual minimum sales requirements in the additional territories are not met during the first ten years after initial commercial sale in Canada, Mexico or Brazil. In addition, we are eligible to receive up to an aggregate of \$1.19 billion in one-time purchase price adjustments and other payments based on Eisai's annual net sales of BELVIQ in all of the territories under our agreement on an aggregate basis, with the first and last amounts payable with annual net sales of \$250.0 million and \$2.5 billion, respectively. Of these payments, Eisai will pay us a total of \$330.0 million for annual net sales of up to \$1.0 billion. We are also eligible to receive up to an additional \$185.0 million in one-time purchase price adjustment payments based on Eisai's annual net sales of BELVIQ in the non-US territories under our agreement, with the first and last amounts payable upon first achievement of annual net sales of \$100.0 million and \$1.0 billion in such territories, respectively. We are also eligible to receive milestone payments totaling \$54.5 million based on achievement of regulatory filings and approvals.

With respect to Ildong Agreement, we will receive \$3.0 million upon the approval of BELVIQ by the KFDA. We will manufacture BELVIQ at our facility in Switzerland, and sell BELVIQ to Ildong for marketing and distribution in South Korea for a purchase price starting at 35% of Ildong's annual net sales. The purchase price will increase on a tiered basis up to 45% on the portion of annual net sales exceeding \$15.0 million. If certain annual net sales amounts are not met, we can convert Ildong's right to commercialize BELVIQ in South Korea to be non-exclusive.





---

## **Table of Contents**

With respect to commercializing BELVIQ in other territories, we will need additional funds or a collaborative or other agreement with one or more pharmaceutical companies.

In addition to the potential payments from Eisai and Ildong described above, as well as the public and private financial markets, potential sources of liquidity in the long term include (i) milestone and royalty and other payments from any future collaborators or licensees, and (ii) revenues from sales of any drugs we commercialize on our own. The length of time that our current cash and cash equivalents and any available borrowings will sustain our operations will be based on, among other things, the rate of adoption and commercial success of BELVIQ, regulatory decisions, our prioritization decisions regarding funding for our programs, progress in our clinical and earlier-stage programs, the time and costs related to current and future clinical trials and nonclinical studies, our research, development, manufacturing and commercialization costs (including personnel costs), our progress in any programs under collaborations, costs associated with intellectual property, our capital expenditures, and costs associated with securing any in-licensing opportunities. Any significant shortfall in funding may result in us reducing our development and/or research activities, which, in turn, would affect our development pipeline and ability to obtain cash in the future. If we determine it is advisable to raise additional funds, we do not know whether adequate funding will be available to us or, if available, that such funding will be available on acceptable terms.

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 acquisition or license or we use our cash to finance the acquisition or license.

### *Sources and Uses of Our Cash*

Net cash used in operating activities decreased by \$27.5 million to \$35.0 million in the nine months ended September 30, 2012, compared to \$62.5 million in the nine months ended September 30, 2011. This decrease was primarily the result of a \$21.3 million decrease in our net loss.

Net cash used in investing activities increased by \$1.1 million to \$1.4 million in the nine months ended September 30, 2012, compared to \$0.3 million in the nine months ended September 30, 2011. This increase was primarily the result of purchases of equipment and improvements to our facilities, primarily for our manufacturing facility in Switzerland. We expect that our 2012 capital expenditures will increase over the 2011 amount due to deferrals of capital spending in previous years.

Net cash of \$143.9 million was provided by financing activities in the nine months ended September 30, 2012, primarily due to net proceeds of (i) \$65.7 million from a public offering of 12,650,000 shares of our common stock at \$5.50 per share, (ii) \$32.5 million from the portion of Deerfield's formerly outstanding warrants to purchase a total of 23,000,000 shares of our common stock that were cash exercised, (iii) \$27.9 million, after prepayment of \$5.0 million of loan principal, from the sale to Deerfield of 9,953,250 shares of our common stock and 9,953 shares of our preferred stock (subsequently converted in full into 9,953,250 shares of our common stock) and (iv) \$24.7 million from the sale of 14,414,370 shares of common stock under an equity line of credit agreement with Azimuth Opportunity, L.P. These proceeds were partially offset by principal payments to Deerfield totaling \$22.3 million. Net cash of \$10.2 million was used in financing activities during the nine months ended September 30, 2011, primarily due to principal payments of \$37.7 million to Deerfield and \$7.3 million to Siegfried in the nine months ended September 30, 2011. These payments were partially offset by net proceeds of \$35.3 million from the sale of 12,150,000 shares of our common stock and 12,150 shares of our preferred stock (subsequently converted in full into 12,150,000 shares of our common stock) to Deerfield.

### *Contractual Obligations*

In May 2007, pursuant to an agreement that was originally with BioMed Realty, L.P., a Maryland limited partnership, or BioMed, and later assigned by BioMed to one of its subsidiaries, BMR-6114-6154 Nancy Ridge Drive LLC, a Delaware limited liability company, or BMR, we sold to BMR three of our US properties and our right, title and interest in the option to purchase a fourth US property, which we were leasing from another lessor. In connection with this transaction, we also (i) entered into agreements with BMR to lease back the properties under 20-year leases and (ii) agreed that, upon the exercise of the option on the fourth property, we would continue to lease such property, but with BMR for a term that is concurrent with the leases for the other three properties.

In April 2012, BMR exercised its option and purchased the fourth property. As a result of the purchase, we are obligated to lease this property through May 2027, which resulted in an operating lease obligation of \$14.2 million over the term of this lease. In addition, subject to certain restrictions, we have the option to repurchase this property, as well as the other three properties, on the 10th, 15th or 20th anniversary of the May 2007 execution date of the leases, and earlier if the leases are terminated under certain circumstances.



---

## Table of Contents

Other than this additional future obligation, there have been no material changes to the contractual obligations set forth in our 2011 Annual Report.

### **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:

**Revenue recognition.** Our revenues to date have been generated primarily through collaborative agreements and a manufacturing services agreement. Our collaborative agreements may contain multiple elements including commercialization rights, research and development services and manufacturing. Consideration we receive under these arrangements may include upfront payments, research and development funding, cost reimbursements and milestone payments. We recognize revenue when there is persuasive evidence that an arrangement exists, title has passed, the price is fixed or determinable, and collectability is reasonably assured. Any advance payments we receive in excess of amounts earned are classified as deferred revenues on our consolidated balance sheets until earned.

We adopted revised guidance on accounting for revenue arrangements involving multiple elements on January 1, 2011, on a prospective basis, for agreements we entered into or materially modified after adoption. This updated guidance (i) relates to whether multiple deliverables exist, how the deliverables in a revenue arrangement should be separated and how the consideration should be allocated, (ii) requires companies to allocate revenues in an arrangement using estimated selling prices of deliverables if a vendor does not have vendor-specific objective evidence or third-party evidence of selling price and (iii) eliminates the use of the residual method and requires companies to allocate revenues using the relative selling price method.

Since adoption of this guidance, we evaluate deliverables in a multiple-element arrangement to determine whether each represents a separate unit of accounting. A deliverable constitutes a separate unit of accounting when it has standalone value to the customer and there are no customer return rights for the delivered elements. Items are considered to have standalone value when they can be sold separately by any vendor or when the customer can resell the item on a standalone basis. If these criteria are not met, we combine the deliverable with the undelivered elements and allocate the consideration and recognize revenue for the combined unit as a single unit. We allocate the consideration to each unit of accounting at the inception of the arrangement based on the relative selling price.

For agreements that we entered into prior to adoption of the revised multiple-element guidance, if fair value exists for the undelivered and delivered elements whereby such elements have standalone value, we allocate the consideration to the elements based on their relative fair values. In cases where fair value exists for the undelivered elements but does not exist for the delivered elements, we use the residual method to allocate the arrangement consideration. In cases where fair value does not exist for the undelivered elements in an arrangement, we account for the transaction as a single unit of accounting.

We typically defer non-refundable upfront payments received under our collaborative agreements when associated with future performance, and recognize them on a straight-line basis over the period in which we expect to have significant involvement or perform services, based on various factors specific to each collaboration. Amounts we receive for research funding are recognized as revenue as the services are performed. For reimbursements of out-of-pocket expenses for research and development activities where we control the activities, with discretion to choose suppliers, bear credit risk and perform part of the services when required, we record revenue for the gross amount of the reimbursement. The costs associated with such reimbursements are reflected as a component of research and development expense in our consolidated statements of operations and comprehensive loss.

Under the milestone method, we recognize revenue that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. A milestone is an event (i) that can be achieved in whole or in part on either our performance or on the occurrence of a specific outcome resulting from our performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due us. A milestone payment is considered substantive when the consideration payable to us for each milestone (a) is consistent with our performance necessary to achieve the milestone or the increase in value to the collaboration resulting from our performance, (b) relates solely to our past performance and (c) is reasonable relative

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

to all of the other deliverables and payments within the arrangement. In making this assessment, we consider all facts and circumstances relevant to the arrangement, including factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether any portion of the milestone consideration is related to future performance or deliverables. Other contingent event-based payments received for which payment is either contingent solely upon the passage of time or the result of our collaborator's performance are not considered milestones and are recognized when earned.

---

## **Table of Contents**

We manufacture drug products under a manufacturing services agreement for a single customer. Upon the customer'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 this customer for them to provide us with administrative and other services in exchange for a fee. We determined that we are receiving an identifiable benefit for these services, and are recording such fees in the operating expense section of our consolidated statements of operations and comprehensive loss.

**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 recognized in the subsequent period in which the actual costs become known. Historically, these differences have not been material; however, material differences could occur in the future.

**Derivative liabilities.** We account for our warrants and other derivative financial instruments as either equity or liabilities based upon the characteristics and provisions of each instrument. Warrants classified as equity are recorded as additional paid-in capital on our consolidated balance sheets and no further adjustments to their valuation are made. Some of our warrants were determined to be ineligible for equity classification because of provisions that may result in an adjustment to their exercise price. Warrants classified as derivative liabilities and other derivative financial instruments that require separate accounting as liabilities are recorded on our consolidated balance sheets at their fair value on the date of issuance and will be revalued on each subsequent balance sheet date until such instruments are exercised or expire, with any changes in the fair value between reporting periods recorded as other income or expense. We estimate the fair value of these liabilities using the Black-Scholes option pricing model, which is affected by our stock price on the date of grant, as well as assumptions regarding other subjective variables. Changes in the assumptions used could have a material impact on the resulting fair value.

**Share-based compensation.** We recognize compensation expense for all of our share-based awards based on the grant-date fair value. We determine the grant-date fair value of share-based awards by using the Black-Scholes option pricing model, which is affected by our stock price on the date of grant, as well as assumptions regarding other subjective variables. These assumptions include, but are not limited to, our expected stock price volatility over the term of the awards, the risk-free interest rate and the expected term of awards. Changes in the assumptions used could have a material impact on the compensation expense we recognize.

Share-based compensation expense recognized is based on awards ultimately expected to vest, and, therefore, is reduced by expected forfeitures. We estimate forfeitures based upon historical forfeiture rates, and will adjust our estimate of forfeitures if actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures will be recognized through a cumulative adjustment in the period of the change and will also impact the amount of share-based compensation expense in future periods.

*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 2011 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, 2011.

### **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 President and Chief Executive Officer and Senior Vice President, Finance and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, our President and Chief Executive Officer and Senior 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 at the reasonable assurance level. 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.



**Table of Contents****PART II. OTHER INFORMATION****Item 1. Legal Proceedings.**

Beginning on September 20, 2010, a number of complaints were filed in the US District Court for the Southern District of California against us and certain of our current and former employees and directors on behalf of certain purchasers of our common stock. The complaints have been brought as purported stockholder class actions, and, in general, include allegations that we and certain of our current and former employees and directors violated federal securities laws by making materially false and misleading statements regarding our BELVIQ program, thereby artificially inflating the price of our common stock. The plaintiffs are seeking unspecified monetary damages and other relief. On November 19, 2010, eight prospective lead plaintiffs filed motions to consolidate, appoint a lead plaintiff, and appoint lead counsel. The Court took the motions to consolidate under submission on January 14, 2011. On August 8, 2011, the Court consolidated the actions and appointed a lead plaintiff and lead counsel. On November 1, 2011, the lead plaintiff filed a consolidated amended complaint. On December 30, 2011, we filed a motion to dismiss the consolidated amended complaint. The motion to dismiss has been fully briefed and the Court took the motion to dismiss under submission on April 13, 2012. In addition to the class actions, a complaint involving similar legal and factual issues has been brought by at least one individual stockholder and is pending in federal court. On December 30, 2011, we filed a motion to dismiss the stockholder's complaint. The motion to dismiss has been fully briefed and the Court took the motion to dismiss under submission on April 13, 2012. We intend to defend against the claims advanced and to seek dismissal of these complaints. Due to the early stage of these proceedings, we are not able to predict or reasonably estimate the ultimate outcome or possible losses relating to these claims.

On September 24, 2010, a stockholder derivative complaint was filed in the Superior Court of California for the County of San Diego against certain of our current and former employees and directors, and other stockholder derivative complaints were subsequently filed in state court. On October 19, 2010, the Superior Court ordered that the pending state derivative actions be consolidated. The Superior Court also ordered that later filed, related state derivative actions be consolidated as well. We refer to the consolidated state derivative actions as the State Derivative Action. In November 2010, plaintiffs in the State Derivative Action filed a consolidated stockholder derivative complaint. We filed a demurrer to the consolidated stockholder derivative complaint on February 15, 2011. On October 6, 2010, a stockholder derivative complaint was filed in the US District Court for the Southern District of California. Thereafter, a number of other stockholder derivative complaints were also filed in federal court. On March 3, 2011, the federal court ordered that the pending federal derivative actions be consolidated. The federal court also ordered that later filed, related federal derivative actions be consolidated as well. We refer to the consolidated federal derivative actions as the Federal Derivative Action. We refer to the State Derivative Action and the Federal Derivative Action collectively as the Derivative Actions. The Derivative Actions allege breaches of fiduciary duties by the defendants and other violations of law. In general, the Derivative Actions allege that certain of our current and former employees and directors caused or allowed for the dissemination of materially false and misleading statements regarding our BELVIQ program, thereby artificially inflating the price of our common stock. On September 9, 2011, we and lead counsel for the plaintiffs in the Derivative Actions entered into a stipulation of settlement to resolve the Derivative Actions. The current and former employees and directors named as individual defendants in the Derivative Actions have also entered into the stipulation of settlement. On October 19, 2011, the Superior Court of California entered an order preliminarily approving the proposed settlement. On December 16, 2011, the Superior Court of California issued its final order and judgment approving the settlement and dismissing the State Derivative Action with prejudice. On December 29, 2011, the US District Court issued an order dismissing the Federal Derivative Action with prejudice. In accordance with the terms of the settlement, and in exchange for a release of all claims by the plaintiffs, among others, we agreed to adopt certain corporate governance measures and cause our insurers to pay the plaintiffs' attorneys a total of \$1.1 million. The time for appeals of the settlement of the Derivative Actions has lapsed without any appeal.

**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 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 new risk factors or ones 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*

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

*December 31, 2011, as filed with the Securities and Exchange Commission, or SEC.*

*In June 2012, the US Food and Drug Administration, or FDA, approved our internally discovered drug, BELVIQ® (lorcaserin HCl), for chronic weight management in adults who are obese or are overweight with at least one weight related comorbid condition. BELVIQ (pronounced BEL-VEEK ) is the trade name for lorcaserin hydrochloride in the United States. While BELVIQ may in the future be marketed outside of the United States as BELVIQ or under a different trade name, we use BELVIQ in this report to refer to the finished drug product for lorcaserin hydrochloride or, depending on the context, lorcaserin hydrochloride or other solid state forms of lorcaserin.*



---

## Table of Contents

### *Risks Relating to Our Business*

**\*Our prospects are highly dependent on the success of BELVIQ, our first and only FDA-approved drug. To the extent BELVIQ is not commercially successful, our business, financial condition and results of operations would be materially adversely affected and the price of our common stock would likely decline.**

We are focusing a significant portion of our activities and resources on BELVIQ, and we believe our prospects are highly dependent on, and a significant portion of the value of our company relates to, the successful commercialization of BELVIQ in the United States and potentially in additional territories. The marketing approval and successful commercialization of BELVIQ is subject to many risks, including the risks discussed in other risk factors, and BELVIQ may not receive marketing approval from any other regulatory agencies. If the results of the regulatory process, the anticipated or actual timing and plan for commercializing, the market acceptance, new clinical trials and preclinical studies, or other actions and decisions related to BELVIQ do not meet our, your, analysts' or others' expectations, the market price of our common stock could decline significantly.

The FDA approval of BELVIQ includes the following limitations of use: (i) the safety and efficacy of coadministration of BELVIQ with other products intended for weight loss including prescription drugs (e.g., phentermine), over-the-counter drugs, and herbal preparations have not been established, and (ii) the effect of BELVIQ on cardiovascular morbidity and mortality has not been established.

In connection with approving BELVIQ, the FDA recommended to the US Drug Enforcement Administration, or DEA, that it be classified as a Schedule IV drug. BELVIQ will not be commercially available in the United States until the DEA provides the final scheduling designation. BELVIQ will be marketed in the United States by Eisai Inc., or Eisai, under the Amended and Restated Marketing and Supply Agreement, or Eisai Agreement, between Eisai and our wholly owned subsidiary, Arena Pharmaceuticals GmbH, or Arena GmbH.

Arena GmbH has also entered into a Marketing and Supply Agreement, or Ildong Agreement, for BELVIQ with Ildong Pharmaceutical Co., Ltd., or Ildong. Under the Ildong Agreement, Arena GmbH granted Ildong exclusive rights to market and distribute BELVIQ in South Korea for weight loss or weight management in obese and overweight patients, subject to regulatory approval of BELVIQ by the Korea Food and Drug Administration.

We expect that revenues under the Eisai Agreement and, to a lesser extent, the Ildong Agreement will constitute the majority of our revenues over the next several years, and future payments to us under the agreements will substantially depend on the achievement of milestones and BELVIQ product sales. Each of these agreements may be terminated early in certain circumstances, in which case we may not receive additional milestone or other payments under the agreement. We cannot guarantee if or when any milestones or BELVIQ product sales under these agreements will be achieved or paid in the future.

We have not received regulatory approval for BELVIQ in any territories outside of the United States, nor do we have any marketing and supply agreements or similar arrangements in place other than the Eisai Agreement and the Ildong Agreement, which cover most of North and South America and South Korea, respectively. We are seeking regulatory approval for BELVIQ in the European Union and Switzerland, and plan to seek regulatory approval for BELVIQ in other territories, but there is no assurance that any of our pending or future regulatory applications will be approved. We also plan to enter into marketing and supply agreements or similar arrangements with one or more pharmaceutical companies to commercialize BELVIQ in additional territories, but there is no assurance that we will be able to do so at all or on terms that you or others view as favorable.

In the United States, the degree of market acceptance and commercial success of BELVIQ, and our revenues, will depend on a number of factors, including the following, as well as other risks identified in other risk factors:

the DEA's scheduling designation for BELVIQ, which designation may take longer and be more restrictive than we or others expect;

the successful launch of BELVIQ and growth of commercial sales;

the number of patients with the potential to use BELVIQ, the number of patients receiving BELVIQ treatment and the results achieved by such patients;

the pace of market acceptance, which may depend on the timing and impact of competition and BELVIQ's perceived advantages or disadvantages over alternative treatments (including relative convenience, ease of administration and prevalence and severity of any adverse events, including any unexpected adverse events);

**Table of Contents**

the actual and perceived safety and efficacy of BELVIQ on both a short- and long-term basis among actual or potential patients, healthcare providers and others in the medical community, regulatory agencies and insurers and other payers;

incidence and severity of any side effects, including as a result of off-label use;

new data relating to BELVIQ, including as a result of additional studies, trials or analyses;

physicians may not prescribe, and patients may not take, BELVIQ until at least results from our required post-marketing studies are available or other long-term efficacy and safety data exists;

the claims, limitations, warnings and other information in BELVIQ's current or future labeling;

Eisai's establishment and maintenance of an effective sales force and medical affairs and related functions, and its sales, marketing and other representatives accurately describing BELVIQ consistent with its approved labeling;

BELVIQ's commercial price and perceived cost-effectiveness;

the ability of patients and physicians and other providers to obtain and maintain sufficient coverage and reimbursement, if any, by third-party payers, including government payers;

the ability of group purchasing organizations, or GPOs, including distributors and other network providers, to sell BELVIQ to their constituencies; and

the establishment and maintenance of adequate commercial manufacturing capabilities ourselves or through third-party manufacturers, our ability to meet commercial demand for BELVIQ and supply chain issues.

If BELVIQ is approved in territories outside the United States, the degree of market acceptance and commercial success of BELVIQ in these territories, and our revenues, will depend on similar factors as in the United States, as well as territory-specific risks.

We cannot predict the extent to which BELVIQ will be utilized by patients in the United States or, subject to applicable regulatory approval, patients in other territories, or whether physicians, healthcare insurers or maintenance organizations, or the medical community in general, will accept or utilize BELVIQ. The potential population of patients eligible for treatment with BELVIQ may be reduced based on the limitations for use included in the approved label. Our and others' efforts to educate the medical community and third-party payers regarding the benefits of BELVIQ will require significant resources and may not be successful in achieving the objectives. If BELVIQ does not achieve sufficient market acceptance in the United States, and ultimately in other territories, the revenues we generate from sales will be limited and our business may not be profitable.

**\*Data generated or analyzed with respect to reported adverse safety events following marketing and with respect to future studies and clinical trials may result in decreased demand, lower sales, product recall or regulatory action.**

A New Drug Application, or NDA, holder is responsible for assessing and monitoring the safety of a drug that has been approved for marketing. In addition, as a condition to obtaining FDA approval of BELVIQ, we and Eisai committed to conduct post-marketing studies, including evaluation of the effect of long-term treatment with BELVIQ on the incidence of major adverse cardiovascular events in overweight and obese subjects with cardiovascular disease or multiple cardiovascular risk factors. The cardiovascular outcomes trial will include echocardiographic assessments. In addition, we or others may decide or need to conduct additional studies, clinical trials or analyses of BELVIQ, including in connection with seeking regulatory approval of BELVIQ outside of the United States.

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

New data relating to BELVIQ, including from adverse event reports, post-marketing studies and trials in the United States, and registration and other studies and trials in territories outside the United States, may result in label changes and may adversely affect sales or result in withdrawal of BELVIQ from the market. Foreign regulatory agencies may also consider the new data in reviewing BELVIQ marketing applications in their territories or impose post-approval requirements that require significant additional expenditures. Furthermore, the discovery of significant problems with a product or class of products similar to BELVIQ could have an adverse effect on the BELVIQ program, including commercialization.

In addition, new data or other information, including information about product misuse, may lead government agencies, professional societies, practice management groups or organizations involved in various diseases to publish guidelines or recommendations related to the use of BELVIQ or place restrictions on sales. Such guidelines or recommendations may lead to lower sales of BELVIQ.

## Table of Contents

**\*Our forecasting of BELVIQ sales will be difficult due to uncertainty about the timing of launch, the rate of adoption and other aspects of commercialization. If our BELVIQ revenue projections are inaccurate, our business may be harmed and our stock price may be adversely affected.**

Our business planning requires us to forecast demand and revenues despite numerous uncertainties, which may be increased because we rely to at least some extent on our collaborators providing us accurate and timely information. Actual results may deviate materially from projected results for various reasons, including the following, as well as risks discussed in other risk factors:

uncertainty relating to the timing and results of the DEA scheduling process;

uncertainty relating to the timing of the launch and rate of adoption;

uncertainty related to pricing, reimbursement, competition and others aspects of commercialization;

Eisai controls the commercialization of BELVIQ in most of North and South America, and Ildong controls the commercialization of BELVIQ in South Korea, including related strategy and their allocation of resources;

lack of patient and physician familiarity with BELVIQ;

lack of patient use and physician prescribing history; and

lack of commercialization experience for BELVIQ, in particular, and weight loss drugs, in general.

The extent to which any of these or other factors individually or in the aggregate may impact sales of BELVIQ is uncertain and difficult to predict. This may lead to lower than expected revenue, inefficiency in expenditures and increased difficulty in operational planning. Revenue shortfalls would have a negative impact on our cash flow and on our business in general. In addition, our quarterly results may greatly fluctuate, including in the near-term, and such fluctuations can adversely affect the market price of our common stock, perceptions of our ability to forecast demand and revenues, and our ability to maintain and fund our operations.

**\*We will need to further collaborate or obtain additional funds to conduct our planned research, development and commercialization efforts; we may not be able to further collaborate or obtain adequate funds, your ownership may be substantially diluted if we do obtain additional funds, and you may not agree with the manner in which we allocate our available resources; and we 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 and operating expenses may continue to be substantial for at least the short term.

BELVIQ will not be commercially available in the United States until after the DEA provides the final scheduling designation, which designation may take significantly longer or be more restrictive than we or others expect. All of our other programs are in the research or early development stage, and we may not have adequate funds 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 marketed drugs.

Even if Eisai begins to market BELVIQ under our agreement, we cannot assure you that any additional payments we receive under such agreement will be sufficient to fund our planned research and development and other activities or to result in profitability. We will need to enter into marketing and supply agreements or other arrangements with one or more pharmaceutical companies, or obtain additional funds, to

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

commercialize BELVIQ in additional territories. We may not be able to enter into any such agreement or obtain additional funds, on terms that we or third parties, including investors or analysts, view as favorable, if at all.

Our ability to enter into new collaborations for BELVIQ or any of our drug candidates, and our ability to raise funds in the capital markets on terms that you or others view as favorable, may depend on the outcomes of regulatory applications for marketing approval or additional preclinical and clinical testing. We do not control these outcomes.

We may allocate our resources in ways that do not improve our results of operations or enhance the value of our assets. Our stockholders and others may also not agree with the manner in which we choose to allocate our resources. Any failure to apply our resources effectively could have a material adverse effect on our business or the development of our drug candidates and cause the price of our common stock to decline.

In addition, if we experience a significant setback or delay, particularly with regard to BELVIQ, or adequate funding is not available, we may eliminate or postpone or scale back some or all of our research or development programs or delay the advancement of one or more of such programs, including in ways with which our stockholders or others may not agree. Any such reductions may adversely impact our development and commercialization timeline for BELVIQ or narrow or slow the development of our pipeline, which we believe would reduce our opportunities for success and result in a decline in the market price of our common stock.

---

## **Table of Contents**

We have been opportunistic in our efforts to obtain cash, and we expect to continue to evaluate various funding alternatives from time to time. If we obtain additional funding, it may adversely affect the market price of our common stock.

**\*If we are unable to obtain marketing approvals for BELVIQ outside the United States, or if we are significantly delayed or limited in doing so, our results of operations and business will be materially and adversely affected and our stock price would likely decline.**

In March 2012, we filed a Marketing Authorization Application, or MAA, for BELVIQ in the European Union, and the European Medicines Agency, or EMA, accepted the filing for review. In July 2012, we filed an MAA for BELVIQ with the Swiss health authority, Swissmedic, and Swissmedic has accepted the filing for review. We expect Eisai and Ildong to seek regulatory approval for the marketing of BELVIQ in territories under our agreements, and we plan to seek regulatory approval of BELVIQ in additional territories independently or with one or more pharmaceutical companies.

Despite the FDA's approval of BELVIQ, we cannot assure you or predict with any certainty that any other regulatory authority will grant marketing approval for BELVIQ, or the expected timeframe of any such approval. For example, VIVUS, Inc., announced in October 2012 that, despite the FDA's approval of its drug candidate for chronic weight management, the EMA's Committee for Medicinal Products for Human Use, or CHMP, recommended against approval of its MAA for such drug candidate. The review and potential approval of BELVIQ carries many risks and uncertainties, and our or others' BELVIQ regulatory submissions outside of the United States may not be satisfactory to the applicable regulatory authorities, including with regard to demonstrating adequate safety and efficacy for regulatory approval. We have made, and expect to make in the future, assumptions, estimations, calculations and decisions as part of our analyses of data and regulatory submissions, and the applicable regulatory authorities may not accept or agree with our assumptions, estimations, calculations, decisions or analyses or may interpret or weigh the importance of data differently.

Furthermore, as was the case with FDA approval, other regulatory approvals, even if obtained, may be limited to specific indications, limit the type of patients in which the drug may be used, or otherwise require specific warning or labeling language, any of which might reduce the commercial potential of BELVIQ. As with the FDA's approval of BELVIQ, regulatory authorities in other territories may condition BELVIQ marketing approval on the conduct of specific post-marketing studies to further evaluate safety and efficacy, in either particular or general patient populations or both. The results of these studies, discovery of previously unknown issues involving safety or efficacy or failure to comply with post-approval regulatory requirements, including requirements with respect to manufacturing practices, reporting of adverse effects, advertising, promotion and marketing, may result in restrictions on the marketing of BELVIQ or the withdrawal of BELVIQ from the market.

With respect to the European Union, the CHMP reviewed our MAA for BELVIQ and provided us feedback in the form of a 120-day assessment report and list of questions. The report provided CHMP's quality, clinical and non-clinical questions and comments, which include a similar range of issues previously raised by the FDA. Three issues were identified as major objections: the tumor findings in rats, the dropout rate in clinical trials and how this affects the analysis of efficacy, and the incidences of valvulopathy. In October 2012, we submitted our response to the 120-day assessment report and list of questions. We cannot assure you that such, or any further, response will be sufficient to the CHMP, the EMA or others, that the CHMP, the EMA or others will consider our BELVIQ program or data, including with regard to BELVIQ's efficacy or safety, as sufficient, that the CHMP will recommend to the EMA that BELVIQ be approved, or that the EMA will ever approve BELVIQ.

**\*Our development and commercialization of BELVIQ may be adversely impacted by cardiovascular side effects associated with drugs used for the treatment of obesity.**

We developed BELVIQ to more selectively stimulate the serotonin 2C receptor than did fenfluramine or dexfenfluramine 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. In *in vitro* studies examining affinity, activity and serotonin receptor subtype specificity, BELVIQ demonstrated affinity for, and activity at, serotonin 2A, 2B and 2C receptors, but demonstrated greater affinity, activity and selectivity for the serotonin 2C receptor than for the serotonin 2A and 2B receptors. Activation of the latter two receptors has been associated with undesirable effects. Activation of the 2A receptor has been associated with central nervous system, or CNS, effects, including altered perception, mood and abuse potential, and activation of the 2B receptor has been associated with cardiac valvulopathy.

We may not be correct in our belief that more selectively stimulating the serotonin 2C receptor will avoid these undesired side effects, or BELVIQ's selectivity profile may not be adequate to avoid these side effects. BELVIQ's selectivity profile and the potential relationship between the activity of BELVIQ and the activity of fenfluramine and dexfenfluramine may result in increased FDA, EMA or other regulatory scrutiny of the safety of BELVIQ, may raise potential adverse publicity and may affect enrollment of any future clinical trials or product sales. In addition, we cannot guarantee that any other regulatory authority will find our safety data to be sufficient to approve BELVIQ for marketing outside of the United States.





---

## **Table of Contents**

As a condition to obtaining FDA approval of BELVIQ, we and Eisai committed to conduct post-marketing studies to, among other things, evaluate the effect of long-term treatment with BELVIQ on the incidence of major adverse cardiovascular events in overweight and obese subjects with cardiovascular disease or multiple cardiovascular risk factors. The cardiovascular outcomes trial will include echocardiographic assessments, and the results of such trial and assessments may be unfavorable. Unfavorable results from these studies or other studies we or others conduct could negatively impact the commercialization of BELVIQ, limit the revenues we generate from sales, result in BELVIQ's withdrawal from the market, and preclude us from achieving or sustaining profitability.

**\*We are dependent on marketing and supply agreements for BELVIQ and the failure to maintain such agreements, or poor performance under such agreements, could negatively impact our business.**

Eisai has primary responsibility for the commercialization of BELVIQ in the United States, as well as other territories in North and South America, and Ildong has primary responsibility for the regulatory approval and, ultimately, marketing and distribution of BELVIQ in South Korea. We have limited control over the amount and timing of resources that Eisai and Ildong will dedicate to such activities. In addition, Eisai and Ildong are responsible for compliance with certain regulatory requirements.

We are subject to a number of other risks associated with our dependence on the Eisai Agreement and Ildong Agreement, including:

Eisai or Ildong may not comply with applicable regulatory guidelines with respect to BELVIQ, which could adversely impact the development or commercialization of BELVIQ;

there could be disagreements regarding the agreements or the study or development of BELVIQ that delay or terminate the research, study, development or commercialization of BELVIQ, delay or eliminate potential payments under the agreements or increase our costs under the agreements; or

Eisai or Ildong may not perform as expected, including with regard to making any required payments, and the agreements may not provide adequate protection or may not be effectively enforced.

We and Eisai or Ildong, as applicable, each have the right to terminate our agreement in certain circumstances. We and Eisai or Ildong, as applicable, could also agree to amend the terms of our agreement, and we or others, including investors and analysts, may not view any amendments as favorable. If either agreement is terminated early, we may not be able to find another company to further develop and commercialize BELVIQ in the covered territory on acceptable terms, if at all, and even if we elected to pursue further development or commercialization of BELVIQ on our own, we might not have the funds, or otherwise be able, to do so successfully.

We may enter into additional agreements for the commercialization of BELVIQ or one or more of our drug candidates, and may be similarly dependent on the performance of third parties with similar and potentially company-specific risks.

**\*We are responsible for supplying Eisai and Ildong with BELVIQ, including for commercial sale. We rely to an extent on other companies, including third-party manufacturers, and we or such other companies may encounter failures or difficulties that could adversely affect the commercial production of BELVIQ or the clinical development or regulatory approval of our drug candidates.**

Under the Eisai Agreement and Ildong Agreement, we are the exclusive supplier of BELVIQ. Arena GmbH owns and operates a manufacturing facility in Switzerland that will produce finished drug product for BELVIQ and potentially for one or more of our drug candidates. Arena GmbH is currently our only source for finished drug product of BELVIQ. In addition, we do not own or operate manufacturing facilities that can produce active pharmaceutical ingredient, or API, intermediates and other material required to make BELVIQ and our drug candidates, or finished drug product for all of our drug candidates. Accordingly, we must either develop such facilities, which would require substantial time and additional funds, or rely on third-party manufacturers for such production. We currently contract with other companies to supply API, intermediates and other materials. Certain of these materials are available from only one or a small number of suppliers, and using a new supplier, if available, for finished drug product, API and certain of the other materials could result in substantial delay and greater cost. We expect Siegfried AG (formerly Siegfried Ltd, and referred to herein collectively as Siegfried) will be the only source of BELVIQ API for at least the short term. Our dependence on one source of finished drug product and API, as well as our dependence on other third parties in the supply chain, may adversely affect our ability to develop and deliver drug products on a timely and competitive basis, or at all.

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

Any performance failure on the part of us or a third-party manufacturer could delay or otherwise adversely affect the sales of BELVIQ or the clinical development or regulatory approval of BELVIQ or one or more of our drug candidates. We or third-party manufacturers may encounter difficulties involving production yields, regulatory compliance, lot release, quality control and quality assurance, as well as shortages of qualified personnel. Approval of BELVIQ, as well as one or more of our drug candidates, could be delayed, limited or denied if the applicable regulatory authority does not approve our processes or facilities or those of a third-party manufacturer. Moreover, the ability to adequately and timely manufacture and supply drug product 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;

---

**Table of Contents**

capacity of our facilities or those of our contract manufacturers;

facility contamination by microorganisms or viruses or cross contamination;

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

changes in actual or forecasted demand;

timing and 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 unrest or changes, social unrest, intentional misconduct or other factors inherent in operating complex manufacturing facilities. Supply chain management is complex, and involves sourcing from a number of different companies and foreign countries. Commercially available starting materials, reagents and excipients may be or become scarce or more expensive to procure, and we may not be able to obtain favorable terms in agreements with subcontractors. We or our third-party manufacturers may not be able to operate our respective manufacturing facilities in a cost-effective manner or in a time frame that is consistent with our expected future manufacturing needs. If we or our third-party manufacturers cease or interrupt production or if our third-party manufacturers and other service providers fail to supply materials, products or services to us for any reason, such interruption could delay progress on our programs, or interrupt the commercial supply, with the potential for additional costs and lost revenues. If this were to occur, we may also need to seek alternative means to fulfill our manufacturing needs.

We may not be able to enter into agreements for the manufacture of BELVIQ or one or more 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, corresponding state and foreign authorities and other regulatory 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, Arena GmbH has contracted with Siegfried to provide to us certain technical and business services, including safety, health and environmental services. 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 BELVIQ or one or more 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.

**\*Negative US and global economic conditions may pose challenges to our business strategy, which relies on access to capital from the markets or collaborators, and creates other financial risks for us.**

Negative conditions in the United States or global economy, including credit markets and the financial services industry, 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 vendors or our distributors, licensees and collaborators, which we sometimes refer to generally as our collaborators. If negative economic conditions persist or worsen, we may be unable to secure additional funding to sustain our operations or to find suitable collaborators to advance our internal programs, even if we achieve positive results from our research and development or business development efforts. Such negative conditions could also impact commercialization of BELVIQ or any other drugs we develop as well as our financial condition.

From time to time, we may 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, we rely on credit rating agencies to help evaluate the riskiness of investments, and such agencies may not accurately predict such risk. In addition, such 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 and certain of our current and former employees and directors have been named as defendants in litigation that could result in substantial costs and divert management's attention.**

Beginning in September 2010, a number of lawsuits were filed against us and certain of our employees and directors on behalf of certain purchasers of our common stock. The lawsuits in general include allegations that we and certain of our employees and directors violated laws by making materially false and misleading statements regarding our BELVIQ trials, thereby artificially inflating the price of our common stock. The plaintiffs are seeking unspecified monetary damages and other relief.

---

## **Table of Contents**

There is no guarantee that we will be successful in defending these lawsuits. Also, our insurance coverage may be insufficient, our assets may be insufficient to cover any amounts that exceed our insurance coverage, and we may have to pay damage awards or otherwise may enter into settlement arrangements in connection with such claims. A settlement of any of these lawsuits could involve the issuance of common stock or other equity, which may dilute your ownership interest. Any payments or settlement arrangements could have material adverse effects on our business, operating results, financial condition or your ownership interest. Even if the plaintiffs' claims are not successful, this litigation could result in substantial costs and significantly and adversely impact our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results or financial condition. In addition, such lawsuits may make it more difficult to finance our operations, obtain certain types of insurance (including directors' and officers' liability insurance), and attract and retain qualified executive officers, other employees and directors.

### **\*Our stock price could decline significantly based on the results and timing of clinical trials and preclinical studies of, and decisions affecting, BELVIQ or one or more of our drug candidates.**

The results and timing of clinical trials and preclinical studies can affect our stock price. Preclinical studies include experiments performed in test tubes, in animals, or in cells or tissues from humans or animals. These studies, which are sometimes referred to as nonclinical 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 BELVIQ or one or more of our drug candidates may not be viewed favorably by us or third parties, including investors, analysts, current or potential collaborators, the academic and medical communities, and regulators. The same may be true of how we design individual studies, trials and development programs of BELVIQ as well as for any of our drug candidates, and regulatory decisions (including by us or regulatory authorities) affecting those programs. Stock prices of companies in our industry have declined significantly when such results and decisions were unfavorable or perceived negatively or when a drug candidate did not otherwise meet expectations.

From time to time we have drug programs 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 drug candidates and those under collaborative agreements.

As a condition to obtaining FDA approval of BELVIQ, we and Eisai committed to conduct post-marketing studies to assess the safety and efficacy of BELVIQ for weight management in obese pediatric patients, as well as to evaluate the effect of long-term treatment with BELVIQ on the incidence of major adverse cardiovascular events in overweight and obese subjects with cardiovascular disease or multiple cardiovascular risk factors. The cardiovascular outcomes trial will include echocardiographic assessments. In addition we may decide or need to conduct additional studies, clinical trials or analyses of BELVIQ, including in connection with seeking regulatory approval of BELVIQ outside of the United States. Unfavorable results from these studies, trials or analyses could negatively impact market acceptance of BELVIQ, limit the revenues we generate from sales, result in BELVIQ's withdrawal from the market, and preclude us from achieving or sustaining profitability.

We may not be successful in initiating or completing our studies or trials or advancing our programs on our projected timetable, if at all. Any failure to initiate or delays in our studies, trials or development programs, or unfavorable results or decisions or negative perceptions regarding any of our programs, could cause our stock price to decline significantly. This is particularly the case with respect to BELVIQ.

We may report top-line data from time to time, which is based on a preliminary analysis of then-available efficacy and safety data, and such findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. In addition, we make assumptions, estimations and calculations as part of our analyses of data, and others, including regulatory agencies, may not accept or agree with our assumptions, estimations, calculations or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular drug candidate or drug and our company in general.

---

## **Table of Contents**

**\*If we do not commercialize BELVIQ with one or more pharmaceutical companies outside of the territories under existing collaborations, our lack of corporate experience and resources may negatively impact our ability to commercialize BELVIQ in such territories.**

Subject to applicable regulatory approval, we expect to commercialize BELVIQ outside of the territories under existing collaborations with one or more collaborators or independently. We may not be able to enter into agreements to commercialize BELVIQ in such territories on acceptable terms, if at all. If we are unable to enter into such agreements, and we develop our own capabilities to commercialize BELVIQ in any territory independently, we may require additional capital to develop such capabilities and the marketing and sale of BELVIQ in such territory may be delayed or otherwise impeded by our lack of resources. We may not be successful in developing the requisite capabilities to commercialize BELVIQ without a collaborator. Even if we were able to do so, we have not previously commercialized a drug, and our limited experience may make us less effective at commercial planning, marketing and selling than a more experienced pharmaceutical company. Our lack of corporate experience and adequate resources may impede our efforts to successfully commercialize BELVIQ independently.

We face competition in our search for pharmaceutical companies to commercialize BELVIQ in additional territories. In addition, if our competitors are able to establish commercialization arrangements with companies who have substantially greater resources than we have (or, with respect to commercializing BELVIQ in a territory under an existing collaboration, than our collaborator has), our competitors may be more successful in marketing and selling their drugs, and our ability to successfully commercialize BELVIQ will be limited.

**\*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 preclinical and clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, marketing and distribution, and other possible activities relating to BELVIQ and our drug candidates are, and any other resulting drugs will be, subject to extensive regulation by the FDA and other regulatory agencies. We are subject to periodic unannounced inspections by the FDA, the DEA and other regulatory agencies, and are also subject to inspections at Arena GmbH by the FDA, Swissmedic and other regulatory agencies. Failure to comply with applicable regulatory requirements may, either before or after product approval, subject us to administrative or judicially imposed sanctions that may negatively impact the commercialization of BELVIQ or approval of one or more of our drug candidates or otherwise negatively impact our business. Regulatory agencies have in the past inspected certain aspects of our business in the United States and Switzerland, and we were provided with observations of objectionable conditions or practices with respect to our business in the United States. We believe we satisfactorily addressed such observations, but there is no assurance that regulatory agencies will not provide us with observations in future inspections or that we satisfactorily addressed observations provided to us in past inspections.

Neither collaborators nor we are permitted to market a drug candidate in the United States until the particular drug candidate is approved for marketing by the FDA. 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 an 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. Following its review of an NDA or a response to a Complete Response Letter, or CRL, the FDA may approve the NDA or issue a CRL.

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 FDA's review goals are subject to change, and it is unknown whether any particular FDA review will be completed within the FDA's review goals or will be delayed. Moreover, the duration of the FDA's review may depend on the number and types of other submissions with the FDA around the same time period. As with BELVIQ, any drug that acts on the CNS has the potential to be scheduled as a controlled substance by the DEA. DEA scheduling is an independent process that can delay drug launch beyond an NDA approval date. For example, the FDA approved the NDA for BELVIQ in June 2012, but BELVIQ cannot be marketed in the United States until the DEA makes its final scheduling designation, which may take several months or longer to complete. The FDA has recommended that the DEA classify BELVIQ as a Schedule IV drug. DEA scheduling ranges from I to V, with I being the most tightly controlled category. If BELVIQ were to be scheduled in a tightly controlled category, such scheduling could negatively impact the ability or willingness to prescribe or dispense BELVIQ, the likelihood that patients will use it and other aspects of our and Eisai's ability to commercialize it.

Regulatory approval of an NDA is not guaranteed. The number and types 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. Despite the time and expense exerted in preclinical and clinical studies, 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 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;

---

**Table of Contents**

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

the FDA's interpretation and our interpretation of data from preclinical studies and clinical trials may differ significantly;

our or our contractors' or collaborators' failure to comply with applicable FDA and other regulatory requirements, including those identified in other risk factors;

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 an NDA or other submission due to, among other reasons, the content or formatting of the submission. 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, restricted distribution methods or other limitations, such as those required by a Risk Evaluation and Mitigation Strategies, or REMS.

With the exception of our regulatory submissions for BELVIQ, we have not previously submitted an application for marketing approval in the United States or any other jurisdiction. This lack of corporate experience may impede our ability to obtain regulatory approval in a timely manner, if at all, for BELVIQ in territories in which regulatory approval is our responsibility or for any of our drug candidates. Our preclinical and clinical data, other information and procedures relating to a drug candidate may not be sufficient to support approval by the FDA or any other US or foreign regulatory authority, or regulatory interpretation of these data and procedures may be unfavorable. 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 or our collaborators develop.

To market any drugs outside of the United States, we and our current or future 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 risks, some of which may be unanticipated.

In March 2012, we filed an MAA for EU approval of BELVIQ, and the EMA accepted the filing for review. The EU regulatory authorities could determine that our application and data from our BELVIQ studies and trials is not sufficient for EU approval. The approval requirements in the European Union are different than in the United States. For example, the EMA guidelines provide that clinical trials assessing drug candidates intended for weight control should subject patients to a weight reducing diet run-in period, and our Phase 3 clinical trials did not include a run-in period. Such EMA guidelines also provide primary and alternative primary efficacy criteria for weight loss drug candidates. We believe BELVIQ will satisfy the EMA's alternative primary efficacy criterion, which is the proportion of responders achieving more than 10% weight loss at the end of a 12-month period. However, we do not believe BELVIQ meets the more stringent EMA primary efficacy criterion, which requires demonstrating weight loss of at least 10% of baseline weight that is also at least 5% greater than that associated with placebo. The EMA has also raised questions regarding the dropout rate in our clinical trials and how this affects the analysis of efficacy in those trials. In addition, in October 2012, we submitted our response to the CHMP's 120 day assessment report and list of questions regarding the BELVIQ MAA. The report provided CHMP's quality, clinical and non-clinical questions and comments, which include a similar range of issues previously raised by the FDA. Three issues were identified as major objections: the tumor findings in rats, the dropout rate in clinical trials and how this affects the analysis of efficacy, and the incidences of valvulopathy. We cannot assure you that our response to such report, or any further, response will be sufficient to the CHMP, the EMA or others, that the CHMP, the EMA or others will consider our BELVIQ program or data, including with regard to BELVIQ's efficacy or safety, as sufficient, that the CHMP will recommend to the EMA that BELVIQ be approved, or that the EMA will ever approve BELVIQ.

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 a country, any delay or setback in obtaining such approval, or our regulatory strategy or decisions could adversely affect the regulatory approval or commercialization of our drug



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

candidates in other countries, including that our drug candidates may not be approved for all indications requested, that such approval may be subject to limitations on the indicated uses for which the drug may be marketed, and with regard to the pricing or reimbursement of any approved drugs.

**\*Our drugs will still be subject to extensive post-marketing regulation if approved.**

Following regulatory approval of any of our drug candidates, we and our collaborators will be subject to ongoing obligations and continued regulatory review from the FDA and other applicable regulatory agencies, such as continued adverse event reporting requirements. As with BELVIQ, there may also be additional post-marketing obligations imposed by the FDA or other regulatory agencies. These obligations may result in significant expense and limit the ability to commercialize such drugs.

---

## Table of Contents

The FDA or other regulatory agencies may also require that the sponsor of the NDA or foreign equivalent, as applicable, conduct additional clinical trials to further assess approved drugs after approval under a post-approval commitment. Such additional studies may be costly and may impact the commercialization of the drug. For example, as part of the approval of BELVIQ, we and Eisai committed to conduct post-marketing studies to assess the safety and efficacy of BELVIQ for weight management in obese pediatric patients, as well as to evaluate the effect of long-term treatment with BELVIQ on the incidence of major adverse cardiovascular events in overweight and obese subjects with cardiovascular disease or multiple cardiovascular risk factors. These trials are costly and time consuming, and unfavorable results could negatively impact market acceptance of BELVIQ, limit the revenues we generate from sales, result in BELVIQ's withdrawal from the market, negatively impact the potential approval of BELVIQ in other territories and preclude us from achieving or sustaining profitability.

The FDA or other regulatory agencies may also impose significant restrictions on the indicated uses for which a drug may be marketed. Additionally, the FDA may require a REMS, including in connection with a drug's approval, to help ensure that the benefits of the drug outweigh its risks. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate healthcare providers of the drug's risks, limitations on who may prescribe or dispense the drug, requirements that patients enroll in a registry or undergo certain health evaluations or other measures that the FDA deems necessary to ensure the safe use of the drug.

With regard to BELVIQ and any of our drug candidates that receive regulatory approval, 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, we will also become subject to the DEA's regulations. The FDA has recommended to the DEA that BELVIQ be classified as a Schedule IV drug. If BELVIQ were to be scheduled in a tightly controlled category, such scheduling could negatively impact the ability or willingness to prescribe or dispense BELVIQ, the likelihood that patients will use it and other aspects of our and Eisai's ability to commercialize it. 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, such noncompliance 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 collaborators;

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

restrictions on operations, including costly new manufacturing requirements; and

product recalls or seizures.

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

## **Table of Contents**

**\*Our ability to generate revenues from BELVIQ or any of our drug candidates that receive regulatory approval 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 patients, healthcare providers, 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 our drugs and competitive drugs;

actual and perceived efficacy and safety of our drug candidates;

incidence and severity of any side effects;

potential or perceived advantages or disadvantages as compared to 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 fail to achieve market acceptance, we may not be able to generate significant revenues to achieve or sustain profitability.

**\*Drug development programs 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. In addition, the FDA or other regulatory authority may require us to, or we or others may decide to, conduct additional research and development of any of our approved drugs. For example, the FDA is requiring us to conduct post-marketing trials of BELVIQ, and we or others may conduct additional studies or trials of the drug. Clinical trials and preclinical studies are needed to demonstrate that drug candidates are safe and effective to the satisfaction of the FDA and similar non-US regulatory authorities. These trials and studies are expensive and uncertain processes that may take years to complete. Failure can occur at any stage of the process, and successful early preclinical studies or clinical trials do not ensure that later studies or trials will be successful. In addition, the commencement or completion of our planned preclinical studies or clinical trials could be substantially delayed or prevented by several factors, including the following:

limited number of, and competition for, suitable patients required for enrollment in our clinical trials or animals to conduct our preclinical studies;

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

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

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

delay or failure to obtain sufficient supplies of drug candidates, drugs or other materials for the trial or study;

delay or failure to reach agreement on acceptable agreement terms or protocols; and

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

Even if the results of our development programs are favorable, the development programs of our most advanced drug candidates, including those being developed by collaborators, may take significantly longer than expected to complete. In addition, the FDA, other regulatory authorities, 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;

**Table of Contents**

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 or 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;

lack of sufficient funding to continue clinical trials or preclinical studies; or

changes in business priorities or perceptions of the value of the program.

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. We have experienced setbacks in our internal and partnered 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 BELVIQ or any 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 we or others believe are favorable, and our stock price would likely decrease significantly.

**\*The results of preclinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidates or any approved drugs 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. Favorable results in 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 or drugs in later-stage trials may fail to show desired safety and efficacy despite having progressed through earlier-stage trials. Unfavorable results from ongoing preclinical studies or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials, or abandonment of a 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 program to be abandoned.

**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 sufficient therapeutic potential, and any of our preclinical compounds 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.

---

**Table of Contents**

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

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, such as strategic collaborations, joint ventures, spin-offs, restructurings, divestitures, business combinations and investments. In addition, another entity may pursue us as an acquisition target. Any such transaction may be viewed as unfavorable by our stockholders or others and 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.**

Many of the drugs we or our collaborators are or may attempt to discover and develop may 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.

For example, with regard to BELVIQ, in July 2012, the FDA approved VIVUS's drug candidate for chronic weight management, and VIVUS announced the US market availability of its drug in September 2012. VIVUS is also seeking regulatory approval for its drug candidate in the European Union. In addition, Orexigen Therapeutics, Inc., is seeking FDA approval for a drug candidate for a similar indication. With respect to future weight-loss treatments, we expect that companies and others may allocate resources to discover and develop additional drugs, additional drug candidates may be approved and that competition may increase.

Our competitors, particularly large pharmaceutical companies, may 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 marketing exclusivity rights. In addition, our competitors' drugs may have fewer side effects, more desirable characteristics (such as efficacy, route of administration or frequency of dosing), or be viewed more favorably by patients, healthcare providers, healthcare payers, the medical community, the media or others 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, and we may not realize the full commercial potential of our drug candidates.**

We may have conflicts with our prospective, current or past collaborators, such as conflicts concerning the interpretation of preclinical or clinical data, the achievement of milestone or other payments, the ownership of intellectual property, or research and development or commercialization strategy. Collaborators may stop supporting our drug candidates or drugs, including if they no longer view the program as in their best financial or other interests or they develop or obtain rights to competing drug candidates or drugs. In addition, collaborators may fail to effectively develop or commercialize our drugs, which may result in us not realizing their full commercial potential. If any conflicts arise with any of our current, past or prospective collaborators, the other party 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 drug candidates or drugs, and in turn prevent us from generating revenues:

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



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

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;

---

**Table of Contents**

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

litigation or arbitration.

**\*Setbacks and consolidation in the pharmaceutical and biotechnology industries and inadequate third-party coverage and reimbursement could make entering into agreements with pharmaceutical companies to collaborate or commercialize our drugs more difficult and diminish our revenues.**

Setbacks in the pharmaceutical and biotechnology industries, such as those caused by safety concerns relating to drugs like Meridia, 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, the FDA may be more cautious in approving our drug candidates based on safety concerns relating to these or other drugs or drug candidates, or 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 have been or 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. In addition, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, PPACA, was passed, which has significantly affected the pharmaceutical industry. In addition to extending coverage to patients otherwise uninsured, PPACA includes, among several other provisions relating to pharmaceuticals, measures that impose a new nondeductible fee on certain branded drugs based on market share in government healthcare programs, increases in rebates for government programs such as Medicaid, and the creation of a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Given the continuing discussion regarding the cost of healthcare, managed care, universal healthcare coverage and other healthcare issues, we also 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. PPACA and any additional legislation or regulations 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 and demand for our drugs.

**We rely on third parties to conduct our clinical trials and many of our preclinical studies. If those parties do not comply with regulatory and contractual requirements, 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 preclinical studies or 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 regulatory requirements and our protocols, our preclinical studies or 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 collaborators, and we do not control their research and development, clinical trial or regulatory activities.



---

**Table of Contents**

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

Our success depends on the continued contributions of our principal management, development and scientific personnel, and the ability to hire and retain key and other personnel. We face competition for such personnel, and we believe that risks and uncertainties related to our business, including the regulatory process and our filings, our available and anticipated cash resources, pending and possible future litigation involving us, and the volatility of our stock price, may impact our ability to hire and retain key and other personnel. The loss of services of any principal member of our management or scientific staff or other personnel, particularly Jack Lief, our Chairman, President and Chief Executive Officer, and Dominic P. Behan, Ph.D., our Executive Vice President and Chief Scientific Officer, or a combination of different key employees, could adversely impact our operations and ability to generate or 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 for any product liability claims or otherwise as a drug product manufacturer.**

We develop, test, manufacture and expect to commercialize drugs for use 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 with the commercialization of BELVIQ as well as with any other approved drugs. In addition, under the Eisai Agreement, Arena GmbH has agreed to indemnify Eisai for certain losses resulting from product liability claims, except to the extent caused by Eisai's negligence, willful misconduct, violation of law or breach of such agreement or related agreements.

Whether or not we are ultimately successful in any product liability or related 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. In addition, damages awarded in a product liability action could be substantial and could have a negative impact on our financial condition.

An individual may bring a liability claim against us if one of our drugs or drug candidates causes, or merely appears to have caused, an injury. Regardless of merit or eventual outcome, liability claims may result in:

decreased demand for our drug;

injury to our reputation;

increased difficulty to attract, or withdrawal of, clinical trial subjects;

costs of related litigation;

substantial monetary awards to subjects or other claimants;

loss of revenues; and

the inability to commercialize our drug candidates.

We have limited product liability insurance that covers our clinical trials and product liability. We may not be able to maintain or obtain insurance coverage at a reasonable cost, and we may not have insurance coverage that will be adequate to satisfy any liability that may arise, which could have an adverse effect on our capital sources and financial condition.

Arena GmbH manufactures drug products for Siegfried and will manufacture BELVIQ for commercialization in the United States and, subject to applicable regulatory approval, in other territories. Arena GmbH is subject to liability for non-performance, product recalls and breaches of the agreements with Siegfried, Eisai and Ildong.

**\*We have significant contractual obligations, which may adversely affect our cash flow, cash position and stock price.**

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

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

increasing our vulnerability to general adverse economic conditions;

---

## **Table of Contents**

limiting our ability to obtain additional funds; and

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

**\*We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.**

In the United States, drug manufacturers and marketers are subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal False Claims Act. There are similar laws in other countries. These laws may impact, among other things, the sales, marketing and education programs for our drugs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willingly soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and, despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Moreover, the PPACA, among other things, amends the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them. The PPACA also provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Suits filed under the False Claims Act, known as qui tam actions, can be brought by any individual on behalf of the government and such individuals, commonly known as whistleblowers, may share in any amounts paid by the entity to the government in fines or settlement. The filing of qui tam actions has caused a number of pharmaceutical, medical device and other healthcare companies to have to defend a False Claims Act action. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Various states have also enacted laws modeled after the federal False Claims Act.

We are unable to predict whether we could be subject to actions under any of these or other fraud and abuse laws, or the impact of such actions. If we are found to be in violation of any of the laws described above and other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare reimbursement programs and the curtailment or restructuring of our operations, all of which could have a material adverse effect on our business and results of operations.

**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.**

The headquarters of our operations outside of the United States is in Switzerland. Activities conducted at this location include manufacturing, quality control, quality assurance, development of manufacturing processes, qualifying suppliers and otherwise managing the global supply chain, regulatory compliance, distribution of finished products, and European strategic planning and development. There are significant risks associated with 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, foreign currency exchange rates and the impact of shifts in the United States and local economies on those rates, and integration of our policies and procedures, including disclosure controls and procedures and internal control over financial reporting, with our international operations.

**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;

---

**Table of Contents**

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.

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 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 in Zofingen, Switzerland, and we expect that, at least for the foreseeable future, this facility will be the sole location for the manufacturing of BELVIQ finished drug product. We depend on our facilities and on collaborators, contractors and vendors for the continued operation of our business, some of whom are located in Europe and Asia. Natural disasters or other catastrophic events, including interruptions in the supply of natural resources, political and governmental changes, severe weather conditions, wildfires and other fires, explosions, actions of animal rights activists, terrorist attacks, 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 and adversely affect, which may include stopping, our commercial production.

**Our executive officers and directors may sell shares of their stock, 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. Our executive officers and directors may sell stock in the future, either as part, or outside, of trading plans under SEC Rule 10b5-1.

**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 agreements 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 rules adopted by the SEC and by NASDAQ, 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 directors and officers liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on our board committees or as executive officers. We cannot estimate accurately the amount or timing of additional costs we may incur to respond to these laws, rules and regulations.

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



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

Our success will depend on our own and on current or future collaborators' abilities to obtain, secure and defend patents. In particular, the patents directed to BELVIQ and our drug candidates are important to commercializing drugs. We have numerous US and foreign patent applications pending for our technologies. There is no assurance that any of our patent applications will issue, or that any of the patents will be enforceable or will cover a drug or other commercially significant technology or method, or that the patents will be held to be valid for their expected terms.

---

## Table of Contents

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

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

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

Some of our academic institution licensors, research collaborators and scientific advisors have rights to publish data and information to which we have rights. We generally seek to prevent our collaborators from disclosing scientific discoveries before we have the opportunity to file patent applications on such discoveries. In some of our collaborations, we do not control our collaborators' 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.

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 our industry, changes in US patent laws could have a profound effect on our future profits, if any. It is unknown which, if any, patent laws will change, how changes to the patent laws will ultimately be enforced by the courts and the impact on our business. For example, in September 2011 the America Invents Act was signed into US law, which changes include, among others, the awarding of a patent to the first inventor to file a patent as opposed to the first inventor to make an invention and the creation of new administrative procedures for challenging US patents. It may be several years before the impact of the America Invents Act on patent law is understood, and we cannot predict with certainty whether or to what extent the changes may impair our business.

**\*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 depends upon our ability to develop and manufacture our drugs and drug candidates, market and sell drugs, 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 drugs, 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 G protein-coupled receptors, or 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



---

## **Table of Contents**

applications, unknown to us, which may later result in issued patents that our drugs, drug candidates or technologies may infringe. There also may be existing patents, of which we are not aware, that our drug candidates or technologies may infringe. Further, there may be issued patents or pending patent applications in fields relevant to our business, of which we are or may become aware, that we believe (i) are invalid or we do not infringe; (ii) relate to immaterial portions of our overall drug discovery, development, manufacturing and commercialization efforts; or (iii) in the case of pending patent applications, the resulting patent would not be granted or, if granted, would not likely be enforced in a manner that would materially impact such efforts. We cannot assure you that others holding any of these patents or patent applications will not assert infringement claims against us for damages or seek to enjoin our activities. We also cannot assure you that, in the event of litigation, we will be able to successfully assert any belief we may have as to non-infringement, invalidity or immateriality, or that any infringement claims will be resolved in our favor.

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

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

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

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

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

be costly, regardless of the outcome.

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

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

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

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.

**Table of Contents**

***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, 2010, to November 1, 2012, the market price of our stock was as low as \$1.21 per share and as high as \$13.50 per share.

Very few drug candidates being tested will ultimately receive regulatory approval, and companies in our industry sometimes experience significant volatility in their stock price. Our stock price may fluctuate significantly depending on a variety of factors, including:

legislation or regulatory actions or decisions affecting BELVIQ, including the timing and outcome of the DEA's scheduling designation and the decisions of other regulatory authorities relating to BELVIQ, or other drugs or drug candidates, including those of our competitors;

the commercial launch and success or failure of BELVIQ or any of our drug candidates;

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

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

inaccurate sales or cash forecasting, or fluctuation in quarterly results;

supply chain or manufacturing issues;

discussions or recommendations affecting our drugs or drug candidates by FDA advisory committees or other reviewers of preclinical or clinical data or other information related to BELVIQ, drug candidates or other drugs;

results or decisions affecting the development or commercialization of BELVIQ or any of our drug candidates, including the results of studies, trials and other analyses;

the development and implementation of our continuing development and research plans, including outcome studies and other research and development for BELVIQ;

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

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

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

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

the success, failure or setbacks of our or a perceived competitor's drugs or drug candidates;

expenses related to, and the results of, litigation, other disputes and other proceedings;

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 that may become eligible for future sale in the public market, and the sale of our common stock could cause the market price of our common stock to fall.**

As of November 1, 2012, we had outstanding a seven-year warrant issued in June 2006 to purchase 1,467,405 shares of our common stock at an exercise price of \$8.76 per share and a seven-year warrant issued in August 2008 to purchase 1,965,418 shares of our common stock at an exercise price of \$4.34 per share. Such seven-year warrants were adjusted as a result of certain equity sales following their issuance to decrease the exercise price and increase the number of shares issuable upon exercise of the warrants. Certain future equity issuances below the pre-defined warrant adjustment price may result in additional adjustments to any such warrants then outstanding.

---

**Table of Contents**

Along with our outstanding warrants, as of November 1, 2012, there were (i) options to purchase 13,378,223 shares of our common stock outstanding under our equity incentive plans at a weighted-average exercise price of \$4.26 per share, (ii) 15,352,176 additional shares of common stock remaining issuable under our 2012 Long-Term Incentive Plan, (iii) 1,331,897 shares of common stock remaining issuable under our 2009 Employee Stock Purchase Plan, as amended, and (iv) 79,169 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. As of November 1, 2012, there were 217,292,992 shares of our common stock outstanding.

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

We have primarily financed our operations, and we may continue to finance our operations, by issuing and selling our common stock or securities convertible into or exercisable for shares of our common stock. 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 common stock and other securities may take actions that are contrary to your interests, including selling their stock.**

A small number of stockholders may hold or acquire a significant amount of our outstanding stock. These stockholders may support competing transactions and have interests that are different from yours. In addition, 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 may also be involved with 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.

**\*Certain of our agreements, provisions in our charter documents, possible future agreements 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.**

There is a standstill agreement in the Eisai Agreement, and we may enter into similar agreements. In addition, we may in the future adopt a stockholders' rights agreement, which would cause substantial dilution to any person who attempts to acquire us in a manner or on terms not approved by our board of directors. These agreements, 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, our charter 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 5. Other Information.**

In October 2012, the Rights Agreement, dated October 30, 2002, we entered into with Computershare Trust Company, Inc., as amended, expired pursuant to its terms. On November 5, 2012, we filed a certificate of elimination with the Secretary of State of the State of Delaware with regard to the related Series A Junior Participating Preferred Stock. This certificate of elimination, which was effective upon filing, eliminated from our Fifth Amended and Restated Certificate of Incorporation, as amended, all matters set forth in the Certificate of Designations with respect to the Series A Junior Participating Preferred Stock. No shares of the Series A Junior Participating Preferred Stock were issued or outstanding at the time of the filing of the certificate of elimination.

**Table of Contents**

**Item 6. Exhibits.**

EXHIBIT NO.	DESCRIPTION
3.1	Fifth Amended and Restated Certificate of Incorporation of Arena (incorporated by reference to Exhibit 3.1 to Arena's quarterly report on Form 10-Q for the quarter ended June 30, 2002, filed with the Securities and Exchange Commission on August 14, 2002, Commission File No. 000-31161)
3.2	Certificate of Amendment of the Fifth Amended and Restated Certificate of Incorporation of Arena (incorporated by reference to Exhibit 4.2 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 28, 2006, Commission File No. 333-135398)
3.3	Certificate of Amendment No. 2 of the Fifth Amended and Restated Certificate of Incorporation of Arena, as amended (incorporated by reference to Exhibit 4.3 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 30, 2009, Commission File No. 333-160329)
3.4	Certificate of Amendment No. 3 of the Fifth Amended and Restated Certificate of Incorporation of Arena, as amended (incorporated by reference to Exhibit 3.4 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 20, 2012, Commission File No. 333-182238)
3.5	Amended and Restated Bylaws of Arena (incorporated by reference to Exhibit 3.1 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on October 4, 2007, Commission File No. 000-31161)
3.6	Certificate of Designations of Series A Junior Participating Preferred Stock of Arena, dated November 4, 2002 (incorporated by reference to Exhibit 3.3 to Arena's quarterly report on Form 10-Q for the quarter ended September 30, 2002, filed with the Securities and Exchange Commission on November 14, 2002, Commission File No. 000-31161)
4.1	Rights Agreement, dated October 30, 2002, between Arena and Computershare Trust Company, Inc. (incorporated by reference to Exhibit 4.1 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on November 1, 2002, Commission File No. 000-31161)
4.2	Amendment No. 1, dated December 24, 2003, to Rights Agreement, dated October 30, 2002, between Arena and Computershare Trust Company, Inc. (incorporated by reference to Exhibit 4.1 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on December 30, 2003, Commission File No. 000-31161)
4.3	Amendment No. 2, dated November 16, 2006, to Rights Agreement, dated October 30, 2002, between Arena and Computershare Trust Company, Inc. (incorporated by reference to Exhibit 4.3 to Amendment No. 2 to Arena's registration statement on Form 8-A filed with the Securities and Exchange Commission on November 16, 2006, Commission File No. 000-31161)
4.4	Form of common stock certificate (incorporated by reference to Exhibit 4.2 to Arena's registration statement on Form S-1, as amended, filed with the Securities and Exchange Commission on July 19, 2000, Commission File No. 333-35944)
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(B) promulgated under the Securities Exchange Act of 1934
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

\* Furnished herewith.



**Table of Contents**

**SIGNATURES**

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

Date: November 8, 2012

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  
Senior Vice President, Finance and Chief Financial Officer (principal financial and accounting officer authorized to sign on behalf of the registrant)

**Table of Contents****EXHIBIT INDEX**

EXHIBIT NO.	DESCRIPTION
3.1	Fifth Amended and Restated Certificate of Incorporation of Arena (incorporated by reference to Exhibit 3.1 to Arena's quarterly report on Form 10-Q for the quarter ended June 30, 2002, filed with the Securities and Exchange Commission on August 14, 2002, Commission File No. 000-31161)
3.2	Certificate of Amendment of the Fifth Amended and Restated Certificate of Incorporation of Arena (incorporated by reference to Exhibit 4.2 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 28, 2006, Commission File No. 333-135398)
3.3	Certificate of Amendment No. 2 of the Fifth Amended and Restated Certificate of Incorporation of Arena, as amended (incorporated by reference to Exhibit 4.3 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 30, 2009, Commission File No. 333-160329)
3.4	Certificate of Amendment No. 3 of the Fifth Amended and Restated Certificate of Incorporation of Arena, as amended (incorporated by reference to Exhibit 3.4 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 20, 2012, Commission File No. 333-182238)
3.5	Amended and Restated Bylaws of Arena (incorporated by reference to Exhibit 3.1 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on October 4, 2007, Commission File No. 000-31161)
3.6	Certificate of Designations of Series A Junior Participating Preferred Stock of Arena, dated November 4, 2002 (incorporated by reference to Exhibit 3.3 to Arena's quarterly report on Form 10-Q for the quarter ended September 30, 2002, filed with the Securities and Exchange Commission on November 14, 2002, Commission File No. 000-31161)
4.1	Rights Agreement, dated October 30, 2002, between Arena and Computershare Trust Company, Inc. (incorporated by reference to Exhibit 4.1 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on November 1, 2002, Commission File No. 000-31161)
4.2	Amendment No. 1, dated December 24, 2003, to Rights Agreement, dated October 30, 2002, between Arena and Computershare Trust Company, Inc. (incorporated by reference to Exhibit 4.1 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on December 30, 2003, Commission File No. 000-31161)
4.3	Amendment No. 2, dated November 16, 2006, to Rights Agreement, dated October 30, 2002, between Arena and Computershare Trust Company, Inc. (incorporated by reference to Exhibit 4.3 to Amendment No. 2 to Arena's registration statement on Form 8-A filed with the Securities and Exchange Commission on November 16, 2006, Commission File No. 000-31161)
4.4	Form of common stock certificate (incorporated by reference to Exhibit 4.2 to Arena's registration statement on Form S-1, as amended, filed with the Securities and Exchange Commission on July 19, 2000, Commission File No. 333-35944)
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(B) promulgated under the Securities Exchange Act of 1934
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

\* Furnished herewith.